Technical Trade Measures System Construction Project CS03-13							
Guidelines for Cosmetic Label Management in Various Countries							
China Institute of Inspection and Quarantine							
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# 1. Scope of application

This guide aims to provide the regulations, standards, requirements and differences between my country's cosmetics major export target countries (regions) in terms of cosmetics labels, and put forward suggestions and guidelines to meet the requirements of the target market.

Applicable to all cosmetics companies that export or prepare to export.

2 II. Overview of the basic situation of imported and exported cosmetics

#### 2.1 Terms and definitions

Cosmetics: refers to products that are applied to any part of the human body surface (skin, hair, nails, lips), teeth and oral mucosa by smearing, sprinkling, spraying or other similar methods to achieve the purpose of cleaning, fragrance, changing appearance, correcting human odor, maintenance, and maintaining good condition.

Labeling: refers to the words, numbers, symbols, patterns and explanatory materials placed in the sales packaging that are pasted, connected or printed on the sales packaging of cosmetics.

Sales packaging: refers to the packaging delivered to consumers together with the contents for the purpose of sales.

Contents: refers to the products contained in the packaging container.

Display panels: refers to the surface of the cosmetics that can be seen by consumers in their natural state when displayed.

Visible panels: refers to any surface of the cosmetics that can be seen by consumers without destroying the sales packaging.

Net content: refers to the actual mass, volume or length of the contents after removing the packaging container and other packaging materials.

Shelf life: refers to the period of time during which the quality of cosmetics is maintained under the conditions specified in the cosmetic product standards and labels. During this period, the cosmetics are completely suitable for sale and meet the quality specified in the product standards and labels.

Expiration date: refers to the best use date of cosmetics under the conditions specified in the cosmetic product standards and labels. During this period, the cosmetics are completely suitable for sale and meet the quality specified in the product standards and labels. After this period, the quality of the cosmetics may change and the cosmetics are no longer suitable for sale.

Primary packaging product: refers to cosmetics that are packaged once.

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The commodities involved in this guideline are cosmetic products. The corresponding customs export catalog commodity codes of such products are shown in Table 2.1 (data from the "China Customs Statistical Yearbook" compiled by the General Administration of Customs of the People's Republic of China).

Table 2.1 List of corresponding customs codes for cosmetic products

Product name Commodity number (customs code)

Essential oils including extracts and absolutes; balms; extracted oleoresins 3301

Orange oil 33011200

Lemon oil 33011300

Lime oil (lime oil) 33011910

Other citrus essential oils 33011990

Peppermint oil 33012400

Other mint oils 33012500

Camphor oil 33012910

Citronella oil 33012920

Fennel oil 33012930

Cinnamon oil 33012940

Litsea cubeba oil 33012950

Eucalyptus oil 33012960

Geranium oil (geranium oil) 33012991

Non-citrus fruit essential oils 33012999

Iris gel 33013010

Other ointments 33013090

Extracted oleoresins 33019010

Terpene byproducts of deterpenization of citrus fruit essential oils 33019020

Products containing concentrated essential oils; other terpene byproducts and essential oil liquids 33019090

Perfumes and floral water 3303

Perfumes and floral water 33030000

Beauty products or cosmetics and skin care products; nail cosmetics 3304

Lip cosmetics 33041000

Eye cosmetics 33042000

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4 (Continued table)

Product name Commodity number (customs code)

Nail cosmetics 33043000

Powder, whether or not pressed 33049100

Other beauty products or cosmetics and skin care products 33049900

Hair care products 3305

Shampoo 33051000

Perm 33052000

Fixed hair 33053000

Other hair care products 33059000

Oral and dental cleaning products; yarn (dental floss) for cleaning between teeth 3306

Toothpaste 33061010

Other tooth cleaning products 33061090

Yarn (dental floss) for cleaning between teeth 33062000

Oral cleaning products 33069000

Aromatic products and cosmetics and toiletries; 3307

Shaving preparations 33071000

Deodorants and antiperspirants 33072000

Bath salts and other bath preparations 33073000

Depilatory agents and unlisted aromatic products and cosmetics and toiletries 33079000

2.2 Latest customs statistics

Statistical caliber: the annual total import and export value and quantity of such products.

2.3 Import and export statistics in the past five years

2.3.1 Statistics on China's cosmetics import and export value from 2007 to 2011

In the past five years, my country's cosmetics import and export have generally shown an upward trend, and have grown rapidly in the past two years.

According to statistics, in 2011, my country's cosmetics exports increased by 427,700 tons compared with 2007, an increase of

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175.51%, export value increased by 1.493 billion US dollars, an increase of 145.17%; the number of cosmetic imports increased by 55,100 tons, an increase of 103.50%, and the import value increased by 1.474 billion US dollars, an increase of 214.34%.

my country's cosmetics trade is mainly export-oriented. With the adjustment of the structure, it has gradually tended to balance import and export trade in recent years. According to statistics, from 2007 to 2011, my country's cosmetics trade surplus fell from 341 million US dollars to 0 million US dollars, and then increased slightly to 360 million US dollars, and the trend gradually stabilized. During this period, my country's total import and export trade of cosmetics increased from 1.716 billion US dollars to 4.684 billion US dollars, an increase of 172.88%.

Compared with the rapid growth of trade value, my country's cosmetics still have a great disadvantage in terms of quality. In 2007, the average unit price of imported cosmetics was \$12.92/kg, and the average unit price of exported cosmetics was \$4.22/kg, accounting for 32.66% of the import unit price; in 2011, the average unit price of imported cosmetics was \$19.96/kg, and the average unit price of exported cosmetics was \$3.76/kg, accounting for 18.84% of the import unit price. It can be seen that the gap is still widening. This price disadvantage shows that the gold content of my country's exported cosmetics is low, and maintaining trade growth is based on a large amount of exports, which is achieved at the cost of sacrificing value. This situation has raised a very serious issue for my country's cosmetics manufacturers, and they should improve product quality as soon as possible and vigorously increase added value. Table 2.2 List of the quantity and value of my country's cosmetics exports from 2007 to 2011

Year Quantity

(10,000 tons) Growth

(10,000 tons) Growth rate

(%) Amount

(US\$ billion) Growth

(US\$ billion) Growth rate

(%)

2007 24.37 ? ? 10.29 ? ?

2008 20.20 -4.17 -17.11 9.36 -0.93 -9.04

2009 31.37 11.17 55.30 11.66 2.30 24.57

2010 41.58 10.21 32.55 17.50 5.84 50.09

2011 67.14 25.56 61.47 25.22 7.72 44.11

Table 2.3 List of cosmetics import quantity and value from 2007 to 2011

Year Quantity

(10,000 tons) Increase

(10,000 tons) Growth rate

(%) Amount

(100 million US dollars) Increase

(100 million US dollars) Growth rate

(%)

2007 5.32 ? ? 6.88 ? ?

2008 6.11 0.79 14.85 9.36 2.48 36.05

2009 5.90 -0.21 -3.44 10.70 1.34 14.32

2010 7.55 1.65 27.97 15.00 4.30 40.19

2011 10.83 3.28 43.44 21.62 6.62 44.13

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Figure 2.1 Analysis of the number of cosmetic imports and exports in my country from 2007 to 2011

Figure 2.2 Analysis of the value of cosmetic imports and exports in my country from 2007 to 2011

2.3.2 Composition of China's cosmetic exports from 2007 to 2011

In the past five years, my country's cosmetic exports have mainly been skin cosmetics, hair cosmetics, oral cosmetics and beauty cosmetics, accounting for more than 80% of the total export value. Among them, the growth rate of skin cosmetics ranked first, with an average annual growth of US\$142 million, and the proportion increased by 14%; followed by oral cosmetics,

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The average annual growth reached 61 million US dollars, and the proportion increased by 8%; the next is beauty cosmetics, with an average annual growth of 36 million US dollars, and the proportion decreased by 23%; the growth rate of other categories is relatively low.

Table 2.4 List of the quantity and value of various cosmetics exports from my country from 2007 to 2011

Unit: 10,000 tons/US\$100 million

Cosmetics category 2007 2008 2009 2010 2011

Quantity Amount Quantity Amount Quantity Amount Quantity Amount Quantity Amount Quantity Amount

Skin cosmetics 4.18 2.32 4.86 2.25 11.38 3.46 14.49 6.12 21.76 9.43

Hair cosmetics 6.09 1.23 5.53 1.19 6.97 1.41 10.06 1.90 10.21 2.26

Oral cosmetics 3.50 0.71 2.14 0.43 5.61 0.97 7.65 1.36 20.60 3.74

Beauty cosmetics 8.91 5.38 6.40 5.00 5.28 4.82 6.60 6.63 7.07 7.18

Perfume cosmetics 0.85 0.53 0.73 0.42 1.36 0.73 1.81 1.07 2.56 1.21

Special function cosmetics 0.78 0.11 0.44 0.07 0.68 0.26 0.77 0.26 0.82 0.33

Other cosmetics 0.05 0.01 0.10 0.01 0.08 0.01 0.21 0.17 4.11 1.06

Total 24.37 10.29 20.20 9.36 31.37 11.66 41.58 17.50 67.14 25.22

Figure 2.3 Analysis of the export value of various cosmetics in my country from 2007 to 2011

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Figure 2.4 Analysis of the proportion of my country's cosmetics export value in 2007

Figure 2.5 Analysis of the proportion of my country's cosmetics export value in 2011

2.4 Major export target markets in recent years

2.4.1 Analysis of the quantity and value of China's cosmetics exports to five continents from 2007 to 2011

According to statistical data, Asia, America and Europe are the main export regions for my country's cosmetics. Compared with 2007, the volume and value of my country's cosmetics exports to Asia in 2011 increased by 130,300 tons and 614 million US dollars respectively, with the former decreasing by 3% and the latter increasing by 19%; the volume and value of exports to America increased by 82,500 tons and 276 million US dollars respectively, with the proportion decreasing by 5% and 10% respectively; the volume and value of exports to Europe increased by 98,700 tons and 388 million US dollars respectively, with the former increasing by 6% and the latter decreasing by 7%; the volume and value of exports to Africa increased by 26,300 tons and 53 million US dollars respectively, with the proportion increasing by 3% and 1% respectively; the volume and value of exports to Oceania increased by 6,100 tons and 1 million US dollars respectively, with the proportion decreasing by 1% and 3% respectively.

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Table 2.5 Quantity and value of cosmetic exports to five continents from 2007 to 2011

Unit: 10,000 tons / US\$100 million

Continent

Year Asia America Europe Africa Oceania

Quantity Value Quantity Value Quantity Value Quantity Value Quantity Value

2007 9.60 2.93 7.40 3.35 4.36 1.97 0.78 0.20 0.91 0.44

2008 9.53 3.56 4.73 2.47 3.31 1.96 1.40 0.31 0.46 0.14

2009 14.38 4.83 6.96 2.71 6.52 2.61 1.67 0.35 0.70 0.19

2010 17.82 6.06 9.67 3.92 8.24 4.21 1.99 0.44 0.78 0.25

2011 22.63 9.07 15.64 6.11 14.23 5.85 3.41 0.73 1.53 0.45

Figure 2.6 Analysis of the proportion of cosmetics exported by my country to various continents in 2007

Figure 2.7 Analysis of the proportion of cosmetics exported by my country to various continents in 2011

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Figure 2.8 Analysis of the proportion of cosmetics exported by my country to various continents in 2007

Figure 2.9 Analysis of the proportion of cosmetics exported by my country to various continents in 2011

2.4.2 Analysis of the quantity and amount of China's cosmetics major export regions from 2007 to 2011

In the past five years, North America, the European Union and Hong Kong have always been the regions with the largest cosmetics exports in my country. In 2011, compared with 2007, the quantity and amount of exports to North America increased by 66,800 tons and US\$204 million, respectively, and the proportion decreased by 2% and 9% respectively; the quantity and amount of exports to the European Union increased by 45,200 tons and US\$300 million, respectively, and the proportion increased by 2% and 3% respectively; the quantity and amount of exports to Hong Kong increased by 58,200 tons and US\$275 million, respectively, and the proportion of quantity decreased by 3%, and the proportion of amount increased by 4%. In 2011, the volume and value of cosmetics exports to these three regions accounted for 60% of the total volume and value of cosmetics exports.

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and above.

Table 2.6 Quantity and amount of cosmetics exported to major regions in my country from 2007 to 2011

Unit: 10,000 tons/US\$100 million Region 2007 2008 2009 2010 2011

Quantity Amount Quantity Amount Quantity Amount Quantity Amount Quantity Amount Quantity Amount

North America 6.56 3.04 3.90 2.14 6.07 2.36 7.93 3.26 13.24 5.08

European Union 2.89 1.60 2.85 1.81 3.56 2.09 4.79 3.58 7.41 4.60

Hong Kong 6.10 1.37 5.48 1.93 8.92 2.66 10.63 3.34 11.92 4.12

East Asia 0.96 0.66 0.82 0.74 1.06 0.82 1.79 1.01 2.93 1.51

ASEAN 0.96 0.80 0.65 0.86 0.99 0.90 1.37 1.29 2.33 1.70

Taiwan 0.82 0.31 0.81 0.36 1.23 0.47 1.41 0.56 1.57 0.62

Middle East 1.26 0.47 1.42 0.41 1.46 0.52 1.71 0.60 2.42 0.80

Latin America 0.83 0.31 0.82 0.33 0.86 0.33 1.71 0.65 2.37 1.02

Eastern Europe 1.43 0.36 0.44 0.14 2.93 0.50 1.37 1.29 2.33 1.70

Oceania 0.91 0.44 0.45 0.14 0.70 0.19 0.78 0.25 1.52 0.45

Africa 0.78 0.20 1.40 0.31 1.67 0.35 1.99 0.44 3.41 0.73

[Note] North America: United States, Canada, 2 countries in total;

European Union: France, Italy, Netherlands, Belgium, Luxembourg, Germany, Ireland, Denmark, United Kingdom, Greece,

Portugal, Spain, Austria, Finland, Sweden, Poland, Latvia, Lithuania, Estonia, Hungary, Czech Republic, Slovakia, Slovenia, Malta, Cyprus, Bulgaria, Romania, a total of 27 countries; East Asia: Japan, South Korea, North Korea, Mongolia, a total of 4 countries; ASEAN: Indonesia, Singapore, Thailand, Philippines, Malaysia, Brunei, Myanmar, Vietnam, Laos, Cambodia, a total of 10 countries; Middle East: Bahrain, Egypt, Iran, Iraq, Israel, Jordan, Kuwait, Lebanon, Oman, Qatar, Saudi Arabia, Syria, United Arab Emirates, Yemen, Palestine, Algeria, Libya, Morocco, Tunisia, Sudan, Mauritania, Somalia, a total of 22 countries; Eastern Europe: Russian Federation, Belarus, Ukraine, Moldova, a total of 4 countries.

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Figure 2.10 Distribution of quantity and proportion of major export regions of cosmetics in my country in 2007

Figure 2.11 Distribution of quantity and proportion of major export regions of cosmetics in my country in 2011

Figure 2.12 Distribution of amount and proportion of major export regions of cosmetics in my country in 2007

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Figure 2.13 Analysis of the distribution and proportion of the amount of cosmetics exported to major export regions in my country in 2011 Figure 2.4.3 Analysis of the number and amount of cosmetics exported to major export countries or regions in China from 2007 to 20011

In 2011, my country's cosmetics export trade involved more than 180 countries or regions. In terms of amount, the top ten countries or regions are: the United States, Hong Kong, the United Kingdom, bonded areas, Japan, Russia, France, Poland, Singapore and Taiwan. In 2011, they imported a total of 408,200 tons of cosmetics from my country, with a value of US\$1.758 billion, accounting for 60.79% and 69.70% respectively. Among them, the United States and Hong Kong far exceeded other countries or regions, with the export volume and amount accounting for more than 50%. However, from the perspective of the average export unit price, Singapore, Poland and France have obvious advantages and higher prices, while Russia has the lowest price, only US\$1.78/kg, which is about 1/10 of Singapore. Table 2.7 Quantity and amount distribution of my country's major cosmetics export countries (regions) from 2007 to 2011

Unit: 10,000 tons/US\$100 million Country 2007 2008 2009 2010 2011

Quantity Amount Quantity Amount Quantity Amount Quantity Amount Quantity Amount

United States 6.36 2.98 3.70 2.06 5.81 2.29 7.58 3.14 12.46 4.85

Hong Kong 6.10 1.37 5.48 1.93 8.92 2.66 10.63 3.34 11.92 4.12

United Kingdom 1.10 0.40 1.26 0.56 1.66 0.77 2.21 1.13 3.77 1.65

Bonded area 0.00 0.00 0.00 0.00 0.00 0.10 0.10 1.23 1.37

Japan 0.73 0.59 0.58 0.65 0.77 0.71 1.44 0.87 2.23 1.27

Russia 1.15 0.26 0.39 0.11 2.45 0.40 2.68 0.47 6.12 1.09

France 0.32 0.45 0.23 0.52 0.27 0.50 0.43 0.86 0.54 0.93

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Country 2007 2008 2009 2010 2011

Quantity Amount Quantity Amount Quantity Amount Quantity Amount Quantity Amount

Poland 0.03 0.02 0.14 0.13 0.11 0.13 0.40 0.69 0.49 0.85

Singapore 0.31 0.42 0.22 0.48 0.35 0.46 0.41 0.72 0.48 0.84

Taiwan 0.82 0.31 0.81 0.36 1.23 0.47 1.41 0.56 1.57 0.62

Figure 2.14 Analysis of the distribution of the quantity and proportion of my country's cosmetics exports to major countries or regions in 2011

Figure 2.15 Analysis of the distribution of the amount and proportion of my country's cosmetics exports to major countries or regions in 2011

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Figure 2.16 Average unit price of cosmetics exported to major exporting countries in 2011

In addition, compared with 2007, the export trade of the above 10 countries or regions has shown different degrees of growth. According to the amount of statistics, the top three countries with the highest growth rate are Poland, Russia and the United Kingdom.

Figure 2.17 Analysis of the number of major exporting countries or regions of cosmetics in my country in 2007 and 2011

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Figure 2.18 Analysis of the amount of cosmetics exported to major countries or regions in my country in 2007 and 2011

2.4.4 Analysis of major export target markets

# 2.4.4.1 The United States

The United States is a global giant in the cosmetics industry. In 2011, my country exported a total of 485 million US dollars of cosmetics to the United States, of which skin cosmetics exported 216 million US dollars, accounting for 44%; beauty cosmetics exported 179 million US dollars, accounting for 37%; other cosmetics exported 29 million US dollars, accounting for 6%; perfume cosmetics exported 28 million US dollars, accounting for 6%; hair cosmetics exported 27 million US dollars, accounting for 6%; special function cosmetics exported 4 million US dollars, accounting for 1%; oral cosmetics exported 2 million US dollars, accounting for less than 0.5%.

Figure 2.19 Analysis of the amount of each type of cosmetics exported to the United States in 2011

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## 2.4.4 .2 Japan

Japan is a relatively developed country in terms of cosmetics production and consumption, and its market size is second only to the United States. It has the largest cosmetics market and research and development center in Asia. After experiencing rapid development, it has now entered a mature stage. In 2011, my country exported a total of 127 million US dollars of cosmetics to Japan, of which skin cosmetics exported 0.47 billion US dollars, accounting for 37%; beauty cosmetics exported 0.40 billion US dollars, accounting for 32%; hair cosmetics exported 0.31 billion US dollars, accounting for 25%; special function cosmetics exported 0.05 billion US dollars, accounting for 4%; other cosmetics exported 0.02 billion US dollars, accounting for 1%; oral cosmetics exported 0.01 billion US dollars, accounting for 1%; perfume cosmetics exported were relatively small, less than 0.01 billion US dollars.

Figure 2.20 Analysis of the proportion of various cosmetics exports from my country to Japan in 2011

#### 2.4.4.3 EU

The EU is my country's largest trading partner, and its cosmetics manufacturing industry is particularly developed. The United Kingdom, France, Germany, and Italy are all traditional cosmetics manufacturing powers with many large cosmetics companies and long-standing leading cosmetics brands. In 2011, my country exported a total of 460 million US dollars of cosmetics to the EU, of which skin cosmetics exports were 212 million US dollars, accounting for 46%; beauty cosmetics exports were 169 million US dollars, accounting for 37%; perfume cosmetics exports were 53 million US dollars, accounting for 12%; hair cosmetics exports were 9 million US dollars, accounting for 2%; oral cosmetics exports were 8 million US dollars, accounting for 2%; other cosmetics exports were 6 million US dollars, accounting for 1%; special function cosmetics exports were 1 million US dollars, accounting for less than 0.3%.

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Figure 2.21 Analysis of the proportion of various cosmetics exported from my country to the EU in 2011

# 2.4.4 .4 Hong Kong

Hong Kong has a relatively developed domestic and re-export trade in cosmetics, and is one of my country's major export destinations. In 2011, my country exported a total of 412 million US dollars of cosmetics to Hong Kong, of which skin cosmetics exported 148 million US dollars, accounting for 36%; beauty cosmetics exported 84 million US dollars, accounting for 20%; hair cosmetics exported 72 million US dollars, accounting for 18%; oral cosmetics exported 56 million US dollars, accounting for 14%; other cosmetics exported 37 million US dollars, accounting for 9%; perfume cosmetics exported 9 million US dollars, accounting for 2%; special function cosmetics exported 5 million US dollars, accounting for 1%.

Figure 2.22 Analysis of the proportion of various cosmetics exported from my country to Hong Kong in 2011

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#### 2.4.4.5 Other markets

With the establishment of the China-ASEAN Free Trade Area, ASEAN has become one of the important markets for my country's cosmetic exports. In 2011, cosmetic exports to ASEAN accounted for 8% of my country's total cosmetic exports, second only to North America, the European Union and Hong Kong. my country's cosmetic exports to ASEAN cover a wide range, including cosmetics, skin care products, aftershave and other advanced finished products, as well as raw material products such as essences and essential oils. This to a certain extent shows that my country's cosmetics industry has richer production technology and experience than ASEAN, and is in a certain competitive advantage. It is worthy of attention from domestic enterprises and they should actively explore the Southeast Asian cosmetics market. In addition, the reduction of cosmetics tariffs between China and ASEAN countries will also promote the growth of import and export trade of related products between the two sides to a certain extent.

2.5 Main advantages of Chinese products in the international market

## 2.5.1 Price advantage

my country's cosmetics are mainly concentrated in low- and medium-end products with excellent quality, but simple packaging and simple product lines, which leads to low cost and low selling price. my country has abundant labor resources and low labor costs. my country has abundant natural resources, which provide raw material guarantee for the production of cosmetics. After my country joined the WTO, the import tariffs on chemical raw materials were lowered, reducing the cost of products.

# 2.5.2 Technical advantages

The production and use of cosmetics in my country has a long history and a profound cultural connotation. my country's cosmetics companies such as Shanghai Jahwa and Tianjin Yumeijing have a long production history, advanced process equipment and strong technical force. They implement standardized production procedures, introduce scientific management methods, create skin care research centers, strictly monitor product quality, and develop a large number of high-quality skin care products; focus on the development of new products, apply modern high-tech means, fundamentally change product structure, and increase product added value and technical content.

Cosmetics are the crystallization of the intersection of multiple disciplines. In recent years, the rapid development of cosmetics-related industries in my country, such as machinery industry, packaging industry, chemical industry, pharmaceutical industry, traditional Chinese medicine industry and microelectronics industry, has provided cosmetics with more high-quality raw materials, packaging materials, equipment technology and expanded the traditional Chinese medicine needed for cosmetics, so that the cosmetics industry continues to progress in depth and breadth, presenting an unprecedented prosperity.

my country has unique resources of Chinese herbal medicines. Chinese herbal cosmetics have a long history, a wide variety of products, and a wide range of dosage forms.

20 The products are diverse and integrated with traditional Chinese medicine, and have obvious functionality. Cosmetics made of chemical synthetic substances are prone to toxic side effects and skin allergic reactions, while cosmetics made of natural plants are safe, reliable, and treat both the symptoms and the root causes. They are the best raw materials for biological functional cosmetics. In the thousands of years of application of traditional Chinese herbal medicines for external and internal use, many records and experiences of efficacy have been accumulated, and their dosage, safety and side effects have also been verified. This has opened up a vast resource for the exploration of raw materials for cosmetics and provided favorable conditions for the development of new cosmetics. Therefore, my country has a strong advantage in the development of natural nutritional and therapeutic cosmetics.

In addition, many multinational cosmetics companies have come to China to invest. They have technical advantages, product advantages, business management advantages, global cooperation advantages and information advantages. They produce world-class brands in China, which has promoted the development of the high-end cosmetics market; they have invested millions or even tens of millions of dollars in China to establish large-scale research institutions and research and development centers, which has promoted the vigorous development of my country's cosmetics industry. In addition, they are also participants in the research and formulation of relevant regulations and product standards of the international cosmetics industry. Relevant government departments propose measures and methods for the supervision and management of cosmetics and provide relevant information, which is more conducive to the faster integration of Chinese cosmetics with the international market.

#### 2.5.3 Scale advantage

At present, there are more than 3,300 cosmetics manufacturers in China, more than 2,500 product varieties, 14 Chinese famous brand production areas, 25 well-known Chinese trademarks and overseas sales areas in more than 150 countries and regions. my country's cosmetics industry has initially formed a huge cosmetics economic chain with cosmetics products as the core. In 2011, the total industrial output value (current price) of my country's cosmetics industry was RMB 79.033 billion, a year-on-year increase of 21.6%, and the sales-to-production ratio was 99%. In 2010, the total output value was RMB 69.507 billion, a year-on-year increase of 18.7%, and the sales-to-production ratio was 100.8%.[1]

## 2.6 Potential target markets

# 2.6.1 Eastern Europe

Due to the entry of cosmetics companies from many countries at the end of the last century, the cosmetics market in Eastern Europe is now close to the mature Western European market. Many leading brands with large sales volumes, such as Oriflame, Dove and Nivea, dominate the entire market, mainly focusing on skin care and hair care products. However, the market segments in different regions are not the same. In Croatia, skin care products are the largest market, with a market value of 56 million euros in 2007, followed by hair care products.

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In 2010, the cosmetics market was valued at 39 million euros; in the Czech Republic, the market value of hair care products exceeded that of skin care products by 150 million euros, reaching 195 million euros; in Estonia, the skin care market was valued at 30 million euros, while the hair care market was valued at only 19 million euros; in Slovenia, the skin care market accounted for the largest share, valued at 39 million euros, followed by hair care products, valued at 36 million euros, ranking first and second in the cosmetics market respectively [3].

#### 2.6.2 Latin America

In recent years, with the recovery of the global economy, some new dynamics have emerged in the cosmetics industry. In 2009, against the backdrop of the global financial crisis, Latin America bucked the trend and cosmetics sales increased by 15% [2]; in 2010, it increased by 20%, with BPC reaching US\$64 million, almost comparable to the North American market [1]. Industry insiders are optimistic about the future of the cosmetics industry market in Latin America. In 2009, the top ten cosmetics brands in Latin America were Avon, Natura, Colgate, Gillette, Botica, Sunsilk, L?Oréal, Nivea, Palmolive and Dove [5]. Brazil, as the sales regional center of the beauty and personal care products industry in Latin America, had a cosmetics market sales of US\$29 billion in 2009, accounting for 1.3% of Brazil?s GDP. Euromonitor International?s analysis report pointed out that in the future, driven by greater consumption, such as increased purchase frequency and changes in consumption concepts among low-income groups, sunscreen care products, baby care products, depilatories and color cosmetics will maintain dynamic growth [5]. At the same time, local Latin American companies such as Natura Cosmestics, Botica Comercial Farmaceutica Ltda, L?Bel and Unique-Yanbal Group are also growing stronger [1]. The cosmetics industry in Latin America is working hard to develop and improve natural and organic products, environmental themes, social responsibility, and trade between different countries in the region [5].

## 2.6.3 Middle East

In recent years, with the increase in population and the development of local tourism, the Middle East has gradually become one of the fastest growing regions in the world for cosmetics and personal care products. The product categories are mainly beauty cosmetics and perfumes, with an annual sales growth rate of 10% to 15%. According to statistics from the Gulf Cooperation Council, in 2006, the luxury/high-end cosmetics market in the Middle East reached US\$800 million to US\$1 billion, with the UAE accounting for 28% of the market share, and Saudi Arabia, which has one of the largest number of cosmetics consumers in the Middle East, accounting for 45% of the market share. In 2007, Saudi Arabia's cosmetics and perfume sales were US\$1.32 billion and US\$238 million respectively; in 2008, Dubai's cosmetics and perfume sales increased by 39% and 34% respectively.

22 Among the cosmetics consumers in the UAE, 25%~30% are local Arab women, 25%~30% are foreigners, and 15%~20% are tourists. Compared with Saudi Arabia, the market management in the UAE and Dubai is relatively loose, and the development is relatively fast, and consumers are more mature and professional [4].

## 2.6.4 Africa

In recent years, the demand for cosmetics in Africa has been growing rapidly, and the market potential is huge. In South Africa, the annual demand for cosmetics exceeds US\$1.15 billion, and the demand for moisturizers and shampoos in Cote d'Ivoire can reach US\$40 million per year. According to statistics, the annual growth rate of the demand for cosmetics in the entire African market is 30%.

Cosmetics companies from many countries have entered the African cosmetics market one after another. People in any region are unwilling to treat their skin badly, and Africans are no exception. Even in some poor countries, there are many fashionable girls on the streets, and there are countless cosmetics stores, supermarket cosmetics counters and various beauty salons.

Africans like to work hard on their distinctive hair. In African cosmetics stores, there are all kinds of cosmetics for shampooing, hair care, hair dyeing, and hairdressing. As the African continent is generally hot and dry, the skin is prone to lose moisture, so moisturizers, moisturizing oils, and toners are generally favored by consumers. In addition, Africans also prefer to wear lipstick, nail polish, and perfume with strong fragrance, and in this regard, African men are even more than women. African cosmetics are mainly imported. Due to high taxes and high profits, the smuggling of cosmetics is quite serious. French products have the highest market share in Africa, followed by the United States. Chinese cosmetics are still relatively rare in the African market. As Chinese cosmetics companies, we can expand and strengthen our cosmetics brands by participating in African trade fairs, online marketing, and participating in cosmetics exhibitions, so that Africans can understand Chinese cosmetics and enter the African cosmetics market as soon as possible and in a healthy way. Cosmetics produced by Chinese companies are generally not suitable for African skin and hair characteristics. Therefore, if Chinese cosmetics want to enter the African market, they should develop some products specifically for this market. The research and development of new products cannot be omitted.

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III. Cosmetics labeling requirements in major markets and differences with my country

3.1 EU

- 3.1.1 Legal documents
- · Directive 76/768/EEC ("Directive 76/768/EEC"): "EU Cosmetics Directive" (repealed on July 11, 2013)
- · Directive 95/17/EC ("Directive 95/17/EC"): Detailed provisions on whether one or more ingredients of cosmetics may not be marked in the label ingredient list
- (EC) 1223/2009 ("Cosmetics Regulation of the European Parliament and of the Council"): It came into effect on July 11, 2013, and will replace the old Cosmetics Directive 76/768/EEC and its 67 amendments to date (Note: some of the requirements will be implemented before the above date).

## 3.1.2 Competent authorities

Cosmetics are under the jurisdiction of the Cosmetic and Medical Department of the European Commission's Business Directorate, and each member state has its own official agency responsible for its own supervision and management, mainly focusing on post-market management.

The main work of the competent authorities of each government is in three aspects: auditing at the sales, production and distribution sites; reviewing labels; reviewing the documents provided.

There are three main ways of supervision:

- ? Health hazard or follow-up investigation;
- ? Special investigation according to product category;
- ? On-site inspection.
- 3.1.3 Definition of cosmetics

Cosmetics refer to any external part of the human body (skin, hair, nails, lips and genitals) or teeth

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- 24 Substances or products that are applied to teeth and oral mucosa, mainly for cleaning, fragrance or protection, in order to achieve good condition, beautify or eliminate body odor.
- 3.1.4 Classification of cosmetics
- (1) Creams, lotions, liquids, gels and oils (for hands, face, feet, etc.);
- (2) Facial masks (except chemical peeling products);
- (3) Color fixatives;
- (4) Make-up powders, after-bath powders, hygiene powders, etc.;
- (5) Toilet soaps, deodorant soaps, etc.;
- (6) Perfumes, toilet water, cologne;
- (7) Bathing and rinsing products (bath salts, bath bubbles, bath oils, gels, etc.);
- (8) Depilatories;
- (9) Deodorants and antiperspirants;
- (10) Hair products (hair dyes and bleaches, curling, straightening and styling agents, styling products, cleaning products (liquids, powders, shampoos), hair care products (liquids, creams, oils), hair styling products (liquids, brighteners, oils);
- (11) Shaving products (creams, foams, liquids, etc.);
- (12) Makeup and remover products for the face and eyes;
- (13) Products for the lips;
- (14) Products for the protection of teeth and the oral cavity;
- (15) Products for the protection and makeup of nails;
- (16) Products for external use on personal hygiene;
- (17) Products for sunbathing;
- (18) Products for non-sun tanning;

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- (19) Skin whitening products;
- (20) Anti-wrinkle products.
- 3.1.5 Cosmetic labeling requirements
- 3.1.5.1 General requirements for cosmetic labeling

Article 6 of the EU Cosmetics Directive stipulates the requirements for cosmetic labeling, which stipulates that the following must be indicated:

- (1) Product name or type
- (2) Address or registered office of the manufacturer or distributor in the EU

When multiple addresses are provided, the address where the product information is kept must be indicated, and the address can be underlined.

The EU Directive does not require the country of origin of imported cosmetics to be indicated, but some member states may require it;

(3) Net content

Indicated by weight or volume. It is mandatory to indicate SI metric units, and US customary units can also be indicated.

When both units are used, SI metric units must prevail. Dual labeling can only be used until 2009.

Directive 76/211/EC stipulates the labeling requirements for net content, and its amendment introduces a series of management of average volume or weight. The mark "e" next to the net content on the label indicates that the labeling of net content complies with the directive. The Aerosol Directive 75/324/EEC requires that aerosol products be labeled with both weight and volume.

(4) Cosmetic ingredient list

It is required to label the names of all cosmetic ingredients on the outer packaging. If this is not possible for practical reasons, it can be printed on the accompanying booklet, label, tape or card, but at the same time, a simple phrase or the symbol in Appendix VIII should be printed on the outer packaging to instruct consumers to refer to it. The ingredient list should be introduced with "INGERDIENTS" as the introduction at the beginning of the sentence.

The labeling order is:

? The names of the ingredients with a content higher than 1% are listed in descending order of the amount added, and the ingredients with a content lower than 1% can be listed in any order.

? Colorants can be marked after other ingredients in any order.

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26 For cosmetics, all colorants within the scope of use should be listed and marked with the words "may contain" or the symbol "+/-".

Names of labeled ingredients:

? Ingredients must use the names specified or adopted by the following regulations: INCI name (International Nomencalture Cosmetic Ingredient), European Pharmacopoeia name, World Health Organization recommended non-proprietary name, European Inventory of Existing Commercial Chemical Substances (EINECS) index number, International Union of Pure and Applied Chemistry (IUPAC) index number, American Chemical Abstracts (CAS) index number, pigment index number and common name recommended in Article 7 (2).

The following are not considered ingredient substances:

- Impurities in raw materials;
- Excipients used in production but not contained in the finished product;
- Substances used as solvents or carriers for flavors or aromatic substances and the amount used is strictly controlled.
- ? Flavors and aromatic ingredients and their raw materials should be indicated by the word "fragrance" or "fragrance" ("perfume" or "aroma");
- ? Colorants must use the dye color index number (CI number). If there is no corresponding CI number, the INCI name should be used;

When containing substances mentioned in the requirements listed in the "Other restrictions and requirements" table in Annex III, regardless of their function, they should be marked in the ingredient list.

Sometimes, for reasons of commercial confidentiality, manufacturers will apply for not publishing one or more ingredients in the ingredient list. This must comply with the provisions of Directive 95/17/EC.

(5) Shelf life

The shelf life should be marked as: "best used before the end of...", and the date should be marked in one of the following ways:

- Date (in the order of "month, year" or "day, month, year")
- Place to indicate the date

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For cosmetics with a shelf life of more than 30 months, it is not mandatory to label the shelf life, but it is necessary to indicate the time after opening that the product can be used safely. Label according to the symbol "Period After Opening (PAO)" given in Annex VIII (a), and indicate the expiration date after the symbol: "Number + M" indicates the number of months that the product can be used, and does not need to be translated into the native language of each member state; "Number + years" can also be used to indicate the number of years that the product can be used, but "years" must be translated into the native language of the country of sale.

(6) Production batch number or product identification number

If it is not possible to do so due to the small size of the product itself, it is allowed to be marked only on the outer packaging (secondarily, it can also be marked on the outer container).

(7) Necessary warning statements (precautions)

Products containing specific ingredients must be marked with warning statements in accordance with the Annex to the EU Cosmetics Directive. All member states require that warning terms be marked in their respective national languages, and must be marked on both the inner and outer packaging. If this is not possible for practical reasons, it may be marked on the instructions, labels or cards, but at the same time, a simple wording or the symbol in Annex VIII must be printed on the container or outer packaging to indicate to the consumer.

There are special warning provisions for aerosol products and flammable products, see the Aerosol Directive 75/324/EEC and its amendment 94/1/EC. In addition, the European Cosmetic, Tioletry, and Perfumery Association (Colipa) Liaison Committee has issued a policy on the labeling of flammable products, defining the circumstances under which certain cosmetics are required or not required to be marked with this warning statement.

- (8) The necessary instructions for use must be stated in the official language or the native language of the country of sale. This information can be marked on an accompanying booklet, tape or label strip, and printed with a simple wording or the symbol in Annex VIII to indicate to the consumer.
- (9) Necessary storage conditions
- (10) Product efficacy

If the appearance of the product can clearly show its efficacy, it does not need to be labeled.

The efficacy claims must not be misleading. When the competent authority believes that the description, label, or other information provided by the manufacturer or responsible organization of a product may make the product harmful to human health, it will be prohibited

28 Placed on the market. In addition, some member states have detailed national regulations.

"Misleading Advertising 84/450/EEC" and its revised version 97/55/EEC are directives specifically on comparative advertising. It stipulates that comparative advertising is allowed under the conditions specified in the directive.

Among them, the product name or type, the address or registered office of the manufacturer or distributor in the EU, the net content, shelf life, instructions for use, production batch number, necessary warning statements, product efficacy and storage conditions must be marked on both the inner and outer packaging.

All label content should be marked in at least the native language of each country or the official language of the EU or the above two languages.

There is no requirement for font size (except for the net content requirement in "Directive 76/211/EC"). However, it is recommended to use a font size that can ensure that people with normal vision can easily read it at a distance of about 30 cm.

(EC) 1223/2009 (Cosmetics Regulation of the European Parliament and of the Council) will replace the old Cosmetics Directive 76/768/EEC and its 67 amendments to date from July 11, 2013, and will be published in the form of EU regulations and implemented as national laws in 27 EU member states (as well as Norway, Iceland and Liechtenstein). At that time, cosmetics sold in the European Economic Area 1 (EEA) market must comply with the requirements of the newly promulgated EU Cosmetics Regulation (EC) No 1223/20092, some of which will be implemented before the above date, such as the provisions on CMR (carcinogenic, mutagenic or toxic to reproduction) and nanomaterials will be implemented on December 1, 2010 and January 11, 2013 respectively. The new regulation simplifies the requirements for cosmetics in the European Economic Area, making it a single law and eliminating the content that may cause differences in the enforcement process of member states. Cosmetics notifications only need to be submitted to a database jointly developed by the Central Committee and COLIPA (European Cosmetics Association), rather than to each member state as it is now. However, companies need to notify and keep relevant documents on their own, rather than having industry associations manage them. The definition of responsible persons in the Cosmetics Regulation of the European Parliament and the Council of the European Union has become clearer, stipulating that responsible persons specifically include: ? manufacturers within the EEA, ? importers who import products into the EEA, and ? distributors who use their own names or trademarks to put cosmetics on the market or whose changes to cosmetics may affect their regulatory compliance (excluding text translations only). According to the new requirements, responsible persons will bear more legal responsibilities, involving cosmetics manufacturing specifications (GMP), product safety reports, product information files (PIF), product notifications, product declarations, etc. The regulation

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(1) Country of origin;

Cosmetics imported into the EEA must be marked with the country of origin;

(2) Minimum shelf life

The text before the date "best used before the end of" can be replaced by the new egg timer symbol: If the expiration date after opening is irrelevant (confirmed by actual practice), there is no need to indicate the expiration date after opening.

Minimum shelf life egg timer symbol

- (3) Before placing the product on the market, distributors should ensure that the following labelling requirements are met:
- Name or registered name and address of the responsible person;
- Batch number or identification information of the cosmetic product;
- Ingredient list; (the name of the nanomaterial in the ingredient list should be followed by the word "(nano)")
- Derogation for soaps, bath bombs and other small products;
- National regulations on cosmetics that are not pre-packaged, packaged at the time of sale at the request of the buyer, or pre-packaged for immediate sale.

#### 3.1.5.2 Environmental Labels

The EU introduced the eco-label system in 1992 through Regulation EEC 880/92, which set minimum requirements for products claiming to be "environmentally friendly", and further amended and supplemented it through Regulation EU 1980/2000 in 2000. This regulation applies to all member states and provides a mechanism for how to grant eco-labels to products that meet the standards established by their respective industries. It evaluates the impact of a product from production to disposal. The label is voluntary and requires a user fee. Each member state has a designated entity to manage this matter within its own country. So far, no category of cosmetics has established complete standards for the granting of this eco-label. Some member states have their own mandatory environmental labeling laws.

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30 3.1.5.3 Labeling of small-packaged products and other exemptions

The following situations do not require the labeling of net content: ? Samples with a packaging capacity of less than 5g or 5ml; ? Free samples; ? Individually packaged samples; ? Samples usually sold by quantity. However, other mandatory labeling requirements are still required. Warnings (precautions), instructions for use, and ingredient lists can be marked on accompanying instructions, labels, tapes or cards. In this case, symbols must be printed on the outer packaging to instruct consumers to refer to these accompanying information.

"Directive 1999/45/EC on Dangerous Preparations" mentions labeling requirements for cosmetics using hazardous raw materials and specific exemptions from labeling. Article 10 of the directive requires the establishment of safety data sheets (SDSs) at the site where this dangerous product is used. These guidelines are stipulated in "Directive 91/155/EEC", which also exempts cosmetics, but users can request that equivalent product information be given in other ways.

- 3.2 United States
- 3.2.1 Legal documents
- ? The Food, Drugs and Cosmetics Act (FD&C Act): Main regulation for cosmetics
- ? The Fair Packaging and Labelling Act (FPLA): Regulations for labeling, packaging and advertising of cosmetics
- ? Cosmetic Labelling: 21 CFR 701
- ? Cosmetic Labelling Manual
- ? Labeling Requirements for Over-the-Counter Drugs: 21CFR201.66
- 3.2.2 Competent authorities

The Food and Drug Administration (FDA) is responsible for cosmetics and drugs. The Center for Food Safety and Applied Nutrition (CFSAN) is responsible for the supervision and management of cosmetics from production to marketing. It can enter the production plant without notice to conduct inspections and conduct random inspections of products on the market.

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products. Imported products must comply with the "Import Cosmetics Regulations". OTC drugs are managed by the Center for Drug Evaluation and Research (CDER). Products that are both cosmetics and OTC drugs are jointly managed by CFSAN and CDER. For overseas products imported into the United States, FDA can conduct inspections overseas.

# 3.2.3 Definition of Cosmetics

The FD&C Act defines cosmetics as two categories:

## ? Cosmetics

## ? Over-the-counter drugs

Whether a product is a cosmetic or a drug depends on its use, which is determined by the product's efficacy claims and consumer perception (through word of mouth or the therapeutic function of the ingredients). According to the FD&C Act, a product can be a drug, a cosmetic, or both a drug and a cosmetic (just the opposite of the EU).

The third situation only occurs when the product has two uses and meets both definitions, for example: anti-dandruff shampoo is a cosmetic because its claim indicates that the product is used to clean the hair; but it can also be considered a drug because it contains recognized anti-dandruff ingredients and its claim indicates that it is used to treat dandruff. Products determined to be both cosmetics and drugs must meet the regulatory requirements of both categories of products.

Definition of cosmetics: Products other than soaps containing alkaline salts of fatty acids that are applied to the human body (rubbed, poured, sprinkled or sprayed) or any part of it for the purpose of cleansing, beautifying, enhancing attractiveness or improving appearance without affecting the structure or function of the human body.

Definition of drug: Articles used to cure, mitigate, treat or prevent disease in humans and other animals and articles other than food that are used to affect the structure and function of the human or other animals.

Over-the-counter drugs are drugs that can be purchased without a doctor's prescription.

Some products that are classified as cosmetics in the EU are classified as new drugs rather than OTC drugs in the United States. New drugs are drugs that have not yet been widely recognized by experts as safe and effective for their intended use, or drugs that have not yet been used within a specific scope or time.

32 3.2.4 Classification of cosmetics (1) Classification of cosmetics: -Skin care -Perfume -Eye cosmetics -Cosmetics outside the eye -Nail products -Bath oils and foam baths -Mouthwash -Hair dye pretreatment -Shampoo, perm or other hair care products -Deodorant -Shaving products -Children's products -Ch	Guidelines for the labeling management of cosmetics in various countries
Skin care Perfume Eye cosmetics Cosmetics outside the eye Nail products Bath oils and foam baths Mouthwash Hair dye pretreatment Shampoo, perm or other hair care products Deodorant Shaving products Children's products Tanning products (2) Classification of OTC drugs (cosmetics): Anticaries (fluoride-containing) toothpaste Moisturizing products Sunscreen cosmetics Antiperspirants	32 3.2.4 Classification of cosmetics
Perfume -Eye cosmetics -Cosmetics outside the eye -Nail products -Bath oils and foam baths -Mouthwash -Hair dye pretreatment -Shampoo, perm or other hair care products -Deodorant -Shaving products -Children's products -Cassification of OTC drugs (cosmetics): -Anticaries (fluoride-containing) toothpaste -Moisturizing products -Sunscreen cosmetics -Antiperspirants	(1) Classification of cosmetics:
-Eye cosmetics -Cosmetics outside the eye -Nail products -Bath oils and foam baths -Mouthwash -Hair dye pretreatment -Shampoo, perm or other hair care products -Deodorant -Shaving products -Children's products -Tanning products -(2) Classification of OTC drugs (cosmetics): -Anticaries (fluoride-containing) toothpaste -Moisturizing products -Canscreen cosmetics -Antiperspirants	-Skin care
Cosmetics outside the eye  Nail products  Bath oils and foam baths  Mouthwash  Hair dye pretreatment  Shampoo, perm or other hair care products  Deodorant  Shaving products  Children's products  Tanning products  (2) Classification of OTC drugs (cosmetics):  Anticaries (fluoride-containing) toothpaste  Moisturizing products  -Antiperspirants	·Perfume
Nail products Bath oils and foam baths  Mouthwash Hair dye pretreatment Shampoo, perm or other hair care products Deodorant Shaving products Children's products Tanning products (2) Classification of OTC drugs (cosmetics): Anticaries (fluoride-containing) toothpaste Moisturizing products -Antiperspirants	-Eye cosmetics
-Bath oils and foam baths  -Mouthwash  -Hair dye pretreatment  -Shampoo, perm or other hair care products  -Deodorant  -Shaving products  -Children's products  -Tanning products  (2) Classification of OTC drugs (cosmetics):  -Anticaries (fluoride-containing) toothpaste  -Moisturizing products  -Sunscreen cosmetics  -Antiperspirants	·Cosmetics outside the eye
-Mouthwash -Hair dye pretreatment -Shampoo, perm or other hair care products -Deodorant -Shaving products -Children's products -Tanning products (2) Classification of OTC drugs (cosmetics): -Anticaries (fluoride-containing) toothpaste -Moisturizing products -Sunscreen cosmetics -Antiperspirants	-Nail products
-Hair dye pretreatment -Shampoo, perm or other hair care products -Deodorant -Shaving products -Children's products -Tanning products (2) Classification of OTC drugs (cosmetics): -Anticaries (fluoride-containing) toothpaste -Moisturizing products -Sunscreen cosmetics -Antiperspirants	-Bath oils and foam baths
-Shampoo, perm or other hair care products -Deodorant -Shaving products -Children's products -Tanning products (2) Classification of OTC drugs (cosmetics): -Anticaries (fluoride-containing) toothpaste -Moisturizing products -Sunscreen cosmetics -Antiperspirants	·Mouthwash
Deodorant Shaving products Children's products Tanning products (2) Classification of OTC drugs (cosmetics): Anticaries (fluoride-containing) toothpaste Moisturizing products Sunscreen cosmetics Antiperspirants	·Hair dye pretreatment
-Shaving products -Children's products -Tanning products (2) Classification of OTC drugs (cosmetics): -Anticaries (fluoride-containing) toothpaste -Moisturizing products -Sunscreen cosmetics -Antiperspirants	-Shampoo, perm or other hair care products
-Children's products -Tanning products (2) Classification of OTC drugs (cosmetics): -Anticaries (fluoride-containing) toothpaste -Moisturizing products -Sunscreen cosmetics -Antiperspirants	-Deodorant
-Tanning products (2) Classification of OTC drugs (cosmetics): -Anticaries (fluoride-containing) toothpaste -Moisturizing products -Sunscreen cosmetics -Antiperspirants	·Shaving products
(2) Classification of OTC drugs (cosmetics):  -Anticaries (fluoride-containing) toothpaste  -Moisturizing products -Sunscreen cosmetics -Antiperspirants	·Children's products
-Anticaries (fluoride-containing) toothpaste -Moisturizing products -Sunscreen cosmetics -Antiperspirants	·Tanning products
-Moisturizing products -Sunscreen cosmetics -Antiperspirants	(2) Classification of OTC drugs (cosmetics):
-Sunscreen cosmetics -Antiperspirants	-Anticaries (fluoride-containing) toothpaste
·Antiperspirants	-Moisturizing products
	·Sunscreen cosmetics
-Anti-dandruff shampoo	·Antiperspirants
	·Anti-dandruff shampoo

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3.2.5 Cosmetic Label Requirements

3.2.5.1 General Requirements for Cosmetic Labels

Specifies the following information that must be marked on cosmetic labels:

(1) Product name and description: must be marked on the main display surface of the outer packaging.

Use the common name of the cosmetic or an appropriate descriptive name. If the nature of the cosmetic is obvious, a more exotic and interesting name may be used without causing misunderstanding or indistinguishability to the public.

(2) Name and address of the manufacturer, packer or distributor: marked on the inner and outer packaging.

For specific regulations, see Section 701.1.2 of Volume 21 of the Code of Federal Regulations (CFR). Imported cosmetics must be marked in English on the outside of the container with the country of origin and the manufacturer or agent (including the importer). The country of origin is marked with the following statement: "Made in ... (name of country in English)";

or "Product of ... (name of country in English)"; or other statements that clearly indicate the meaning of the country of origin.

If the country of origin is a NAFTA country, it can be in English, French or Spanish.

(3) Net content: marked on the main display panel of the inner and outer packaging.

It is mandatory to mark it in traditional U.S. customary units. In addition, it can also be marked in metric units. If the cosmetic is a liquid, the statement must be in volume units; if the cosmetic is a solid, semi-solid, viscous substance or solid mixture, the statement must be in weight units. Weight is expressed in pounds and ounces. Liquid volume is expressed in U.S. gallons, quarts, pints and fluid ounces. There are slight differences in volume calculations in the United States and in the United Kingdom and other countries. The specific provisions for net content labeling are found in 21 CFR 701.13.

(4) Cosmetic ingredient list: marked on the outer packaging.

See 21 CFR 701.3 for specific regulations. All ingredients of cosmetics must be listed on the cosmetic label for retail products for personal use. Cosmetics that are not generally sold for retail, such as hair products or makeup products that professionals use on customers in professional institutions, and cleansers and moisturizers for people to use in the workplace, and these products are not sold to consumers for their home use, do not need to indicate the ingredients. Perfumes and fragrances are exceptions, which can only list non-trademark names. In addition, for the purpose of commercial confidentiality, with the approval of FDA,

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34 Ingredients exempted from disclosure may not be listed on the label, but must be declared at the end of the label components: "and other ingredients". If there is not enough label space on the package or the container is decorative, an additional label (attached label, tape or card) may be used (for details, see the CTFA labeling manual (The Cosmetic, Toiletry and Fragrance Association, now renamed the Person Care Products Council, the Personal Care Products Council of the United States)).

The labeling order is:

Ingredients with a content higher than 1% are arranged in descending order; ingredients with a content less than 1% can be arranged in any order; color additives are arranged in any order, and are introduced with the statement "Contains...", and the "+/-" symbol cannot be used; "and other ingredients".

The names of the ingredients must be listed in the following order: the designated names listed in 21 CFR 701.30, the CTFA Cosmetic Ingredient Dictionary (see INCI names for this specified name), the name in the United States Pharmacopoeia, the name in the National Formulary, the name in the Food Chemical Codex, the name in the United States Drug Proper Names and Pharmacopeia, the name recognized by consumers, the chemical or other technical name or description.

(5) Shelf life

It should state the period of time during which it is safe to use.

(6) Batch number

Cosmetics do not require batch identification, but it should be based on healthy commercial activities.

(7) Warning statement: marked on the inner and outer packaging.

The Warning Statements for Cosmetic Products (21 CFR 740) provides detailed regulations on warning statements. Some product labels must carry warning words. For example, cosmetics packaged in self-pressurized containers (such as spray products), women's deodorant sprays and children's foam baths. Once a specific warning is legally recognized, the wording cannot be changed and must be used in accordance with the relevant regulations. If the safety of a cosmetic product is not fully proven and the following clear statement does not appear on the main display panel of the label: "Warning - The safety of this product has not been determined", the cosmetic product will be considered mislabeled. In addition, it is necessary to pay attention to the laws of some states that have special requirements for warnings.

(8) Label storage conditions when necessary.

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(9) If necessary, safe use instructions shall be indicated.

The Act requires or permits all text, statements, and other information to be indicated on the label to be in English, however, if the product is sold only in the Commonwealth of Puerto Rico or in a region where the dominant language is not English, the dominant local language may be used in lieu of English.

## 3.2.5.2 OTC drug labeling requirements

In addition to the above requirements for cosmetic labels, the "OTC drug labeling requirements" also have the following provisions:

- (1) "drug facts" must be marked;
- (2) Product presentation: required to be marked on both the main display surface of the inner and outer packaging;
- (3) In the ingredient statement, first list the active ingredients according to their USP names in the form of "Active ingredient" or "Active ingredients", followed by inactive ingredients in descending order of content;
- (4) Active ingredients must be listed on both the inner and outer packaging;
- (5) If there is a dosage instruction on the label and no shelf life is indicated, the stability period data shall be at least 3 years;
- (6) The production batch number or code must be marked, see 21CFR 188 and 21CFR 211 for details;
- (7) Instructions for use and precautions must be marked;
- (8) Warning statements for OTC drugs are specified in a separate OTC monograph. See the corresponding parts of 21CFR 201 and 21CFR 330 for details.

# 3.2.5. 3 Environmental Labeling

No mandatory requirements. Environmental claims are subject to legal effect. At the federal level, environmental claims are regulated by the 1992 Federal Trade Commission (FTC) Environmental Marketing Guidelines. Some states often use unfair trade enforcement statutes to regulate environmental claims, which usually contain a small part of FTC statutes, or make certain types of environmental claims under special legal conditions.

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36 3.2.5. 4 Labeling of Small Packaged Products Exemptions

Small packaged cosmetics weighing less than 1/4 ounce or less than 1/8 fluid ounce in volume only need to be labeled with the manufacturer's name and address and any required warning statements in the smallest font on the package.

3.3 Japan

- 3.3.1 Legal Documents
- · Pharmaceutical Affairs Law
- · Enforcement Regulations of the Pharmaceutical Affairs Law
- · Fair Competition Codes for Cosmetic Labeling:

Regulations on cosmetic labeling and advertising established by the Cosmetic Fair Trade Council in accordance with the Pharmaceutical Affairs Law.

- Enforcement Regulation of Fair Competition Codes for Cosmetic Labeling: Detailed requirements for labeling and advertising, including the terms that can be used for efficacy for each cosmetic category.
- The Law for the prevention of Unreasonable Premiums and Misrepresentation Concerning Products and Services and the Standards for Fair Advertising Practices of Drugs, Quasi-Drugs, Cosmetics and Medical Devices: PAB Notice No. 1339, issued in October 1980.
- 3.3.2 Competent Authority The Drug and Medical Safety Bureau of the Ministry of Health, Labour and Welfare (MHLW) of Japan is responsible for the licensing, product review, and corporate supervision and management of cosmetics and quasi-drugs. In terms of product quality management, the competent authority shall ensure strict compliance with the standards of the Ministry of Health, Labour and Welfare when licensing; in terms of post-market product safety management, the competent authority shall collect data on product quality, efficacy and safety, and proper use, and make appropriate measures based on the above circumstances.

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Japan has established the Fair Trade Commission (JFTC) to ensure the full implementation of the market legal system. It is under the jurisdiction of the Prime Minister. Its main powers include the power of adjudication, partial adjudication, investigation and duty execution, etc., which are very extensive and exercised independently. The cosmetics labeling and advertising are formulated and supervised by the Cosmetics Fair Trade Consultation Committee under it. In April 2005, the latest revision of the "Implementation Rules for Fair Competition Provisions on Cosmetics Labeling" was issued, which detailed the content, efficacy terms, special terms and prohibited labels that should be marked on the label.

## 3.3.3 Definition of Cosmetics

The Pharmaceutical Affairs Law divides cosmetics into the following two categories:

- ? Cosmetics: refers to products that are applied to the human body by rubbing, spraying or other similar methods, with the purpose of cleaning, beautifying, enhancing attractiveness or improving appearance and maintaining the good condition of skin and hair, and whose effect on the human body is appropriate.
- ? Quasi-drugs: refers to products that have a fixed purpose and have a mild effect on the body, but are not used to diagnose, treat, or prevent diseases, or affect the structure and function of the body. It includes cotton products for hygienic purposes and specific products that have a mild effect on the human body.

The main functions of quasi-drugs are:

Preventing nausea or other discomfort, unclean breath and body odor;

Preventing stinging burning and pain and similar phenomena;

Preventing hair loss, promoting hair growth or for hair removal;

Eradicating or resisting rats, flies, mosquitoes, fleas, etc., used to protect the health of humans and other animals.

"Quadri-drugs" in the scope of cosmetics are called "medical cosmetics", and there are many cases of "medical use". "Medical cosmetics" refer to products that have the functions and effects of preventing skin roughness, acne formation, whitening, skin sterilization, etc., and are recognized by the Pharmaceutical Affairs Law as "quasi-drugs", and have the same purpose and method of use as cosmetics.

38 3.3.4 Classification of cosmetics
(1) Classification of cosmetics:
? Cleansing products
? Hair care products
? Care products
? Make-up products
? Perfumes
? Sunscreen products
? Nail products
? Eyeliner
? Lip products
? Oral products (mouthwash, non-disinfectant)
? Bath products
(2) Classification of quasi-drugs:
? Oral rinse products (for oral disinfection)
? Deodorants
? Talc (containing active ingredients)
? Hair growth products
? Hair removal products
? Hair dye products (oxidants)
? Bath preparation products (containing active ingredients)
? Perm products

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- ? Medicated cosmetics (including anti-dandruff shampoos and lotions, anti-acne, anti-cracking and antifreeze lotions, creams and packs, whitening and antibacterial products)
- ? Insect repellent products
- ? Medicated toothpaste
- ? Cotton products for hygiene purposes
- 3.3.5 Requirements for cosmetic labeling
- 3.3.5.1 General requirements for cosmetic labeling

The following must be marked on the cosmetic label:

- (1) Product name (trade name)
- (2) Product description
- (3) Name and address of the manufacturer or seller; name and address of the importer; name of the country of origin.

The "Implementation Rules for Fair Competition Provisions on Cosmetic Labeling" stipulate that "place of origin" means the place of business of the manufacturer. If the place of business is a well-known non-national place name (city, province, place),

this may be used as the place of origin instead of the country of origin.

(4) Net content

Japan uses the international SI metric system. Net content is expressed by weight, volume and number. Weight is expressed in (g) or (gram), volume is expressed in (ml) or (millilitre), and quantity is expressed in number.

(5) Cosmetic ingredient list

All ingredients of the cosmetic are required to be labeled.

The labeling order is as follows: ingredients with a content higher than 1% are listed in descending order; ingredients with a content less than 1% can be listed in any order; all ingredients of the mixture must also be listed, and extracts must describe the extracted components, extraction solvents and dilution solvents; possible components (+/-) can be indicated by shading; colorants are labeled in any order after other ingredients. For commercial confidentiality considerations, ingredients that can be kept secret with the approval of the MHLW are labeled as "other ingredients".

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40 The names of ingredients to be labeled should be Japanese names translated and transliterated from INCI names, which are developed and edited by the Trademark Naming Committee of the Japan Cosmetics Industry Association (JCIA) and published as the Japanese Cosmetic Labeling Name Dictionary (JCLD), which can be obtained from the JCIA website and CTFA online, and includes the names of approximately 3,300 ingredients. If a company does not find the required INCI name in this list, it can apply to JCIA for translation.

Any cosmetic containing animal-derived ingredients included in Chapter 1 of MHLW Announcement No. 1293 (issued on December 12, 2000) must indicate the source animal of each animal-derived ingredient, for example, hydrolyzed collagen (cow). If the source animal can be easily seen from the name of the ingredient, it is not necessary to state it, for example, lanolin.

- (6) Shelf life: Not required. Article 166 of the MHLW Notice of September 26, 1980 requires that cosmetics containing ascorbic acid, its esters or salts, enzymes and other substances that are susceptible to quality changes within 3 years of manufacture or importation be labeled with a shelf life. The shelf life label must indicate the year and month and the word "expiration date".
- (7) Instructions for use
- (8) Batch number/code
- (9) Warning statement

Specific precautions are described in the law, including precautions for hair dyes (MHLW PAB Notice No. 11, issued on January 6, 1977), color and dye removers (MHLW PAB Notice No. 1135, issued in 1979), and permanent perms (MHLW PAB Notice No. 727, issued on October 5, 1966).

Products containing formaldehyde preservatives must be subject to certain restrictions and must state on the label "Not for use on infants and people allergic to formaldehyde".

There are also some unofficial cosmetic labeling standards that vary depending on the type of product. For example, all cosmetics used on the skin should have a label warning: "This product may occasionally cause some unexpected reactions. If so, please stop using it!"; cosmetics for nails should have a label warning: "If any abnormality occurs on the nails, please stop using it!".

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The labeling requirements for hazardous substances are described in the "Government Control Order on Hazardous Substances" (Article 55 of the Prime Minister's Office Decree, promulgated on September 29, 1959. Amended by the Ministry of National Affairs on February 5, 1990), which is promulgated in accordance with the "Fire Alert Order" (Article 186 of the Ministry of National Affairs Law, promulgated on July 24, 1948). The content on the label includes: restrictions on use, product name, chemical name of hazardous substances, hazard level, water solubility, and quantity. However, depending on the net content and type of hazardous substances, the label content, location, color of letters, and font size are also different. There are 6 categories of hazardous substances in the "Fire Alert Order" (the definition and classification of hazardous substances are described in the amendment to Decree No. 55 of May 24, 1988). Category 1 is for permanent hair perm products, and Category 2 and Category 4 are for cosmetics and quasi-drugs. The product catalog is established in accordance with Article 1 of the Law of the Ministry of National Affairs promulgated on February 17, 1989, and revised on February 5, 1990.

Among them, the product name (trade name), product presentation, name and address of the manufacturer or seller, name and address of the importer, name of the country of origin, net content, instructions for use, and production batch number/code must be marked on both the inner and outer packaging.

All necessary label information must be accurately and legally described in official Japanese, and double labels can be used.

# 3.3.5.2 Quasi-drug labeling requirements

In addition to the above requirements for cosmetic labeling, quasi-drugs have the following special requirements:

- (1) The words "quasi-drug" must be on the container or box;
- (2) Product description is not required;
- (3) All ingredients are not required to be disclosed, but the ingredients of 138 quasi-drugs specified by MHLW and the names of synthetic organic colorants must be indicated; however, starting from April 1, 2006, JICA implemented the recommended standard of disclosing all ingredients (their activity must be indicated), and there is a two-year grace period for implementation of this standard. In principle, the names of ingredients on the quasi-drug label must use the names on the product approval form, but aliases and abbreviations included in the JICA ingredient list may also be used;
- (4) Storage conditions: Labeling is required in certain specific cases.

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42 3.3.5.3 Cosmetic Efficacy Claims

Cosmetic labels must also comply with the provisions of the Law on the Prevention of Unreasonable Extra Charges and False Statements of Products and Services and the Implementation of Fair Advertising Standards for Drugs, Quasi-drugs, Cosmetics and Medical Devices, and adopt fair competition codes for unified management. This law prohibits misleading, deceptive or any product advertising that exceeds the scope of MHLW argumentation, and also has restrictions on comparative advertising, endorsements, certificates and awards.

When manufacturers label cosmetic efficacy, they must do so within the scope permitted by the Pharmaceutical Affairs Law. The Rules for the Implementation of Fair Competition Provisions on Cosmetic Labeling specify in detail the efficacy claims and special terms for each type of cosmetics. Specified efficacy Claims:

Cleans scalp and hair. Fresh fragrance can inhibit odor generated by hair and scalp.

Protects the health of scalp and hair. Gives hair elasticity and texture.

Moisturizes scalp and hair. Protects the moisture of scalp and hair.

Makes hair soft. Makes hair easy to comb.

Protects the luster of hair. Gives hair luster.

Removes itching and dandruff. Inhibits scalp itching and dandruff.

Protects and replenishes moisture and oil in hair. Prevents hair from split ends, withering, and hair breakage.

Tidys and maintains hairstyle. Prevents hair from being charged.

(Removes dirt) Cleans skin (cleansing) Prevents the formation of acne and prickly heat (facial cleansing products).

Tidys the skin. Can adjust skin texture.

Protects skin health. Prevents skin from becoming rough.

Tightens skin. Moisturizes skin.

Replenishes and maintains moisture and oil in skin. Maintains skin softness.

Protects skin. Prevents skin from drying out.

Makes skin soft. Gives skin elasticity.

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(Continued table)

Give skin a radiance Make skin smooth

Make beards easier to remove Groom skin after shaving

Prevent the formation of prickly heat Protect from the sun

Prevent the formation of spots and freckles after sun exposure Give fragrance

Protect nails Keep nails healthy

Moisturize nails Prevent chapped lips

Organize lip texture Moisturize lips

Make lips healthy Protect lips from dryness

Prevent lip peeling caused by dryness Make lips smooth

Special terms:

Terms indicating safety Terms such as "safe" and "peace of mind" that indicate safety cannot be used in a decisive tone.

Terms indicating completeness Terms such as "complete", "perfect" and "determined" that indicate complete absence of flaws cannot be used in a decisive tone.

Words that express omnipotence Words that express omnipotence, such as "omnipotence", "perfect", and "whatever" cannot be used in an assertive tone.

Words that express superlatives Words that express superlatives, such as "largest", "highest", "smallest", and "unparalleled", cannot be used unless they are based on specific numerical values ??of objective facts or there is a basis for them.

Words that express superiority Words that express superiority, such as "world's best", "number one", "only our company", "first in Japan", "excellent", "epoch-making", and "ideal", cannot be used unless they are based on specific numerical values ??of objective facts or there is a basis for them.

Words that express new products Words that express "new product" and "new release" using media such as newspapers, magazines, television, radio, and the Internet can only be used within 6 months of release.

3.3.5.4 Quasi-drug efficacy claims

Specified efficacy claims:

44 Cosmetic type Effect

Shampoo Prevent dandruff and itching

Prevent sweat odor of hair and scalp

Keep hair and scalp healthy Choose one

Make hair flexible Choose one

Hair conditioner Prevent dandruff and itching

Replenish moisture and oil in hair

Prevent hair from splitting, splitting, breaking and splitting

Make hair flexible

Keep hair and scalp healthy Choose one

Make hair flexible Choose one

Toner Prevent rough skin, chapped skin, prickly heat, frostbite, chapped skin, acne, oily skin

Prevent shaving allergy

Prevent wrinkles and freckles caused by sun exposure

Skin becomes hot and red after sun exposure, wind and snow

Make skin tight, clean skin, and tidy skin.

Protect skin health and moisturize skin

Cream, lotion, hand cream

Cream, cosmetic oil Prevent rough skin, chapped skin, prickly heat, frostbite, chapped skin, acne, oily skin

Prevent shaving allergy

Prevent wrinkles and freckles caused by sun exposure

Prevent skin from getting hot and red after sun exposure, wind and snow

Make skin tight, clean skin, and tidy skin

Protect skin health and moisturize skin

Protect skin and prevent skin dryness

Shaving agent Prevent shaving allergy

Protect skin and make shaving easier

Sunscreen Prevent rough skin caused by sun exposure, wind and snow

Prevent sun exposure, wind and snow

Prevent wrinkles and freckles caused by sun exposure

Protect skin

Facial mask Rough skin, rough skin

Prevent acne

Oily skin

Prevent dark spots and freckles caused by sun exposure

Red spots after sunburn and snow exposure

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(Continued Table)

Cosmetic Type Efficacy

Medicinal Soap (including facial cleanser) ?Contains effective antiseptic ingredients?

Cleaning, sterilizing and disinfecting the skin

Preventing body odor, sweat odor and acne

?Contains effective anti-inflammatory ingredients?

Cleaning the skin, preventing acne, shaving allergies and skin allergies

## 3.3.5. 5 Environmental Labels

Japan implements a voluntary environmental labeling system supervised by the Environmental Agency. Personal care aerosols that do not contain chlorofluorocarbons (CFCs), recycled paper and recycled plastics, and certain other products can apply for an eco-label (human arm pattern) to indicate that the product is environmentally friendly. There are different product standards for different product categories, but truly qualified products should promote the ecological environment when they are discarded, or at least cause no or little environmental pollution.

The High Pressure Gas Safety Law, Decree 204 of June 7, 1951, issued by the Ministry of International Trade and Industry, provides for the application of aerosols. Imported products are evaluated and certified by the Japan Aerosol Manufacturers Association, which is required for all aerosol products.

Labeling requirements for aerosol products are set forth in the Ministry of International Trade and Industry Decree 139 of March 24, 1997 and Decree 153 of March 27, 1998, "Notices on Strengthening Regulations of the High Pressure Gas Safety Law." Labeling requirements vary depending on the type of fuel, the sealing mechanism, and the combustion volume (not the dissolved volume) of the contents. There are also regulations on the color and size of the label letters. Warning labels must be framed and must indicate regulatory information (combustibility, warning information, name of the packaged gas, manufacturer, manufacturing barcode). If the solvent is toxic, the label must comply with the Fire Service Ordinance. The manufacturer's name can be indicated by the respective barcode number. These marks also indicate that the manufacturer has passed the standard test certification.

# 3.3.5. 6 Label exemption for small package products

When the net content of the product is 50mg (mL) or less and there is no outer packaging, the ingredient list can be listed on a separate attached page, and the label of the container must state "the ingredient list is listed on the attached page"; similarly, 10g (mL)

For products with a size of 46 or less and with secondary packaging, the ingredient list can also be listed on a separate attached page, and the label of the secondary packaging must state "the ingredient list is listed on the attached page".

- 3.4 South Korea
- 3.4.1 Legal documents
- ? Cosmetic Law
- ? Enforcement of Cosmetic Law: MOHW Decree No. 163
- ? Pharmaceutical Affairs Law
- ? Pharmaceutical Affairs Law Enforcement Regulation
- 3.4.2 Competent authorities

The Korea Food and Drug Administration (KFDA) established the Cosmetics Committee in accordance with Presidential Decree No. 16869. The head of the KFDA Drug Administration is the head of the committee. The committee is composed of officials in charge of cosmetics, pharmaceutical affairs agencies, consumer organizations and experts. It is responsible for the management of cosmetics in the following aspects:

- ? Publication and revision of the Cosmetic Ingredient Code
- ? Cosmetic specifications
- ? Inspection, investigation and evaluation of the safety and efficacy of cosmetics
- ? Other related matters

Ministry of Health and Welfare of Korea The Ministry of Health and Welfare (MOHW) is responsible for formulating mandatory enforcement regulations in accordance with the Cosmetics Act.

3.4.3 Definition of cosmetics

Cosmetics: refers to cosmetics that have a moderate effect on the human body and are used to cleanse, beautify, enhance attractiveness, improve appearance

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Articles that improve or maintain the appearance of skin or hair.

Functional cosmetics: refers to any of the following cosmetics specified by the regulations of the Ministry of Health and Welfare: ? Cosmetics used to whiten skin tone; ? Cosmetics used to reduce the appearance of wrinkles on the face and body; ? Cosmetics used to protect the skin from ultraviolet damage in sunlight or to enhance the natural appearance of the skin.

- 3.4.4 Classification of cosmetics
- (1) Classification of cosmetics:
- ? Baby products
- ? Bath products
- ? Eye cosmetics
- ? Fragrances
- ? Hair products
- ? Hair color products
- ? Make-up products
- ? Nail products
- ? Shaving products
- ? Skin care products
- (2) Classification of functional cosmetics: As defined in the three categories.
- 3.4.5 Cosmetic Labeling Requirements
- 3.4.5.1 Cosmetic Labeling General Requirements

Labeling requirements are stipulated in Article 10 of the Cosmetics Law and Article 13 of the Regulations for the Implementation of the Cosmetics Law. It is stipulated that the following contents must be marked on the label:

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- 48 (1) Product name (trademark name): marked on the inner and outer packaging.
- (2) Product description: For general cosmetics, the product name shall indicate the product type; for functional cosmetics, the product name must indicate that it is a functional cosmetic in Korean.
- (3) Name and address of the manufacturer or distributor: marked on the outer packaging.
- (4) Name and address of the importer: marked on the inner and outer packaging.
- (5) Place of origin: can be expressed in Korean, Chinese or English as follows: "place of production; or place of origin; or place of manufacture; or product from...; or product produced from...".
- (6) Net content: must use the SI metric system and be marked in Korean, but double labeling is allowed.
- (7) Cosmetic ingredient list: all cosmetic ingredients are required to be marked, using the INCI Korean names.

The following situations require that the percentage of the ingredient content be indicated: ? The ingredient name is used in the product name; ? The content of ?-hydroxy acid (AHA) used is greater than 10%; ? Sodium phosphate is used in shampoo and hair dye; ? The ingredient contains gold.

- (8) Production batch number/code: Marked on the first layer of packaging (inner packaging).
- (9) Production date: Marked on the outer packaging.
- (10) Warning statement: Must be marked in Korean on the outer packaging. Precautions for specific products are stipulated in Article 14 of the "Regulations for the Implementation of the Cosmetics Act", which is more extensive than the regulations of the United States and the European Union.
- (11) Directions for use: Not mandatory but recommended to be marked in Korean on the outer packaging.
- (12) Storage conditions: For some products, not mandatory but recommended to be marked in Korean on the outer packaging.
- (13) Price: Marked by the seller who sells directly to the end consumer in accordance with the prescribed method.

Cosmetics labels should be labeled in Korean letters, and can be written in Chinese and other foreign languages.

3.4.5.2 Cosmetics efficacy claims

The "Regulations for the Implementation of the Cosmetics Law" prohibit cosmetics from using medical efficacy claims or discrediting other companies' products.

Cosmetic Label Management Guidelines for Various Countries 49 Products. Before-and-after comparison claims are not allowed unless the company can provide proof. The "Regulations for the Implementation of the Cosmetics Law" stipulates the terms for cosmetic efficacy claims: Cosmetic Type Efficacy **Baby Products** (Excluding Quasi-drugs) Baby Shampoo Baby Lotion and Cream Baby Oil Other Baby Products · Make the scalp and hair clean and soft · Prevent dry skin and make the skin soft · Prevent rough skin · Keep skin healthy **Bath Products** (Excluding Quasi-drugs) Bath Oil, Soap and Bath Salt **Bath Capsules** Bath Foam **Body Cleanser** Other Bath Products · Keep skin clean and soft · Give body a fragrant smell · Make it fresh after bath Eye Cosmetics Eyebrow Pencil Eyeliner Eye Shadow Mascara Eye Makeup Remover Other Eye Cosmetics ·Color effect beautifies the edge of the eye ·Makes the eye contour clear and beautiful ·Beautifies eyebrows ·Protects eyebrows and eyelashes ·Protects the upper eye skin Removes eye makeup (limited to eye makeup remover). Fragrances Perfumes

Powders

Fragrances

Colognes

Other fragrances · Scents

Hair products Conditioners

Nourishing hair

Hair grooming aids

Hair creams

Hair oils

Pomades

Hair sprays

Mousse

Other hair products · Make hair shiny and smooth

- · Keep scalp and hair healthy
- · Protect damaged hair
- · Prevent rough and chapped hair
- · Make hair smooth
- · Replenish and maintain moisture and oil (excluding hair nourishing products)
- $\cdot$  Prevent static electricity and keep hair neat (excluding hair nourishing products)
- · Clean scalp and relieve itching (limited to hair nourishing products).
- · Maintain the effect of hairstyle
- · Create the desired hairstyle

Guidelines for the labeling management of cosmetics in various countries 50 (Continued Table 1) Cosmetic type Function Hair products Shampoo Conditioner ·Cleanses the scalp and hair, inhibits dandruff and relieves itching ·Makes hair smooth ·Keeps the scalp and hair healthy ·Makes hair shiny ·Prevents static electricity and keeps hair neat ·Protecting damaged hair Permanent perm cream · Makes hair curl ·Keeps hair curled Straightening cream ·Straightens and maintains curly hair Hair dyes (Excluding quasi-drugs) Hair color Hair color spray Other hair color products ·Temporarily changes hair color Cosmetics Blush Powder (cake) Foundation (liquid, cream, cake) Make-up base Make-up fixatives Lipstick (cream, pen) Lip gloss Other cosmetics (including body paint, etc.) - Produce color effects on the skin Protect the skin and prevent dryness · Masking the skin from glistening due to water or oil as well as the skin's defects. · Preventing rough skin · Maintaining makeup effect - lipstick and lip gloss · Giving lips color effect · Making lips shiny and soft · Keeping lips healthy · Protecting lips and preventing dryness · Giving lips makeup effect Nail products Base coat Nail polish and nail enamel Oiling Nail cream and lotion Nail polish remover Other nail products - Base coat, nail polish and nail enamel, oiling · Beautifying nails · Improving the adhesiveness at the surface membrane of nail enamel prior to application of nail enamel (limited to base coat ). · Moisturizing nails after using nail enamel (limited to oiling) · Adding color and gloss after using nail enamel (limited to nail enamel).

Guidelines for the labeling management of cosmetics in various countries
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(Continued from Table 2)
Cosmetic type Function
Nail products Base coat
Nail polish and nail polish
Oil
Nail cream and lotion
Nail polish remover
Other nail products - Nail cream
Replenish the moisture and oil of the nails
Protect the nails to keep healthy
Remove nail makeup
•Making the skin around the cuticle layers,
fingernails and toenails supple
Shaving products Men's talcum powder
Preshave water
Shaving cream
Beard softening Other shaving products. Aftershave letion and mon's talcum powder.
Other shaving products - Aftershave lotion and men's talcum powder
Protect the sharpness and structure of the razor after shaving
•Moisturize the skin and keep the skin soft
-Protect the skin to keep it healthy
Prevent razor damage to the skin
Shrink pores after shaving to make the skin healthy
- Soften the beard, preshave lotion, beard cream
Soften beard for easy shaving
Soften skin to reduce damage caused by razor,
easy to shave
Skin care products
(excluding quasi-drugs) Skin softener
Massage cream
Lotion
Astringent
Nutrient oil (liquid)
Powder
Facial cleansing cosmetics
Body cosmetics (liquid, oil, cream
and powder)
Packs
Eye cream
Other skin care products ·Prevent skin roughness and regulate texture
·Cleanse skin
·Moisturize skin and keep skin soft
-Protect skin to make skin healthy
·Tighten skin to make skin elastic
-Remove makeup (limited to facial cleansing)
3.4.5.3 Environmental label
It can only be a recyclable mark certified by the local industry, and the building material coding section can be referred to.
3.4.5.4 Small package product label exemption
Article 13 of the "Cosmetics Law" stipulates that in the following cases, the container or package capacity is less than 15ml (g) or less

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52 For cosmetics containers and packaging intended for user trials before production or importation, only the following need to be marked: (1) product name; (2) manufacturer?s name; (3) price. If the cosmetic is marked as ?not for sale? or ?sample?, the price may be omitted.

3.5 ASEAN

3.5.1 Legal documents

? ASEAN Cosmetic Directive 05/01/ACCSQPWG

? ASEAN Technical Documents for Cosmetics: defines detailed requirements for various aspects of cosmetics, with Appendix I as ASEAN Definition of Cosmetic s and Illustrative List by Category of Cosmetic Products; Appendix II as ASEAN Cosmetic Labeling Requirements; and Appendix III as ASEAN Cosmetic Claim Guidelines

3.5.2 Competent authorities

ASEAN Cosmetic Committee (ACC) is responsible for the implementation of cosmetics regulations. ACC is composed of an official representative from each member country's cosmetics authority, who can lead his country's delegation to attend ACC meetings. In performing its duties, ACC makes decisions through consultation and is responsible for the following matters (but not limited to): coordination, inspection, and supervision of the implementation of ASEAN cosmetics regulations; revision and updating of ASEAN cosmetics technical documents. ASEAN member countries have their own official agencies responsible for the supervision and management of their own cosmetics.

3.5.3 Definition and classification of cosmetics ASEAN adopts the same definition and classification of cosmetics as the EU.

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3.5.4 Cosmetic Labeling Requirements

# 3.5.4.1 Cosmetic Labeling General Requirements

Product labels shall comply with Article 6 of the ASEAN Cosmetics Directive and the ASEAN Cosmetic Labeling Requirements.

The following information shall be marked on the outer packaging of cosmetics, or on the direct packaging if there is no outer packaging. The marked information shall be clear, easy to understand and non-fading.

- (1) Product name and function: If the appearance of the product can clearly show its function, it may not be marked.
- (2) Country of production: The name and address of the company or individual responsible for the product placed on the local market.
- (3) Net content: Measured by weight or volume, indicated in SI metric units, or metric and imperial units together.
- (4) Cosmetic ingredient list: All ingredients of cosmetics must be marked. The ingredient nomenclature refers to the latest version of the Chinese standard in Appendix A, including: INCI name, British Pharmacopoeia, United States Pharmacopoeia, CAS index number, Japanese Cosmetic Ingredient Standard, and Japanese Cosmetic Ingredient Codex. Plant raw materials and extracts should be marked with their family and genus, where the family can be represented by abbreviation. Similar to the EU, the following are not considered ingredients: Impurities in raw materials; Excipients used in production but not in the finished product; Substances that are used as solvents or carriers for fragrances or aromatic substances and whose usage is strictly controlled.
- (5) Production date or expiration date, "year and month" must be indicated.
- (6) Manufacturer's batch number.
- (7) Instructions for use: If it can be clearly known from the name and appearance of the product, it can be omitted.
- (8) Precautions during use, especially those listed in the column "Conditions or uses and warnings that must be printed on the label" in Appendix III, IV, VI, VII, and VIII, as well as any other precautions that require special attention, must be marked on the label.

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- 54 Member States may have their own special warning statements according to their own needs. For example, ingredients obtained from animals should be marked with the following warnings:
- ? The presence of animal-derived ingredients must be declared on the product label (in any form);
- ? For ingredients of bovine and porcine origin, the exact animal source must be declared;
- ? Ingredients from human placenta must be specifically declared on the product label.
- (9) Registration number of the country of origin or registration country.

If it is not possible to list all the above information due to volume, shape, etc., appendices, brochures, signs, display boards, shrink wrap, etc. may be used, but at least the product name and manufacturer's batch number must be indicated on the inner packaging.

Use English and/or the national language and/or a language acceptable to consumers in the place of sale.

## 3.5.4.2 Cosmetic efficacy claims

Product claim requirements should comply with Article 7 of the ASEAN Cosmetics Directive and the ASEAN Cosmetic Claims Guidelines.

Whether a product is classified as a cosmetic or a drug is determined by its components and uses, among which the use of the product is the main factor that determines its classification. In advertisements, appendices, and especially on labels, the main use of the product should be informed to consumers through product claims.

In general, cosmetics should only be allowed to make claims of cosmetic properties, and not medical properties or therapeutic properties. The efficacy of any claim should be consistent with that generally accepted internationally, and can be verified by technical data, product formula or product raw materials. As long as the manufacturer or product holder has reasons to explain the scientific nature of its use plan, these plans can be used to derive the above technical data.

#### 3.6 Middle East

Middle Eastern countries have their own cosmetics management authorities and legal documents. However, there are many similarities in the requirements for cosmetics labels: for example, they all need to label the alcohol content; they do not require the labeling of cosmetic ingredients, etc. For detailed requirements for cosmetics labels, please refer to the relevant laws and regulations of each country. The following is a brief introduction to Saudi Arabia, Egypt and Jordan as examples.

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To be introduced.

3.6.1 Saudi Arabian cosmetic labeling requirements

The Ministry of Health and the Ministry of Commerce are responsible for the management of cosmetics. Different types of products have different labeling requirements and their own independent standards, which are formulated by the Saudi Standards Organization. It is stipulated that cosmetic labels must indicate the following:

- (1) Product name
- (2) Name and address of the manufacturer, distributor and importer. The country of origin of imported cosmetics should be written as follows: "made in "
- (3) Net content: indicated in international SI metric units.
- (4) Cosmetic ingredient list: It is not required to list all components. According to the applicable standards, specific restricted components must be marked on the label.
- (5) Shelf life: If the product is stable for less than 30 months, the shelf life should be indicated as follows: "Best used before the end of ... " followed by month and year.
- (6) Batch number
- (7) Warning: For products placed in pressurized containers and products containing restricted ingredients, there is a requirement to include a warning statement on the label. In addition, all ethanol-based fragrance products must include a warning statement in red Arabic: "For external use only".
- (8) Depending on the composition of the product, label the use and storage instructions as necessary. Labels are required to be marked in Arabic, and some standards accept English on the packaging.
- 3.6.2 Requirements for cosmetic labeling in Jordan

The Department of Standards and Metrology and the Ministry of Health are responsible for the management of cosmetic labeling. Cosmetics are divided into two categories: cosmetics and medicinal cosmetics.

56 stipulate that cosmetic labels must indicate: product name (trade name); product description; name and address of the manufacturer and representative; origin of imported cosmetics and name and address of the importer; net content; instructions for use; storage instructions; necessary warning statements; alcohol content. Cosmetic ingredients do not need to be labeled.

In addition to the above-mentioned mandatory contents of cosmetics, pharmaceutical cosmetics must also indicate the production batch number/code, production date, shelf life, registration number, and ingredient content percentage.

Arabic is the native language of Jordan. English is allowed on the label, but it must be translated into Arabic at the same time. Product functions must also be marked in the native language.

# 3.6.3 Requirements for cosmetic labeling in Egypt

Cosmetics are managed by the Ministry of Health and the General Directorate of Standardization and Quality Control (an independent agency under the Ministry of Industry). Ministerial Decree 16/93 stipulates the requirements for product labeling and packaging.

It is stipulated that cosmetic labels must indicate: product name (trademark); product type; name and address of manufacturer and representative; place of origin and name and address of importer of imported cosmetics; net content; production batch number/code; production date; shelf life (required to be marked when less than 5 years); instructions for use; registration number; necessary precautions; alcohol content. Cosmetic ingredients and storage instructions are not required to be marked.

Labels must be marked in Arabic, and other languages ??can be used simultaneously with Arabic.

#### 3.7 China

## 3.7.1 Legal documents

- ? National Standard "Instructions for Use of Consumer Products General Labeling of Cosmetics" (GB 5296.3-2008): Replaced GB 5296.3-1995, issued by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China and the Standardization Administration of China on June 17, 2008, and implemented on October 1, 2009.
- ? "Regulations on Cosmetic Labeling Management": issued by the General Administration of Quality Supervision, Inspection and Quarantine on August 27, 2007, and will be implemented on September 1, 2008.

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# 3.7.2 Competent Authorities

Currently, some places in my country have transferred the supervision and management of cosmetics to the food and drug supervision and management system, and a considerable part of them are still managed by the health system. The management of cosmetics in my country is in a relatively complicated situation. The following competent authorities and their functions are extracted from the responsibilities assigned to various departments by the State Council and published on the official government website:

Ministry of Health: Comprehensively manage health supervision and law enforcement work, and organize and implement it according to law; be responsible for formulating health law enforcement supervision work norms, procedures and relevant rules and regulations; carry out supervision and management of food, cosmetics hygiene and occupational health according to law; State Food and Drug Administration: Organize relevant departments to draft laws and administrative regulations on cosmetics safety management; organize relevant departments to formulate comprehensive supervision policies and work plans and supervise their implementation. Exercise the comprehensive supervision responsibilities of cosmetics safety management according to law, and organize and coordinate relevant departments to undertake safety supervision work. Organize and carry out investigations and handling of major cosmetics safety accidents according to law; organize and coordinate special law enforcement supervision activities for cosmetics safety nationwide according to the authorization of the State Council; organize, coordinate and cooperate with relevant departments to carry out emergency rescue work for major cosmetics safety accidents. Comprehensively coordinate the testing and evaluation of cosmetic safety; formulate and supervise the implementation of the information release method for cosmetic safety supervision in conjunction with relevant departments, and integrate the cosmetic safety information of relevant departments and release it to the public on a regular basis. Carry out exchanges and cooperation between governments and international organizations related to cosmetic safety management;

General Administration of Quality Supervision, Inspection and Quarantine: Organize the drafting of laws and regulations on quality supervision, inspection and quarantine, study and formulate policies and guidelines for quality supervision, inspection and quarantine, formulate and publish relevant rules and regulations;

Organize the implementation of laws and regulations related to quality supervision, inspection and quarantine, guide and supervise the administrative law enforcement of quality supervision, inspection and quarantine; be responsible for the national technical regulations related to quality supervision, inspection and quarantine. Organize and implement the safety, hygiene, quality supervision, inspection and supervision and management of imported and exported food and cosmetics; manage the health registration of imported and exported food and cosmetics production and processing units, and manage the external health registration of export enterprises;

State Administration for Industry and Commerce: Organize and supervise market transactions in accordance with the law, organize and supervise the quality of goods in the circulation field, organize and investigate and deal with counterfeit and inferior products and other illegal acts, and protect the legitimate rights and interests of operators and consumers. Implement standardized management and supervision of various market operation orders in accordance with the law. Supervise and manage advertisements in accordance with the law and investigate and punish illegal acts. Study and formulate advertising release standards and rules and regulations and specific measures and methods for advertising release management, and supervise their implementation. Organize and guide the supervision of advertising release activities and the investigation and handling of cases. Assist in handling administrative reconsideration of illegal cases of advertising release activities.

Guidelines for Cosmetics Label Management in Various Countries

# 58 3.7.3 Definition of Cosmetics

The "Regulations on Cosmetics Label Management" stipulates that cosmetics refer to products that are applied to the human body (skin, hair, nails, lips, teeth, etc.) by smearing, spraying, sprinkling or other similar methods to achieve the purpose of cleaning, maintenance, beautification, modification and change of appearance, or correction of human body odor and maintenance of good condition. Toothpaste is officially included in the category of cosmetics.

## 3.7.4 Classification of cosmetics

The national standard "Classification of cosmetics" (GB/T 18670-2002) stipulates that cosmetics are mainly classified according to product functions and application sites; for multi-functional and multi-site cosmetics, they are classified according to the main functions and main application sites of the products, and are divided into:

- ? Cleansing cosmetics
- ? Care cosmetics
- ? Beauty/modification cosmetics

The "Regulations on the Hygiene Supervision of Cosmetics" (Ministry of Health) stipulates that special-purpose cosmetics refer to cosmetics used for hair growth, hair dyeing, perming, hair removal, breast enhancement, bodybuilding, deodorization, freckle removal, and sun protection. The "Detailed Rules for the Implementation of the Regulations on the Hygiene Supervision of Cosmetics" (Ministry of Health) stipulate that the meaning of special-purpose cosmetics is:

- ? Hair growth cosmetics
- ? Hair dyeing cosmetics
- ? Perming cosmetics
- ? Hair removal cosmetics
- ? Breast enhancement cosmetics
- ? Bodybuilding cosmetics
- ? Deodorizing cosmetics
- ? Freckle removal cosmetics

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? Sunscreen Cosmetics

3.7.5 Requirements for Cosmetic Labels

Depending on the shape and/or volume of the cosmetic packaging, the following labeling forms can be selected:

- (1) Printed or pasted on the sales packaging of the cosmetic;
- (2) Printed on a booklet, paper tape or card connected to the outside of the sales packaging;
- (3) Printed on the instruction manual placed inside the sales packaging.
- 3.7.5.1 General Requirements for Cosmetic Labels

The following contents must be marked on the cosmetic label:

- (1) Name of the cosmetic
- (2) Name and address of the manufacturer; Imported cosmetics should be marked with the name of the country or region of origin (referring to Hong Kong, Macao, and Taiwan) and the name and address of the agent, importer or distributor registered in China in accordance with the law. The name and address of the manufacturer may not be marked.
- (3) Net content

The marking of net content shall be carried out in accordance with the "Measurement Supervision and Management Measures for Quantitative Packaged Goods". Liquid cosmetics shall indicate the net content by volume; solid cosmetics shall indicate the net content by mass; semi-solid or viscous cosmetics shall indicate the net content by mass or volume.

(4) Cosmetic ingredient list (this clause must be implemented from November 14, 2009)

The names of all cosmetic ingredients shall be truthfully marked. The ingredient list shall be introduced with the introductory phrase "Ingredients: ".

The marking order is as follows:

- ? The names of ingredients in the ingredient list shall be listed in descending order of the amount added. If two or more ingredient names are marked in the same line of the ingredient list, the names of each ingredient shall be separated by ", ";
- ? If the amount of the ingredient added is less than or equal to 1%, the ingredient names can be arranged in any order after the ingredient with an amount greater than 1%;

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60 ? When labeling colorants for cosmetics with multiple colors, "Possible colorants: " should be inserted at the end of the ingredient list as an introductory phrase, and then colorants of all color ranges can be listed in any order.

Names of labeled ingredients:

- ? The names of labeled ingredients should be the names of ingredients in the International Nomenclature of Cosmetic Ingredients (INCI) Chinese Translation (see Appendix A). If the ingredient is not covered by the International Nomenclature of Cosmetic Ingredients (INCI) Chinese Translation, the name, chemical name or botanical name in the Pharmacopoeia of the People's Republic of China may be used in turn;
- ? The fragrance, auxiliary ingredients and carriers in the flavor may not be labeled with their own ingredient names, but the word "flavor" may be used in the ingredient list;
- ? The name of the colorant is the English abbreviation "CI" of the colorant index number (dye index number) plus the colorant index number, such as: "CI 12010", "CI 15630 (3)", etc. If the colorant does not have an index number, the Chinese name of the colorant may be used.

When the ingredient list cannot be marked due to the shape and/or volume of the cosmetic sales package, the font size may be appropriately reduced, or the form of (2) or (3) in 3.7.5 may be used.

(5) Shelf life

The shelf life shall be marked in one of the following two ways:

- ? Production date and shelf life;
- ? Production batch number and expiration date.

Marking method:

- ? Marking of production date: Use the guide words such as "production date" or "production date see packaging", and the date shall be in the order of 4-digit year, 2-digit month and 2-digit day. If marked: "Production date 20020112" or "Production date see packaging" and "20020112" on the packaging, it means that it was produced on January 12, 2002;
- ? Labeling of shelf life: "Shelf life x years" or "Shelf life xx months";
- ? Labeling of production batch number: determined by the manufacturer;
- ? Labeling of expiration date: "Please use before the marked date" or "Expiration date"

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The date should be marked with a 4-digit year, a 2-digit month, and a 2-digit day.

In addition to the batch number, the expiration date or the production date and shelf life should be marked on the visible surface of the cosmetic sales package.

- (6) Production license number, health license number, and product standard number.
- (7) Imported non-special-purpose cosmetics should be marked with the import cosmetics health license registration number.
- (8) Special-purpose cosmetics should be marked with the special-purpose cosmetics approval number.
- (10) Safety warnings required by relevant national laws and regulations or required by the characteristics of the cosmetics, with "Caution: " or "Warning: " as the guide.
- (11) When necessary, the instructions for use of the cosmetics or a diagram of the instructions for use should be marked.
- (12) When necessary, the storage conditions that meet the shelf life or expiration date should be marked.
- (13) Contents that explicitly or implicitly indicate medical effects should not be marked.

The product name and net content should be marked on the display surface of the sales package. The product name should be marked on the display surface, with the product name marked in a prominent position. If it is not possible to mark it on the display surface due to the shape and/or volume of the cosmetic sales package, it can be marked on its visible surface; other information should be marked on the visible surface of the sales package.

The words used on the cosmetic label must be standardized Chinese characters, except for trademarks registered in accordance with the law. Label content

It is allowed to use Chinese pinyin or minority languages ??or foreign languages ??at the same time, but they must be spelled correctly.

3.7.5.2 Labels of small packages and other exemptions

For products with a maximum surface area of ????the packaging (container) of less than 10 square centimeters and a net content of no more than 15g or 15mL, it is only necessary to mark the name of the cosmetic, the name and address of the manufacturer, the net content, the ingredient list and the shelf life. The content of the ingredient list can be marked in the explanatory materials other than the above three label forms.

Cosmetics that are free for consumers to use and have corresponding labels (such as gifts, not for sale, etc.) can be exempted from marking the net content and Ingredient list and production license number, hygiene license number and product standard number, imported cosmetics hygiene license filing number, special-purpose cosmetics approval number.

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62 3.8 Differences in cosmetic labeling requirements between major export markets and my country

3.8.1 Comparison of cosmetic classification and pre-registration requirements

The EU and ASEAN have a broad definition and classification of cosmetics, dividing cosmetics into 20 categories, and any cosmetics can basically meet one of the categories; while in China, the United States, Japan, and South Korea, they are divided into cosmetics and marginal products. Specifically, they include: special-purpose cosmetics (China), OTC drugs (USA), quasi-drugs (Japan), and functional cosmetics (South Korea).

For the same product, the classification of categories varies from country to country. For example, sunscreen products are classified as marginal products in China, the United States, and South Korea, but as cosmetics in Japan, the EU, and ASEAN; anti-wrinkle products are not considered as an independent category in China, the United States, and Japan, but as cosmetics in the EU and ASEAN, and as functional products in South Korea; hair dye products are special-purpose cosmetics in China, oxidative hair dye products are quasi-drugs in Japan, and are cosmetics in the EU, the United States, South Korea, and ASEAN.

Depending on the classification of cosmetics, different countries have different regulations on them, especially for marginal products, which vary greatly from country to country.

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Table 3.1 Comparison of Cosmetic Classification and Pre-registration Requirements in Various Countries

China EU United States Japan South Korea ASEAN

Classification of Cosmetics Cosmetics

Special-purpose cosmetics Cosmetics

Cosmetics

Over-the-counter drugs Cosmetics

Quadrivalent cosmetics Cosmetics

Functional cosmetics Cosmetics

Pre-registration requirements Requirements for products before they are put on the market General cosmetics are subject to filing, and filing materials are submitted 2 months after they are put on the market;

Special-purpose cosmetics must obtain an approval number No requirement, but member states may require Cosmetics are subject to voluntary registration;

Over-the-counter drugs must be registered within 5 days of the start of production, and the product list is updated every 2 years Mandatory notification of product name;

Quadrivalent drugs and cosmetics containing ingredients specified by the Minister are required to apply for pre-marketing permission; other cosmetics are not required Mandatory notification of product name Product registration Obligation of manufacturer?s initial notification of manufacturer?s health license Cosmetics are subject to voluntary registration;

Over-the-counter drug manufacturers must register within 5 days of starting production, and register once a year thereafter. Licenses are renewed every 3 years. Report approval. Permit

64 3.8.2 General requirements for cosmetic labels

Generally speaking, the contents that must be marked on cosmetic labels in various countries include: the name of the cosmetic; the name and address of the manufacturer and distributor; the net content; the necessary storage conditions, instructions for use and warning statements. For imported cosmetics, the country of origin and the name and address of the importer are required to be marked. The EU, Japan and other countries require domestic distributors, and the United States can accept addresses outside the United States. In terms of marking the production date, shelf life, production batch number/code, product efficacy claims, etc., the regulations of various countries are different. The detailed differences are shown in Table 3.2

In addition, various countries have different regulations on the designated marking locations of various label contents on the packaging and the exemption of small-package cosmetic labels.

The EU, the United States, Japan, South Korea, and ASEAN all require the full ingredient list of cosmetics to be marked, while Middle Eastern countries do not require marking. my country does not require labeling at present, but the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China and the National Standardization Administration have issued a new national standard "Instructions for Use of Consumer Products - General Labeling of Cosmetics" (GB 5296.3-2008) on June 17, 2008, replacing GB 5296.3-1995, requiring that cosmetics produced two years after the date of publication of the standard must be labeled with a full ingredient list. The names of cosmetic ingredients in various countries mainly use INCI names. The EU, the United States, and Japan have somewhat different requirements for the names of cosmetic ingredients, as follows: the EU labels pigment additives according to the dye color index number (CI number), the United States labels the full name or abbreviation of the name specified by the US FDA, and Japan labels the MHLW name. There are also different ingredient names for commonly used raw materials, the so-called "common names", such as the EU writes water as "aqua" and beeswax as "Cera Alba". The European Pharmacopoeia provides popular names derived from Latin. There are also differences in plant names, but they are expected to be unified in the future.

In terms of net content labeling, semi-liquid and viscous products such as creams are labeled by volume in the EU, by weight in the US, and by either mass or volume in China.

In addition, my country stipulates that the production license number, health license number and product standard number of the enterprise must be labeled, but other countries do not have corresponding requirements.

In terms of cosmetic efficacy claims, the US CTFA promotes the claim that cosmetics "make people look good and feel good" (Look Good and Feel Better). If the manufacturer does not have data to prove it, it must indicate "product safety has not been proven" on the label. The EU's requirements for cosmetic labeling are relatively general. As long as the manufacturer can prove the efficacy with scientific methods, it can be labeled and advertised. Japan and South Korea have made mandatory and detailed regulations on the efficacy claims that can be used on the label. ASEAN prohibits cosmetics from making medicinal and therapeutic properties.

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The claimed efficacy of a product should be consistent with that generally accepted internationally and can be verified through technical data, product formula or product raw materials. Other countries in the world, such as Canada, Australia, Belgium, South Africa and Malaysia, have special cosmetics advertising regulations that specify detailed acceptable and unacceptable terms. In these countries, cosmetic efficacy claims are generally used for physical characteristics, and language describing improved appearance is not allowed. Any behavior involving the level of biological tissues is not allowed, such as language such as reducing aging and restoring youth; in addition, claims of therapeutic effects are not allowed. In contrast, my country has no standards and regulations that specify in detail the efficacy labeling of cosmetics, but has stipulated the content that explicitly or implicitly indicates medical effects.

It should be noted that South Korea requires sellers who sell cosmetics directly to end consumers to mark prices according to the method announced by the Ministry of Health and Welfare. In addition, due to religious reasons, Islamic countries generally require the alcohol content to be marked.

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66 Table 3.2 Comparison of general cosmetic labeling requirements in various countries

China EU United States Japan South Korea ASEAN

Net content Mandatory SI metric labeling Mandatory SI metric labeling,

US customary units are allowed to be used until 2009 Mandatory US customary units labeling,

or use with SI metric Mandatory SI metric labeling Mandatory SI metric labeling,

or use with imperial units

Full ingredient labeling Must be labeled

from November 14, 2009 Must be labeled Must be labeled Must be labeled Must be labeled Must be labeled

Ingredient name INCI Chinese translation INCI name INCI name INCI Japanese translation INCI Korean translation INCI name

Shelf life Mark "production date and

shelf life" or "production

batch number and expiration date" If less than 30 months, mark the expiration date; if more than 30 months, mark the time after opening that can be used safely To indicate the period of time within which it is safe to use Designated products need to be labeled Need to label the production date, but not the shelf life Production date or expiration date

Instructions for use Label when necessary Label when necessary Label when necessary Label when necessary Must be labeled Not mandatory but recommended Label when necessary

Production batch number/code Must be labeled Must be labeled Not required to be labeled Must be labeled Must be labeled Must be labeled Warning statement No detailed regulations When a substance is contained, the directive stipulates Yes Yes Yes When a substance is contained, the directive stipulates

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(Continued Table)

China EU United States Japan South Korea ASEAN

Efficacy Claims Medical terms are prohibited. As long as there is scientifically proven efficacy, it can be labeled. Some member countries have detailed regulations. Medical terms are prohibited. Regulations stipulate that the terms are claimed. Regulations stipulate that the terms are claimed. There are relevant regulations. Language requirements Standard Chinese characters, and it is allowed to use Pinyin at the same time. Or minority languages ??or foreign languages. Mother tongues of various countries or official languages ??of the European Union or the above two languages. English, Japanese, Korean; Chinese and other foreign languages ??can be used at the same time. English and/or national language and/or language acceptable to consumers in the sales area.

Guidelines for Cosmetic Label Management in Various Countries

68 3.8.3 Label Requirements for Marginal Products

In general, the label requirements for marginal products in various countries are quite different from those for cosmetics, and are more stringent in comparison. See Table 3.3 for special requirements for their labels. The efficacy and safety of over-the-counter drugs in the United States, quasi-drugs in Japan, and functional cosmetics in South Korea must be tested by the competent authorities. Without prior review, any other claims are not allowed. In these three markets, therapeutic claims are prohibited in cosmetics, but are allowed in over-the-counter drugs, quasi-drugs, or functional products. In addition to requiring the labeling of "functional cosmetics", South Korea does not differ much from general cosmetics in other labeling content. In addition to requiring the labeling of the approval number of special-purpose cosmetics, my country has no special requirements for labels and efficacy claims for special-purpose cosmetics.

Table 3.3 Special requirements for labeling of marginal products in the United States and Japan

United States (OTC drugs) Japan (quasi-drugs)

Special labeling Label ?drug facts? Label ?quasi-drug?

Ingredients List the active ingredients first in the ingredient list, then

inactive ingredients in descending order by content; active ingredients must also be listed on the inner packaging Not all ingredients are required to be disclosed, but MHLW lists

138 ingredients that must be listed on the label

Shelf life If the label has dosage instructions and no shelf life, the stability period data is at least 3 years Labeling is required for designated products Storage conditions Labeling when necessary Labeling is required in certain circumstances

Instructions for use Must be labeled Must be labeled

Batch number Must be labeled Must be labeled

Warning statements Claims and warning terms must comply with the OTC monograph for the individual product category

Required

Efficacy claims Claim efficacy within the scope of the relevant monograph Regulations allow claims, any other claims are not allowed

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Various countries have special regulations on sunscreen cosmetic labeling. Recently, the European Union, the United States and my country have all made changes to the regulations on sunscreen cosmetic labeling.

In July 2007, the European Union announced new requirements for sunscreen product labeling. The most important change is that the sunscreen product labeling must be on the front of the package, indicating the new protection level and the same value as the SPF value. If the value obtained by the continuous pigmentation method for UVA protection is 1/3 of the SPF value or the same protection value is obtained by other in vitro methods, and the minimum wavelength is 370nm, the UVA protection label can be used on the front of the product label.

Instructions for use should be marked to ensure that the product efficacy in the statement can be achieved, and the amount of instructions should be given.

Sunscreen products are not allowed to be labeled with statements that they can block 100% of UV radiation (such as "blocking sunlight" or "complete protection") and that sunscreen products do not need to be reused (such as "all-day protection"). The new announcement also provides consumers with practical advice, such as "Even if you use sunscreen, do not stay in the sun for too long", "Infants and young children should avoid direct sunlight" and "Excessive exposure to the sun poses a serious threat to health".

Table 3.4 New sunscreen labeling in the EU

Level Labeled SPF value Actual SPF value

Low protection 6

10 6~9.9

10~14.9

Medium protection 15

20

25 15~19.9

20~24.9

25~29.9

High protection 30

50 30~49.9

50~59.9

Ultra-high protection 50+ 60

Following the EU's strict regulations on sunscreen product packaging instructions, the United States has also recently announced a new sunscreen labeling system draft, which is expected to take effect as early as 2009. The scope of supervision will cover the ingredients, labeling format and testing criteria of sunscreen products. The FDA-approved SPF value has been raised from the current 2~30+ to 2~50+, and it is recommended that the SPF should not exceed 50, unless the manufacturer can further test the product and prove that the efficacy is consistent with the SPF claimed by the manufacturer. Products must undergo human clinical trials before they can claim to have the ability to block UVA (long-wave ultraviolet rays). At the same time, the FDA has proposed a "4-star" rating standard representing the four levels of low, medium, high and highest UVA protection. The more stars, the higher the protection level. If a sunscreen product does not even have a one-star protection ability, then the FDA

70 It is recommended that the front label of the product should state "no UVA protection" near the SPF value (sun protection factor).

In addition, the following "warning statement" should be included in the "drug instructions" column of all sunscreen products: "Exposure to the sun's ultraviolet rays increases the risk of skin cancer, early skin aging and other skin damage. Reducing sun exposure time, wearing protective clothing and using sunscreen products to reduce ultraviolet exposure are important means to reduce ultraviolet exposure". Sunscreen product labels should guide consumers to apply sunscreen products "largely" and frequently and repeatedly (at least once every two hours) to "prevent its effectiveness from decreasing".

The new version of my country's "Cosmetic Hygiene Standards" has made clear provisions on the SPF value of sunscreen products: "When the SPF (sunscreen cosmetics sun protection factor) value of the measured product is higher than 30, and it is still greater than 30 after subtracting the standard deviation, the maximum value can only be marked as SPF30+, and the actual measured value cannot be marked". Products manufactured or imported from July 1, 2009 must comply with these new regulations; sunscreen products that have been approved by the Ministry of Health before July 1, 2007 and are manufactured or imported before the expiration of the approval certificate can be sold until the expiration date of the product if the sunscreen function label is consistent with that at the time of approval.

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IV. Other issues that should be noted when exporting cosmetics

### 4.1 Cultural issues

Culture refers to the sum of material and spiritual wealth created by human beings in the process of social and historical development, and specifically refers to spiritual wealth, including values, ethics, religion, fine arts, fashions and customs. Culture has a huge impact on people's lives, aesthetics, consumption, etc. Therefore, in foreign trade, it is necessary to pay attention to the cultural differences between regions. Products should be designed according to the cultural characteristics and requirements of each country, and prices should be set according to the different values ??and payment capabilities of consumers in each country. Distribution channels should be selected according to the different cultures and habits of each country, and promotions should be designed according to the cultural characteristics of each country. Packaging and plans. People in European and American countries advocate vacations and outdoor sports, and like to tan their skin. They believe that wheat-colored or bronze-colored skin not only represents a person's fashion level, but also shows a person's status to a certain extent. Too fair skin will also be considered inappropriate or even low-status. The traditional oriental aesthetic view regards fair and delicate skin as beautiful. Therefore, the selling point of European and American sunscreen products is "getting tanned quickly", which is exactly the opposite of the Eastern "not getting tanned after sun exposure".

After the war, with the development of the economy, the Japanese people's emphasis on appearance and dressing has become a kind of etiquette and value.

There is a motto in the Japanese beauty industry: Makeup is to get closer to the ideal self, to pursue "truth, goodness and beauty". In daily life, it is rare to see Japanese women go out with their hair dishevelled and without makeup. They keep up with fashion, making Japanese cosmetics recognized and becoming a veritable "makeup power". In the past two years, there has been a rise in the male beauty craze. Nearly 70% of men trim their eyebrows and use facial cleansers, 30% carry oil-absorbing facial tissues with them, and 25% carry lip balm with them. They are very concerned about daily skin care. They also pay attention to their hairstyle and body shape, and often go to beauty salons for body care. Nonomura Sakae, director of the Kanebo Cosmetics Research Institute, said: "In Japan, makeup is no longer limited to men, women, old or young." In order to meet the needs of an aging society, Japanese cosmetics companies have come up with a variety of ways to prepare "elderly" cosmetics. Korean women, like Japanese women, regard makeup as etiquette, and not wearing makeup is equivalent to being impolite. French people are generally very particular about their clothes, especially Parisians, who are world-renowned for their beautiful and gorgeous clothes. French women are the most fashionable women in the world. Their clothes are fashionable and they use a lot of cosmetics. There are many kinds of lipsticks alone, and they are different for morning, afternoon and evening. Therefore, France's high-end clothing, cosmetics and luxury goods are also famous in the world.

72 Language and characters are an important factor in product information communication. Different countries use different languages, and even different regions in the same country use different languages. For example, Israel has 50 languages. Even if the same language is used, there are still some differences in different places. When selling products in other countries and regions, special attention should be paid to the changes and translation of trademark names. If the trademark name is not right, no one will care about the product even if the quality is good. Due to cultural differences, people's likes and dislikes of certain things are also very different. When translating, full consideration must be given, and flexible, cautious and flexible methods must be adopted to deal with unnecessary problems caused by such differences, so that the translator's readers can get the same experience as the original readers, and the product's function will not be changed.

For example, in the late 1960s, a daily chemical factory in Shanghai, my country produced "Fang Fang" baby talcum powder. At that time, the product was very popular in the domestic market, but it sold very poorly in the international market. After market research, it was found that the problem was the Chinese pinyin "Fang Fang" of the two words "Fang Fang". "Fang" in English means the "fangs" of poisonous snakes. English-speaking people are afraid of this "fanged" baby powder. They dare not ask for it at all. For example, when my country's "Blue Sky" brand toothpaste was exported to the United States, its translated name "Blue Sky" became "the bonds that the company cannot collect", and sales undoubtedly became a problem. Therefore, if a company wants to make its products enter a new market, it must adapt to the local customs and give a name that adapts to the local cultural traditions.

Countries also have different regulations on the use of words on packaging. For example, the Greek Ministry of Commerce stipulates that all words on the packaging of foreign goods imported into Greece, except for statutory exceptions, must be clearly written in Greek. Otherwise, the agent, importer or manufacturer will be prosecuted and punished; the Canadian government stipulates that the packaging of imported goods must use both English and French; food labels sold to Hong Kong must be in Chinese, but the food name and ingredients must be indicated in English at the same time; the packing list and commercial invoice of products sold to France must be in French. For packaging labels, if not written in French, a French translation should be attached; food and beverages sold to the Arab region must be described in Arabic; food sold to Brazil must be accompanied by a Portuguese translation; Japanese people appreciate Roman letters and generally prefer to use paper boxes with text descriptions. Goods exported to Japan are generally described in Japanese, while cosmetics sold in the Japanese market are mostly designed in English and are also very popular, especially high-end cosmetics, which can show the momentum of imported products. Japanese foreign words and popular terms vary greatly, so the text itself must be in line with the trend and simple and clear.

# 4.2 National (religious) customs

Due to the different natural conditions, geographical environment and political and economic factors of various ethnic groups, different language, writing, literature, art, education, science and other characteristics have gradually formed over a long period of time. Different ethnic groups

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Consumption customs are determined by the traditional culture of each nation. Only by deeply studying national customs can we make correct judgments and decisions on the market and produce products that adapt to the characteristics of different nations.

For example, Africans have a variety of hairstyles with profound meanings. The ever-changing hairstyles can also be used to express national characteristics or other meanings. For example, the Cognacs in Guinea worship roosters. They believe that roosters have noble morals, and the hairstyles of men in this tribe are mostly towering rooster crowns. The nomadic Moors have a deep affection for camels and like the hard-working spirit of camels. Some people have hairstyles that resemble towering camel humps.

Currently, 60% of the world's population believes in religion, and religious beliefs greatly affect the social development, political structure, economic form, cultural fashion, ethics, and lifestyles of countries around the world.

According to statistics, about 1/5 of the world's population believes in Islam, and more than 40 countries believe in it as a state religion, mainly in the Middle East, Southeast Asia and other regions. Halal certification is a standard qualification certification recognized by Islamic countries for products consumed and used by people of this religion. Halal, translated into Chinese as "halal", refers to food, medicine, cosmetics and food, medicine and cosmetic additives that meet the living habits and needs of Muslims. Muslims cannot eat materials extracted from pigs or other animals that have not been slaughtered in Islamic ways. Animal raw materials such as cattle, sheep, deer, moose, chickens, ducks, game birds, etc. must also be halal, but they must be slaughtered in accordance with Islamic law before they can be eaten (or used for other purposes). In the manufacturing process of halal products, substances that do not comply with Islamic law must not be added; product storage must comply with Sharia regulations; halal biological materials must be certified by relevant Muslim institutions (such as the Islamic Association); Muslim food, health products, and cosmetics industries all need halal certification when using these materials. In addition, each religious sect and each ethnic group has their own special likes and dislikes in the use of numbers, symbols, patterns and colors. Numbers are very particular in many countries and regions, and residents in many parts of the world still have great superstition about numbers. Some numbers may mean "good luck" in many countries; in other countries, they may represent bad luck. For example, Japan is taboo about the numbers "4" and "9" because "4" is homophonic with "death" and "9" is homophonic with "bitterness"; consumers in Southeast Asian countries generally like "8" because it is homophonic with "fa" and is considered to be very auspicious, and taboo about "9" because it is considered to be a year of famine; Christianity is taboo about "13" and "Friday". Taboos on signs and patterns are usually divided into several types, such as taboos on people, animals, plants and geometric figures. For example, Arab countries stipulate that the packaging of imported goods is prohibited from using six-pointed star patterns because the six-pointed star is similar to the Israeli flag.

74 The patterns on the labels are similar. Arab countries are very disgusted and taboo about things with six-pointed star patterns; Saudi Arabia strictly prohibits the printing of wine bottles, churches, and cross patterns on stationery. Those who violate the rules will be confiscated and destroyed; in Islamic countries, pigs or pig-like patterns, such as bears and pandas, are prohibited on product packaging. Thumbs up and female human body patterns are also prohibited; in Turkey, green triangles should be used with caution. Green triangles are the symbol of free products; in Britain and France, horses are regarded as a symbol of bravery, while peacocks are regarded as evil birds; French, Belgian, Spanish, and Japanese people use chrysanthemums (especially white chrysanthemums) as funeral objects; British trademarks also avoid using human portraits as product packaging patterns; for German products and packaging, Nazi legions and Nazi-like symbols are prohibited; Americans' favorite pattern is the eagle, because the eagle is the symbol of the American national emblem, followed by butterflies, and precious animals such as elephants are avoided; In addition, the international community regards the triangle as a warning sign, so it is forbidden to use the triangle as a trademark for export products. Different ethnic groups have different preferences and taboos for colors. For example, Americans like simple and clean colors, such as ivory and light green, and pure colors and bright colors are more popular; Japanese people avoid green and like red; in India, red represents life, vitality, vigor, and enthusiasm, yellow represents brilliance and magnificence, green represents peace and hope, and black, white, and gray are avoided: Muslims like white and regard cleanliness as beauty, and believe that green can drive away diseases and evil spirits, and yellow is hated because it symbolizes death; French people regard bright colors as noble and very popular, and dark green will make people think of the uniforms of Nazi soldiers and produce disgust; Switzerland uses black as mourning color, and the national flag color that matches primary colors and red and white is very popular; the Dutch regard orange as a lively color, and orange and blue represent the colors of the country; the Danes regard red, white, and blue as auspicious colors; Italians regard purple as a negative color, and prefer light colors for clothing, cosmetics, and high-end packaging; in Mexico, the red, white, and green colors that represent the country are very popular; Brazilians believe that Purple represents sadness, yellow represents despair, and these two colors combined with dark brown represent bad luck, which is extremely offensive; in Egypt, green represents the country and is more popular, while blue is regarded as a symbol of the devil and is unpopular. People regard blue as a devil.

In foreign trade, if these taboos are violated, trading will be hindered. Therefore, it is necessary to have a good understanding of the customs and habits of the relevant countries and regions to avoid trade losses.

4.3 Green consumption

4.3.1 The concept of green consumption

The 21st century is the green century. Green represents life, health and vitality, and is a color full of hope.

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The international understanding of "green" usually includes three aspects: life, energy conservation, and environmental protection. Green consumption, also known as sustainable consumption, refers to a new type of consumption behavior and process characterized by moderate consumption, avoiding or reducing damage to the environment, advocating nature and protecting ecology. It complies with the "three E's" and "three R's", economical (Economic), ecological benefits (Ecological), equality and humanity (Equitable), reducing unnecessary consumption (Reduce), reusing (Reuse) and recycling (Recycle). Green consumption includes a very wide range of content, including not only the purchase and use of green products, but also the recycling of materials, the effective use of energy, the protection of the living environment, the protection of species and other processes that consume materials and energy. It can be said that it covers all aspects of production and consumption behaviors.

Green consumption has been widely recognized by the international community and is entering the lives of more people. People's awareness of advocating nature, environmental protection and health is constantly increasing. According to a survey by the European Union: 67% of Dutch people, 82% of Germans and more than half of British people will consider environmental factors when shopping, and even prefer to pay much higher prices than ordinary goods to buy environmentally friendly products. Seeking harmonious coexistence between humans and the environment has become the common wish of the world.

# 4.3.2 Green consumption of cosmetics

In order to ensure that their skin health is not damaged, green cosmetics with pure natural materials and no toxic side effects are gradually being sought after by people. The mainstream trend of skin care in recent years also shows the prevalence of green cosmetics.

1. Chinese herbal skin care In the next 5 to 10 years, the beauty and skin care market will be dominated by natural plants and Chinese herbal medicine beauty products, among which the development of new products combining traditional Chinese medicine theory with modern high-tech is the hot spot.

In 2007, the annual sales of Chinese herbal medicine in the world exceeded 16 billion US dollars, and increased at a rate of 10% to 20% per year. New information shows that not only Asians are more receptive to traditional Chinese herbal medicine, but also the health concepts of developed countries such as Europe and the United States are changing. Traditional Chinese medicine is profound and rich in resources, and will become the focus of global beauty and skin care product research and development. At present, international companies such as L'Oreal and Shiseido have already or are preparing to launch Chinese herbal medicine projects in China, spending huge sums of money to develop the essence of oriental Chinese herbal medicine.

2. Anti-pollution In recent years, in order to fight against automobile exhaust, dust impurities, computer radiation, external toxins, work pressure, lack of sleep, irregular life, etc., many visionary cosmetics companies have begun to develop anti-pollution and anti-stress skin care products. Nowadays, more and more skin care products with purification and detoxification functions have begun to appear, and many major brands have launched their own targeted anti-pollution and anti-stress skin care products.

76 3. Additive-free skin care The term "additive-free" originated from Japan, which stipulates 102 ingredients that cannot be added to cosmetics that are sensitive and harmful to the skin, in order to avoid "fragrance pollution", "color pollution" and "oil pollution" and cause harm to consumers' bodies. This demand has become a production and consumption trend. But in fact, there is no unified standard for additive-free at home and abroad, but there is a principle that it must have 4 main characteristics:

First, do not add substances that are harmful to the human body (skin), such as whitening agents containing mercury, hormone ingredients, etc.; do not add substances without definite functional ingredients; do not add substances whose purity does not meet the requirements, because substances that do not meet the requirements will become allergens for human skin; do not add unnecessary auxiliary materials.

At the end of 2000, Professor Brian, a famous British scientist, proposed a new concept of green cosmetics:

1. Use pure natural plant raw materials, try not to use pigments, flavors and preservatives that are irritating to the skin,

to reduce the harm caused by chemical synthetics to the human body. 1. Check the raw materials and produce cosmetics that are absolutely safe for the human body. 2. Use clean production technology that is harmless to the environment and the human body in all stages of manufacturing, use and treatment, and transform pollution prevention from end-of-pipe treatment to the production process. 3. Use biodegradable and renewable packaging materials, reduce excessive packaging, and recycle packaging containers as much as possible. 4. Aerosol sprays used in hairspray, shaving products, and spray perfumes are replaced by safe liquefied petroleum and dimethyl ether to eliminate damage to the ozone layer. 5. Abandon chemical synthetic additives and use bioengineering preparations and natural plant extracts to play the role of acne removal, whitening, and anti-aging under the premise of safety and harmlessness. At present, many experts generally agree with Professor Brian's views to a certain extent, but they believe that many details need to be carefully discussed and concretized. As a new thing, there is indeed no strict definition standard for green cosmetics either internationally or domestically. However, many developed countries have already developed some industry standards or corporate standards. For example, the Japanese Cosmetics Industry Association has formulated industry standards for green cosmetics based on the corporate standards of CAC (Marumi). Internationally, green cosmetics have also moved from the concept to the implementation stage. Currently, the world's top companies have launched green products and invested heavily in research. The market share of green cosmetics has increased rapidly.

Guidelines for Cosmetics Label Management in Various Countries

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Since 2009, the EU has banned the testing of cosmetics for toxicity and allergy on animals, and does not allow member states to import and sell cosmetics that violate the above ban from foreign countries. However, three types of toxicity tests will be allowed to continue until 2013 in preparation for finding alternative test materials and test methods. The EU said that this decision is to protect animals as much as possible without harming the interests of consumers. At present, the United Kingdom, Austria and the Netherlands have banned the testing of cosmetic ingredients on animals, but have not banned the import and sale of such products.

As one of the most important cosmetics exporters in the world, China is likely to be affected by this EU move. It usually takes about ten years to establish, verify and finally write alternative experiments into regulations. Chinese cosmetics companies should pay attention to this issue as soon as possible and find alternative methods for experiments.

### 4.4 Market access environment requirements

The market access environment involves many factors, including technical trade measures, tariffs, trade relief measures and customs clearance. Trade relief measures include anti-dumping, countervailing, safeguards and other measures. All trade remedies are administrative protection. As traditional trade barriers (tariffs and quotas) gradually decrease, the application of anti-dumping and anti-subsidy measures will continue to increase. The European Union, the United States, Japan and other countries frequently use trade remedies to restrict Chinese exports. When conducting anti-dumping investigations against China, there is often a lot of discrimination. For example, the European Union lacks transparency in calculating the dumping margin and the degree of dumping damage. The cost advantage of China's exports to the European Union has been distorted by the European Union into a basis for filing anti-dumping lawsuits against China. The EU anti-dumping provisions are included in Article 384/96 of the Trade Guidelines formulated by the European Union, including how to initiate anti-dumping investigations and define dumping and its degree of damage to relevant EU companies. There are also a series of provisions that discriminate against Chinese products in the US anti-dumping law and specific product safeguard measures legislation. There are a lot of unfair practices in the investigation practice, which constitute a great obstacle to China's exports to the United States. These should cause Chinese cosmetics companies to pay enough attention and make corresponding preparations as soon as possible.

## 4.5 Exchange rate issues

Import and export trade is greatly affected by exchange rate fluctuations. Under the fixed exchange rate system implemented in my country, most import and export trade settled in US dollars is basically unaffected, and import and export enterprises are basically insensitive to exchange rate risks. After my country's exchange rate has basically achieved marketization, the exchange rate reflects more market factors. Since the reform and opening up, my country's foreign trade has maintained a high growth rate and has maintained a trade surplus for many years. The appreciation of the RMB will have a series of impacts on the total amount and structure of my country's foreign trade imports and exports. The rise in the RMB exchange rate will increase the price of my country's export products, thereby losing the original low-cost advantage, weakening market competitiveness, and reducing profits. To a certain extent, it restricts my country's product exports and will bring great impacts to enterprises that rely solely on product price advantages.

78 Great impact.

4.6 Other issues

4.6.1 Climate

Different regions have different geographical environments and climate conditions, and people's demand for cosmetics is also different.

In hot and dry areas such as the African continent and the Middle East, the skin easily loses moisture, and moisturizing creams, moisturizing oils, and toners are generally favored by consumers.

ASEAN is located in a very hot and humid area, with a high frequency of cleansing and bathing. The market for facial cleansers and body care products is large, and the demand for coolness is very high. Due to the strong sunlight, anti-ultraviolet and whitening facial care products are also very popular.

The climate in the Middle East is hot, with temperatures as high as 40 or 50 degrees, little cool breeze, and easy sweating. People like to use strong perfumes, and often use hair cream to moisturize the body to prevent heatstroke. They also like to use refreshing and volatile cosmetics. Anti-ultraviolet burn products are also popular, while cosmetics with a lot of oils that are very popular in many high-altitude cold areas are not popular here.

# 4.6.2 Ethnicity and physique

Exported cosmetics should take into account the different physiques of people in different regions, and the products should be suitable for the characteristics of local people.

Africans have thick and hard hair, with a variety of hairstyles and colors. It takes time and effort to take care of them, and they use a lot of cosmetics. In African cosmetics stores, there are countless ointments and medicines for shampooing, dyeing, hair care, and hairdressing.

People's skin color is generally divided into yellow, white, black and brown. As the skin color becomes lighter, the skin's resistance to external stimuli decreases. Caucasians have the highest incidence of skin cancer, while skin cancer rarely occurs in black people. Most of the white people in Europe and the United States are white. They are more sensitive to ultraviolet rays in the sun and their skin is easily irritated. Therefore, various sunscreen cosmetics are very popular in the market.

Europe, the United States and the Middle East have developed human hair and sweat glands, and their body odor is strong. Therefore, both men and women like to spray their bodies.

Guidelines for Cosmetic Label Management in Various Countries

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Spraying perfume has evolved into a social etiquette and even a fashion over time.

Guidelines for Cosmetics Label Management in Various Countries

80 V. Suggestions for Meeting Target Market Requirements

5.1 Strengthening the Role of Government Actions and Business Associations

Coping with foreign technical trade measures is a highly technical and policy-oriented issue. Governments and industry associations

should strive to create a fair, healthy and sustainable trade environment for exporting companies. The government can make full use of the national consultation points on technical standards and regulations provided by WTO member countries under the WTO/TBT Agreement and the WTO/SPS Agreement, as well as my country's overseas commercial and science and technology counselor's offices and other institutions, to timely obtain relevant information on technical trade measures from developed countries and my country's major trading partners, and pay close attention to new trends in changes in global technical trade measures; organize forces to strengthen research on technical policies, relevant regulations and standards, put forward specific countermeasures and suggestions for technical trade measures, break through technical barriers, safeguard the legitimate rights and interests of Chinese enterprises, and use the favorable terms of the WTO/TBT and WTO/SPS agreements to strive for more technical assistance and care; continue to improve the construction of the information network for notification and consultation on foreign technical trade measures, strengthen technical early warning and rapid response, provide information consulting services to enterprises, so that my country's export commodities adapt to and meet the requirements of international standards or importing countries, and avoid falling into the trap of technical barriers; actively participate in international standardization activities , fully reflect some of my country's opinions and requirements into international standards, and create conditions for my country's products to smoothly enter the international market.

As a self-regulatory management organization of enterprises, industry associations have many corporate members, are familiar with industry characteristics, and maintain close contact with the government. They can undertake many necessary but difficult matters for the government and enterprises to undertake directly in the process of responding to technical trade measures, and play their unique role well. Industry associations should actively cooperate with the government to participate in negotiations and assist enterprises in resolving disputes; strengthen contacts, exchanges, communication and consultations with relevant industry organizations at home and abroad, and open up new channels for obtaining relevant information; organize and provide enterprises in the industry with a wide range of WTO rules training and consulting services, especially training on technical trade measures business knowledge; guide enterprises to strengthen self-discipline, learn relevant knowledge, and improve their response capabilities.

5.2 Accelerate the construction of the standard system and actively adopt international standards. my country's cosmetics management regulations should be in line with international standards. Developed countries abroad have formed a relatively mature set of regulations. There are many regulations and standards that can be used as a shortcut for China to reform its cosmetics management regulations, and as a basis and model for absorption and adoption. First of all, we must continue to improve our standard system and strengthen the research on the differences between domestic and foreign standards.

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Research, refer to relevant international standards and foreign advanced standards when formulating and revising standards, vigorously promote the adoption of international standards, coordinate national standards, industry standards with international standards, and improve the scientificity, advancement and rationality of Chinese standards; increase support for standard formulation, timely grasp the dynamics of international standards and their formulation background, analyze carefully and adopt them reasonably, shorten the standard formulation and revision cycle, and pay special attention to strengthening the standard formulation and revision work of key industries and advantageous export products; strengthen the adoption and promotion of international standards and technology introduction work in enterprises, improve enterprise standardization awareness, formulate incentive policies, promote enterprises to adopt international standards, and strengthen the correlation between standards and markets; actively participate in the activities of the International Organization for Standardization and actively participate in the formulation and revision of international standards.

5.3 Accelerate the development and improvement of enterprise certification system and conformity evaluation system

The international authoritative certification of enterprises is an important indicator to measure the quality of enterprises and their ability to break through foreign technical barriers and open up international markets. It plays a very prominent role in promoting exports. Therefore, it is necessary to widely carry out ISO9000 quality system certification and ISO14000 environmental protection system certification in my country's cosmetics enterprises. The ISO9000 series of standards issued by the International Organization for Standardization are world-recognized effective management and quality assurance standards. They are currently the management guidelines and quality assurance criteria adopted by the most countries in the world and are most widely used in various industries. The implementation of ISO9000 standards by my country's cosmetics enterprises can improve internal management, improve product quality, increase customer trust, win the market, and gain a good international market reputation. When an enterprise obtains ISO14000 environmental protection system certification, it is equivalent to obtaining a "green pass" for export, which is conducive to the enterprise to effectively resist the influence of the "green trade barriers" set by developed countries, meet the necessary requirements of many developed countries for market access to this management system, promote export products to meet international standards in terms of environmental standards, reduce trade frictions, and expand product exports. Enterprises can adopt international standards as soon as possible to make their products enter the international market as soon as possible. Early integration with the international community is an important condition for participating in international competition, and it is also an effective way for enterprises to achieve long-term development. At present, the international community has put the good manufacturing practice (GMP) of cosmetics on the agenda. The European Union has first stipulated that the GMP formulated by each member state should be implemented, and at the same time, the EU GMP should be formulated. GMP is the control of the production process. The entire production process is recorded and in a controllable state. It is recommended that ordinary cosmetics manufacturers in my country implement good production practices, establish mandatory standards for special-purpose cosmetics, and enforce good production practices, so as to facilitate the supervision and management of manufacturers by competent authorities. Establish cosmetics (GMP), and actively conduct bilateral recognition with relevant countries and international organizations, so that Chinese enterprises can obtain international recognition while gaining domestic recognition, which can open the door for Chinese cosmetics manufacturers to improve product quality and enter the international market.

82 5.4 Enterprises should attach importance to information collection and improve their own response capabilities

Enterprises should have a more international perspective, widely collect relevant information on technical regulations, standards and conformity assessment procedures in the ever-changing markets of major export target countries, and adjust their standards in a timely manner according to international market demand and development trends; establish an enterprise information collection mechanism, set up a special agency, and equip special personnel to be responsible for the information collection, classification and research of technical trade measures, timely track, learn from and summarize relevant experience and lessons of breaking through the restrictions of technical trade measures, establish an information center and database, strengthen research and guide production, and at the same time strengthen the training of professionals familiar with technical trade measures; actively expand information sources, timely understand the requirements of foreign importers, the facts of export obstruction and information on changes in foreign markets, ensure the timeliness, accuracy and completeness of information, and make timely adjustments to production, marketing and other links to adapt to changes in the market environment. Appendix 7 lists the websites of institutions where information on cosmetic regulations and industry in relevant countries or regions can be obtained for reference.

5.5 Improve the technical content of export products and continuously carry out technological innovation

At present, the technological content of cosmetics in my country is low, and it is still in the imitation stage in terms of scientific formula research and development.

Many enterprises lack scientific research capabilities and new product equipment, focus on sales and neglect research and development, and lack research on enterprise breakthroughs and long-term development strategies. In order to change this situation, it is necessary to strengthen the emphasis on research and development and increase the intensity of research and development investment in both funds and personnel. Research and development should be used to ensure the replacement of new and old products and improve the technological content of products. First, we should pay attention to the investment in scientific and technological talents, including talents in biology, medicine, pharmaceuticals and fine chemicals in many aspects and disciplines; second, attach importance to basic research, and establish cosmetics research institutions in accordance with the scientific research institutions for medical development; third, continuously improve production facilities and improve testing methods. At present, the production, facilities, environmental conditions of most cosmetics enterprises in my country, especially the testing methods for various product quality standards, are still quite backward, and efforts should be made to transform them. The production and testing methods applicable to the production of drugs and biological products can be applied to the production of cosmetics.

5.6 Improve export policies and adjust trade structure

Currently, the quality and grade of cosmetics exported by my country are not high. Although the total export volume has increased rapidly, the unit value of products has not increased significantly. Therefore, the cosmetics trade structure urgently needs to be optimized. On the basis of consolidating the existing market share, change the low-price route, establish brand awareness, and actively guide Chinese enterprises to improve the quality of export products.

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Quantity and grade, encourage industrial upgrading and structural adjustment of the cosmetics industry, and improve the innovation ability of enterprises; improve export policies, by increasing the export tax rebate rate of high-tech, high value-added, and technology-intensive products, reducing or canceling the export tax rebate of low-tech and low value-added products, increasing the technical content of export products, adjusting and optimizing the structure of export products; targeting the gaps in the target market, purposefully develop products that better meet their needs, and adopt more reasonable marketing strategies to seize key breakthroughs.

## 5.7 Pay attention to the brand building of cosmetics companies

Brand is the embodiment of product quality and cultural connotation, and has become an important marketing tool for modern enterprises facing the market economy. Brand is not only an intangible asset of the enterprise, but also a kind of competitiveness of the enterprise, and even a core competitiveness. Brand has four major functions: it is convenient for enterprises to operate and manage; brand helps market segmentation and positioning; brand can establish a stable customer base; registered brand is protected by law. International famous cosmetic brands have invested heavily in designing, maintaining and developing their own brand image, making their own brands a symbol and synonym of dignity, elegance, refinement, quality and taste, and deeply attracting consumers with unique value connotations and brand spirit, so that their products can be sold all over the world and obtain lucrative profits. At present, the strength and methods of brand cultivation of local cosmetics enterprises in my country are still lacking. Most of the cultivated brands are active in the low-end market and have low recognition. A successful brand is inseparable from good management and operation. my country's cosmetics enterprises should scientifically position the brand in the market and formulate correct brand promotion strategies and market expansion strategies based on the analysis and research of consumers, competitors and external market environment; attach importance to building and cultivating unique brand culture, inject cultural background elements and core value concepts that are compatible with the brand according to the brand's market positioning and product concept, and carry out reasonable integration, interpretation, extension and expansion to enhance brand value, enhance brand heritage, enrich brand connotation and support the continuous and healthy development of the brand.

84 VI. Common technical trade measures and common case analysis for my country's cosmetics export enterprises

### 6.1 Technical trade measures

Technical trade measures refer to some mandatory or non-mandatory technical measures taken by a country on the grounds of maintaining national security or protecting human health and safety, protecting the life and health of animals and plants, protecting the ecological environment, or preventing fraudulent behavior and ensuring product quality. These measures become obstacles for the free entry of goods from other countries into the country.

Technical trade measures are mainly reflected in the formulation of mandatory and non-mandatory commodity standards, regulations and the inspection of commodity conformity assessment, that is, through the promulgation of laws, decrees, regulations, provisions, the establishment of technical standards, certification systems, inspection systems, etc., strict technical, sanitary quarantine, commodity packaging and labeling standards are formulated for foreign imported goods, thereby raising product technical requirements, increasing the difficulty of import, and ultimately achieving the purpose of restricting imports.

As countries around the world attach great importance to protecting the environment, protecting the life and health of humans, animals and plants, and protecting the rights and interests of consumers, especially in recent years, they attach great importance to saving resources and energy, and trade protectionism has risen. Related technical trade measures have become a means that countries and regions around the world use and rely on more and more frequently, which has a considerable impact on international trade. In terms of the specific situation of technical trade measures in international trade, it is mainly developed countries such as the United States, Japan, and the European Union that have formulated stringent technical standards, technical regulations, and technical certification systems based on their own technological and economic advantages, which have a huge restrictive effect on the export trade of developing countries. Therefore, studying the status of technical trade measures implemented by developed countries in international trade is of great significance to both my country's export trade and the production of enterprises.

## 6.2 Common technical trade measures for Chinese cosmetics exporters

Take the US FDA as an example. In 2011, the US reported 213 batches of Chinese cosmetics, of which 39 batches were due to labeling issues. The specific reasons were: failure to comply with the relevant cosmetics labeling regulations, incorrect labeling, failure to indicate the name of the cosmetics, failure to indicate that it contained pigments, failure to indicate that it contained instructions for use, or the cosmetics seemed to contain two or more ingredients, but the label did not list the common or generic name of each ingredient.

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122 batches were reported because the products contained banned or restricted substances. Other reasons for the report include: adulteration with other impurities, detection of excessive microorganisms, etc.

86 VII. References

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Appendix

Appendix 1:

(China)

Regulations on the Administration of Cosmetics Labels

Order No. 100 of the General Administration

The Regulations on the Administration of Cosmetics Labels have been reviewed and approved by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China at its executive meeting on July 24, 2007, and are hereby promulgated for implementation on September 1, 2008.

Director

August 27, 2007

Regulations on the Administration of Cosmetics Labels

Chapter I General Provisions

Article 1 In order to strengthen the supervision and management of cosmetics labels, standardize the labeling of cosmetics labels, prevent quality fraud, and protect the personal health and safety of consumers, these Regulations are formulated in accordance with the Product Quality Law of the People's Republic of China, the Standardization Law of the People's Republic of China, the Regulations on the Administration of Industrial Product Production Licenses of the People's Republic of China, and the Special Regulations of the State Council on Strengthening the Supervision and Management of Food and Other Product Safety.

Article 2 These Regulations shall apply to the labeling and management of cosmetics produced (including repackaging) and sold within the territory of the People's Republic of China.

Article 3 Cosmetics as referred to in these Regulations refer to products that are applied to the human body (skin, hair, nails, lips, teeth, etc.) by smearing, spraying, sprinkling or other similar methods to achieve the purpose of cleaning, maintenance, beautification, modification and change of appearance, or correction of human body odor and maintenance of good condition.

The cosmetics label as referred to in these Regulations refers to the general term for the words, symbols, numbers, patterns and other instructions used to indicate the name, quality, efficacy, method of use, production and seller information of cosmetics.

Article 4 The General Administration of Quality Supervision, Inspection and Quarantine (hereinafter referred to as the General Administration of Quality Supervision, Inspection and Quarantine) is responsible for organizing the supervision and management of cosmetics labels nationwide within its authority.

88 Local quality and technical supervision departments at or above the county level shall be responsible for the supervision and management of cosmetics labels within their administrative regions within the scope of their authority.

Chapter II Labeling Contents of Cosmetics Labels

Article 5 Cosmetics labels shall be true, accurate, scientific and legal.

Article 6 Cosmetics labels shall indicate the name of the cosmetics.

The name of a cosmetic generally consists of three parts: the trademark name, the common name and the attribute name, and shall meet the following requirements:

- (i) The trademark name shall comply with the provisions of relevant national laws and administrative regulations;
- (ii) The common name shall be accurate and scientific, and shall not use words that explicitly or implicitly indicate medical effects, but may use words that indicate the main raw materials, main functional ingredients or product functions;
- (iii) The attribute name shall indicate the objective form of the product, and shall not use abstract names; the attribute name of the commonly accepted product name may be omitted.

If national standards or industry standards have provisions on product names, the names specified in the standards shall be marked.

Article 7 Cosmetics marked with "strange names" shall be marked with the product name in adjacent positions and with the same font size in accordance with Article 6 of these Regulations; and shall not violate relevant national regulations and social public order and good customs.

Cosmetics with the same name that are suitable for different groups of people, different colors and fragrances shall be marked in the name or in a prominent position.

Article 8 Cosmetics labels shall indicate the actual production and processing location of the cosmetics.

The actual production and processing location of cosmetics shall be marked at least to the provincial level according to administrative divisions.

Article 9 Cosmetics labels shall indicate the name and address of the manufacturer. The name and address of the manufacturer shall be the name and address of the manufacturer that is registered in accordance with the law and can bear product quality responsibility.

In any of the following circumstances, the name and address of the producer shall be marked in accordance with the following provisions:

- (i) A group company or its subsidiaries that bear legal liability independently in accordance with the law shall mark their respective names and addresses:
- (ii) A branch of a group company or a production base of a group company that cannot bear legal liability independently in accordance with the law may mark the name and address of the group company and the branch (production base), or may only mark the name and address of the group company

Guidelines for the Labeling Management of Cosmetics in Various Countries

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name and address;

- (iii) For cosmetics that are produced and processed by entrustment, if the entrusting enterprise has the production license of the cosmetics it entrusts to process, it shall mark the name and address of the entrusting enterprise and the name of the entrusted enterprise, or only mark the name and address of the entrusting enterprise does not have the production license of the cosmetics it entrusts to process, it shall mark the name and address of the entrusting enterprise and the name of the entrusted enterprise;
- (iv) Repackaged cosmetics shall be marked with the name of the actual production and processing enterprise and the name and address of the repackager, and the word "repackaged" shall be indicated.

Article 10 Cosmetic labels shall clearly mark the production date and shelf life of the cosmetics or the production batch number and the expiration date.

Article 11 Cosmetic labels shall mark the net content. The marking of net content shall be implemented in accordance with the "Measurement and Supervision and Management Measures for Quantitative Packaged Goods". Liquid cosmetics shall indicate the net content by volume; solid cosmetics shall indicate the net content by mass; semi-solid or viscous cosmetics shall indicate the net content by mass or volume.

Article 12 Cosmetic labels shall indicate the full ingredient list. The labeling method and requirements shall comply with the relevant standard regulations.

Article 13 The cosmetics label shall be marked with the national standard, industry standard number or registered enterprise standard number implemented by the enterprise.

The cosmetics label must contain the product quality inspection certificate.

Article 14 The cosmetics label shall be marked with the production license mark and number. The production license mark and number shall comply with the relevant provisions of the "Implementation Measures for the Regulations on the Administration of Industrial Product Production Licenses of the People's Republic of China".

Article 15 Instructions for use shall be added according to the product use needs or when it is difficult to reflect all the product information in the label.

The instructions for use should be easy to understand, and there must be illustrations when drawings are required.

Any cosmetics that are easily damaged by improper use or storage or may endanger human health and personal safety, and cosmetics suitable for special groups such as children, must be marked with precautions, Chinese warning instructions, and storage conditions that meet shelf life and safety requirements.

90 Article 16 Cosmetics labels shall not contain the following content:

- (i) Content that exaggerates functions, makes false claims, or devalues ??similar products;
- (ii) Content that explicitly or implicitly indicates that the product has medical effects;
- (iii) Product names that are likely to cause misunderstanding or confusion to consumers;
- (iv) Content that is prohibited from being labeled by other laws, regulations, and national standards.

Chapter III Labeling Forms of Cosmetics Labels

Article 17 Cosmetics labels shall not be separated from cosmetic packaging (containers).

Article 18 Cosmetics labels shall be directly marked on the smallest sales unit (packaging) of cosmetics. Cosmetics with instructions shall be attached to the smallest sales unit (packaging) of the product.

Article 19 For cosmetics in transparent packaging, if all or part of the label content on the inner packaging or container can be clearly identified through the outer packaging, the corresponding content may not be repeated on the outer packaging.

Article 20 The content of cosmetics labels shall be clear, eye-catching, and durable, so that consumers can easily identify and read them.

Article 21 Except for the registered trademark logo, the content of the cosmetics label must be in standard Chinese.

If pinyin, minority languages ??or foreign languages ??are used, they shall correspond to Chinese characters and comply with the requirements of Article 6 of these Regulations.

Article 22 If the maximum surface area of ??the cosmetics packaging (container) is greater than 20 square centimeters, the font height of the mandatory content in the cosmetics label shall not be less than 1.8 mm. Except for the registered trademark, the pinyin and foreign fonts used in the label shall not be larger than the corresponding Chinese characters.

If the maximum surface area of ??the cosmetics packaging (container) is less than 10 square centimeters and the net content is not more than 15 grams or 15 milliliters, the label may only indicate the name of the cosmetics, the name and address of the manufacturer, the net content, the production date and shelf life or the production batch number and the expiration date. If the product has other relevant explanatory materials, other content that should be marked may be marked on the explanatory materials.

Article 23 Cosmetics labels shall not use the following marking forms:

(i) Mislead consumers by using font size, color difference or suggestive language, graphics, symbols;

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- (ii) Unauthorized alteration of the name, production date and shelf life or production batch number and expiration date of the cosmetics on the cosmetics label;
- (iii) Other forms of labeling prohibited by laws and regulations.

Chapter IV Legal Liabilities

Article 24 If a cosmetics label fails to indicate the name of the cosmetics or the name does not meet the requirements of the regulations in violation of Article 6 and Article 7 of these Regulations, the person shall be ordered to make corrections within a time limit; if the correction is not made within the time limit, a fine of not more than RMB 10,000 shall be imposed.

Article 25 If a cosmetics label fails to indicate the actual place of production and processing of the cosmetics or the name and address of the producer in accordance with the law in violation of Article 8 and Article 9 of these Regulations, the person shall be ordered to make corrections within a time limit; if the correction is not made within the time limit, a fine of not more than RMB 10,000 shall be imposed.

If the place of origin of the product is forged or the name and address of another factory is forged or used inappropriately, the person shall be punished in accordance with Article 53 of the Product Quality Law of the People's Republic of China.

Article 26 If Article 10 and Article 15 of these Regulations are violated, the person shall be punished in accordance with Article 54 of the Product Quality Law of the People's Republic of China.

Article 27 If the net content is not marked as required by Article 11 of these Regulations, the punishment shall be in accordance with the provisions of the "Measurement and Supervision and Management Measures for Quantitative Packaging Commodities".

Article 28 If the cosmetics label does not indicate the full ingredient list in violation of Article 12 of these Regulations, and the marking method and requirements do not comply with the relevant standards, the person shall be ordered to make corrections within a time limit; if the correction is not made within the time limit, a fine of less than 10,000 yuan shall be imposed.

Article 29 If the product standard number or the quality inspection certificate is not marked in violation of Article 13 of these Regulations, the person shall be ordered to make corrections within a time limit; if the correction is not made within the time limit, a fine of less than 10,000 yuan shall be imposed.

Article 30 If the production license mark and number are not marked in accordance with the law in violation of Article 14 of these Regulations, the person shall be punished in accordance with the provisions of Article 47 of the "Regulations on the Administration of Industrial Product Production Licenses of the People's Republic of China".

Article 31 If Article 16 of these Regulations is violated, the person shall be ordered to make corrections within a time limit; if the correction is not made within the time limit, a fine of less than 10,000 yuan shall be imposed; if the relevant laws and regulations are violated, the relevant laws and regulations shall be handled in accordance with the relevant laws and regulations.

92 Article 32 Anyone who violates Article 17 or Article 18 of these Regulations shall be ordered to make corrections within a time limit; if the correction is not made within the time limit, a fine of not more than RMB 10,000 shall be imposed.

Article 33 Anyone who violates Article 21 or Article 22 of these Regulations shall be ordered to make corrections within a time limit; if the correction is not made within the time limit, a fine of not more than RMB 10,000 shall be imposed.

Article 34 Anyone who violates Article 23 of these Regulations shall be ordered to make corrections within a time limit and be fined not more than RMB 5,000; if the correction is not made within the time limit, a fine of not more than RMB 10,000 shall be imposed.

Article 35 The administrative penalties prescribed in this chapter shall be implemented by the local quality and technical supervision departments at or above the county level within the scope of their authority in accordance with the law.

If laws and administrative regulations have other provisions on administrative penalties, such provisions shall prevail.

Chapter V Supplementary Provisions

Article 36 The management of import and export cosmetics labels shall be implemented by the entry-exit inspection and quarantine agencies in accordance with the relevant provisions of the General Administration of Quality Supervision, Inspection and Quarantine.

Article 37 The General Administration of Quality Supervision, Inspection and Quarantine shall be responsible for interpreting these Regulations.

Article 38 These Regulations shall come into force on September 1, 2008.

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Appendix 2:

Instructions for use of consumer products ?
General labeling for cosmetics ICS 71.100.70

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National Standard of the People's Republic of China

GB 5296.3 ?2008

Replaces GB 5296.3 -1995

Published on June 17, 2008 Implementation on October 1, 2009

General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China

Standardization Administration of China

Published

# 94 Foreword

Except for Chapter 7, which is a recommended provision, the rest of this part of GB 5296 is a mandatory provision.

This part replaces GB 5296.3-1995 "Instructions for use of consumer products - General labeling of cosmetics".

From the date of implementation of this part, cosmetics produced and imported and sold in the territory of the People's Republic of China shall comply with the requirements of this part.

Compared with GB 5296.3-1995, the main changes of this part are as follows:

- --Added the reference to the "Measurement Supervision and Management Measures for Quantitative Packaged Goods" Order No. 75 of the General Administration of Quality Supervision, Inspection and Quarantine;
- --Added the reference to the "Implementation Measures for the Administration of Industrial Product Production Licenses of the People's Republic of China" Order No. 80 of the General Administration of Quality Supervision, Inspection and Quarantine;
- --Deleted the statement that the product can have a soothing effect on the application area in the definition of cosmetics in Article 3.1;
- --Supplemented the terms and definitions of Articles 3.5, 3.6 and 3.7;
- --Added the form of labels in Chapter 4 b);
- --Added the requirements for labeling cosmetic ingredients;
- --Added the clauses that can be exempted from labeling in 8.2;
- --Added 9.3 that the use of minority languages ??in cosmetic labels is allowed at the same time.

This part was proposed by the China Light Industry Federation.

This part is under the jurisdiction of the National Technical Committee for Standardization of Fragrances and Fragrances and Cosmetics.

The main drafters of this part are: Wang Hanzhou, Chen Hongrui, Jiao Chenxing, Zhang Yu, Yan Jun, Jiang Yifan.

The previous versions of the standards replaced by this part are:

GB 5296.3-1987;

GB 5296.3-1995.

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Instructions for use of consumer products

General labeling of cosmetics

1 Scope

This part of GB 5296 specifies the form, basic principles, labeling content and labeling requirements of general labeling of cosmetic sales packaging. This part applies to cosmetics sold in the territory of the People's Republic of China.

# 2 Normative references

The provisions in the following documents become the provisions of this part through reference to this part of GB 5296. For all referenced documents with dates, all subsequent amendments (excluding errata) or revisions are not applicable to this part. However, parties to agreements based on this part are encouraged to study whether the latest versions of these documents can be used. For all referenced documents without dates, the latest versions are applicable to this part.

General Administration of Quality Supervision, Inspection and Quarantine Order No. 75 "Measures for the Metrology Supervision and Management of Quantitative Packaged Goods"

General Administration of Quality Supervision, Inspection and Quarantine Order No. 80 "Measures for the Implementation of the Regulations on the Administration of Industrial Product Production Licenses of the People's Republic of China"

National Technical Committee for Standardization of Fragrances and Cosmetics and the Technical Committee for Standardization of Cosmetics of the Ministry of Health jointly compiled "Chinese Translation of International Nomenclature of Cosmetic Ingredients (INCI)"

3 Terms and Definitions

The following terms and definitions apply to this part of GB 5296.

# 3.1 Cosmetics

Products that are applied to any part of the human body (skin, hair, nails, lips, etc.) by smearing, sprinkling, spraying or other similar methods to achieve the purpose of cleaning, fragrance, changing appearance, correcting human odor, maintenance, and maintaining good condition.

3.2 Labeling

Words, numbers, symbols, patterns pasted or connected or printed on the sales packaging of cosmetics and instructions placed in the sales packaging.

3.3 Sales packaging

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96 Packages delivered to consumers together with their contents for the purpose of sale.

3.4 Contents

The product contained in the packaging container.

3.5 Display panels

Any surface of the cosmetics that can be seen by consumers when displayed, except the bottom surface.

3.6 Visible panels

Any surface of the cosmetics that can be seen by consumers without destroying the sales packaging.

3.7 Net content

The actual mass, volume or length of the contents after removing the packaging container and other packaging materials.

3.8 Shelf life

The period of time during which the quality of the cosmetics is maintained under the conditions specified in the cosmetics product standards and labels. During this period, the cosmetics should meet the quality specified in the product standards and labels.

4 Label form

Depending on the shape and/or volume of the cosmetic packaging, the following label forms can be selected:

- (1) Printed or pasted on the sales packaging of the cosmetic;
- (2) Printed on a booklet or paper tape or card connected to the outside of the sales packaging;
- (3) Printed on the instruction manual placed inside the sales packaging;
- 5 Basic principles
- 5.1 The content marked on the cosmetic label should be true. All words, numbers, symbols and patterns should be correct.
- 5.2 The content marked on the cosmetic label should comply with the requirements of current national laws and regulations.
- 6 Required content
- 6.1 Name of cosmetics
- 6.1.1 The name of the cosmetic should reflect the true properties of the cosmetic and be concise and easy to understand.
- 6.1.2 The name of the cosmetic should be marked in a prominent position on the display surface of the sales packaging. If it is impossible to mark it on the display surface of the sales packaging due to the shape and/or volume of the cosmetic sales packaging, it can be marked on its visible surface.
- 6.1.3 The serial number or color code of a series of products may be marked on the visible surface of the sales packaging.

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- 6.2 Name and address of the manufacturer
- 6.2.1 The name and address of the manufacturer who has been registered and assumed the responsibility for the quality of the cosmetics shall be marked.
- 6.2.2 The name and address of the manufacturer who commissions the production or processing of cosmetics shall be marked in accordance with the provisions of Order No. 80 of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China.
- 6.2.3 Imported cosmetics shall be marked with the name of the country or region of origin (referring to Hong Kong, Macao and Taiwan, China) and the name and address of the agent, importer or distributor who is legally registered in China. The name and address of the manufacturer may not be marked.
- 6.2.4 The name and address of the manufacturer, agent, importer or distributor shall be marked on the visible surface of the sales packaging.
- 6.3 Net content
- 6.3.1 The net content of quantitatively packaged cosmetics shall be marked in accordance with the provisions of Order No. 75 of the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China.
- 6.3.2 The net content shall be marked on the display surface of the cosmetic sales package. If it is not possible to mark it on the display surface of the sales package due to the shape and/or volume of the cosmetic sales package, it may be marked on its visible surface.
- 6.4 Cosmetic ingredient list 1)
- 6.4.1 The names of all cosmetic ingredients shall be marked truthfully on the visible surface of the cosmetic sales package.
- 6.4.2 The ingredient list shall be introduced with the introductory phrase "Ingredients:".
- 6.4.3 Order of marking ingredient names
- 6.4.3.1 The ingredient names in the ingredient list shall be listed in descending order of addition amount. If two or more ingredient names are marked in the same line in the ingredient list, the names of each ingredient shall be separated by ",".
- 6.4.3.2 If the addition amount of the ingredient is less than or equal to 1%, the ingredient names may be arranged in any order after the ingredient with an addition amount greater than 1%.
- 6.4.3.3 When labeling colorants for cosmetics with multiple color numbers, "may contain
- colorants:" should be inserted at the end of the ingredient list as an introductory phrase, and then colorants of all color ranges can be listed in any
- 6.4.4 Labeled ingredient names
- 1) Cosmetics produced two years after the release of this part of GB5296 shall comply with this clause.

Guidelines for Cosmetic Label Management in Various Countries

- 98 6.4.4.1 The ingredient names to be labeled shall be the names of the ingredients in the International Nomenclature of Cosmetic Ingredients (INCI) Chinese Translation. If the ingredient is not covered in the International Nomenclature of Cosmetic Ingredients (INCI) Chinese Translation, the name, chemical name or botanical name in the Pharmacopoeia of the People's Republic of China may be used in turn.
- 6.4.4.2 The fragrance, auxiliary ingredients and carriers in the flavors may not be labeled with their own ingredient names, but the word "flavor" may be used in the ingredient list.
- 6.4.4.3 The name of the colorant shall be the English abbreviation "CI" of the colorant index number (dye index number) plus the colorant index number, such as: "CI 12010", "CI 15630 (3)", etc. If the colorant does not have an index number, the Chinese name of the colorant may be used.
- 6.4.5 If the ingredient list cannot be marked due to the shape and/or volume of the cosmetic sales package, the font size may be appropriately reduced, or the form of Chapter 4 b) and c) of this part of GB 5296 may be used. For products with a net content of not more than 15g or 15mL, 8.1 shall apply.
- 6.5 Shelf life
- 6.5.1 The shelf life shall be marked in one of the following two ways:
- a) Production date and shelf life;
- b) Production batch number and expiration date.
- 6.5.2 Marking method
- ??Marking of production date: Use the guide words such as "production date" or "production date see packaging", and the date shall be in the order of 4-digit year, 2-digit month and 2-digit day. For example, if the label is: "Production date 20020112" or "Production date see packaging" and "20020112" on the packaging, it means that it was produced on January 12, 2002;
- ??Labeling of shelf life: "Shelf life  $\times$  years" or "Shelf life  $\times \times$  months";
- ??Labeling of production batch number: determined by the manufacturer;
- ??Labeling of expiration date: use "Please use before the marked date" or "Expiration date see packaging" and other introductory words, and the date is in the order of 4-digit year, 2-digit month and 2-digit day.
- For example, if the label is: "20051105", it means that it should be used before November 5, 2005. The date can also be in the order of 4-digit year and 2-digit month. For example, if the label is: "200505", it means that it should be used before May 1, 2005.
- 6.5.3 In addition to the production batch number, the expiration date or production date and shelf life should be marked on the visible surface of the cosmetic sales packaging.

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- 6.6 The production license number, health license number and product standard number of the enterprise should be marked, and the product standard number may not be marked with the year number. Products that do not implement production licenses and/or health licenses do not need to be marked with production license numbers and/or health license numbers. The production license number and health license number should be marked on the visible surface of the cosmetics sales packaging.
- 6.7 Imported non-special-purpose cosmetics should be marked with the registration number of the imported cosmetics health license.
- 6.8 Special-purpose cosmetics should be marked with the approval number of special-purpose cosmetics.
- 6.9 Where relevant national laws and regulations require or are required according to the characteristics of the cosmetics, safety warning terms should be marked on the visible surface of the cosmetics sales packaging. Safety warning terms should be guided by "Attention:" or "Warning:".
- 7 Contents that should be marked
- 7.1 When necessary, the instructions for use of cosmetics or a diagram of the instructions for use should be marked.
- 7.2 When necessary, the storage conditions that meet the shelf life or expiration date should be marked.
- 8 Others
- 8.1 For products with a net content of no more than 15g or 15mL, only the name of the manufacturer in 6.1, 6.3, 6.4, 6.5 and 6.2 need to be marked. The content of 6.4 can be marked in the explanatory materials other than Chapter 4 a), b) and c) of this part of GB 5296.
- 8.2 Cosmetics that are free for consumers to use and have corresponding labels (such as gifts, not for sale, etc.) can be exempted from marking the contents in 6.3 and 6.4 and 6.6 to 6.8.
- 9 Basic requirements
- 9.1 The content of the cosmetic label should be clear and should ensure that it is eye-catching, easy to identify and read by consumers when purchasing.
- 9.2 The words used on the cosmetic label, except for legally registered trademarks, should be standardized Chinese characters.

The label content specified in this part allows the use of Chinese pinyin or minority languages ??or foreign languages ??at the same time, but the spelling should be correct.

Guidelines for the labelling of cosmetics in various countries

100 Annex 3:

(EU)

Council Directive

(issued on 27 July 1976)

(equivalent to the cosmetics regulations of the Member States)

(76/768/EEC)

(revised until 30 August 2007)

Article 5a

1. No later than 14 December 1994, the Commission shall prepare, in accordance with the procedure laid down in Article 10, a list of ingredients used in cosmetics, based primarily on information provided by the relevant industry.

For the purposes of this Article, cosmetic ingredient means any chemical substance or synthetic or natural preparation, other than flavouring or aromatic ingredients, contained in a cosmetic formulation.

The list shall be divided into two parts: one dealing with flavouring or aromatic raw materials; the other dealing with other substances.

- 2. The list shall include the following:
- the name of the ingredient, including its chemical name, CTFA name, European Pharmacopoeia name, nonproprietary name recommended by the World Health Organization, Einecs index, IUPAC index, CAS index, color index and the common name recommended in Article 7(2),
- the usual function of the ingredient in the finished product,
- the limitations and conditions of use and the warning statements required to be printed on the label in the annex.
- 3. The Commission shall publish the list and update it regularly in accordance with the procedure laid down in Article 10. The list of ingredients is only indicative and does not constitute a list of substances authorized for use in cosmetics.

Article 6

1. Member States shall take all necessary measures to ensure that only substances which are not easily removed, clean and are not marked on containers and packaging shall be marked on containers and packaging.

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Cosmetics can only be placed on the market if they are marked with the following information in a clear and legible font; the information mentioned in (g) may only be marked on the packaging.

(a) Product name or type and the address or registered office of the manufacturer or distributor in the EU.

This information may be abbreviated as long as the company can be identified by the abbreviation. For products produced in countries outside the EU, member states may require the country of origin to be indicated.

(b) Net content when packaged, expressed in weight or volume, except in the following cases: 1) The packaging capacity is less than 5g or 5mL; 2) Free samples; 3) Individual packaging. For products that are generally pre-packaged and sold in batches, their specific weight or volume is meaningless, and the net content does not need to be marked after the quantity is displayed on the packaging.

If the quantity is clearly known from the outside or the product is usually sold individually, this information does not need to be marked.

- (c) The minimum use date shall be indicated by the words "best before..." followed by:
- a date, or
- an indication of where the date is to be marked.

The date shall be clearly stated and shall be marked in the order "month, year" or "day, month, year". If necessary, the storage conditions which ensure the declared shelf life shall be supplemented.

Cosmetics with a minimum use date of more than 30 months are not obliged to indicate a shelf life. For such products, the period of use after opening the packaging shall be marked after which it will not cause any harm to the consumer. This information shall be indicated by the symbol given in Annex VIII (a) followed by the use date (month or year).

- (d) Special warnings to be observed during use, in particular those listed in the table "Conditions of use and warning statements that must be printed on the label" in Annexes III, IV, VI and VII, must appear on both the container and the packaging, as well as any special warnings required for cosmetics intended for professional use, in particular hair products. If this is not possible for practical reasons, the information must be marked on the accompanying brochure, label, tape or card, and the container or packaging must be printed with a simple phrase or the symbol in Appendix VIII to direct consumers to refer to it.
- (e) Production batch number or product identification number. If this is not possible because the cosmetic is too small, this information is allowed to be marked only on the packaging.
- (f) Product efficacy. If the appearance of the product can clearly show its efficacy, it may not be marked.
- (g) The ingredient list is marked in descending order of weight when added. The sentence header should be marked as: "Ingredients". If

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102 If this is not possible for practical reasons, it must be marked on the accompanying brochure, label, tape or card, and a simple wording or the symbol in Appendix VIII must be printed on the packaging to instruct consumers.

The following substances are not ingredients:

- Impurities in the raw materials used;
- Excipients used in production but not contained in the finished product;
- Substances used as solvents or carriers for flavors or aromatic ingredients and the amount used is strictly controlled.

Flavors and aromatic ingredients and their raw materials should be indicated by the word "fragrance" or "fragrance type". However, if it contains substances mentioned in the requirements listed in the "Other restrictions or requirements" table in Appendix III, regardless of their efficacy, they must be marked in the ingredient list.

Ingredients with a content of less than 1% can be listed in any order after ingredients with a content of more than 1%.

Colorants are named according to the pigment index number or Appendix IV, and listed in any order after other ingredients. For cosmetic products with multiple shades, all colourants used shall be listed and marked with the words "may contain" or the symbol "+/-".

The ingredients must be marked by reference to the common names listed in Article 7(2) or, where this is not possible, by reference to one of the names listed in Article 5a(2), indented.

In accordance with the procedure laid down in Article 10(2), the Commission may adapt the principles and conditions set out in Directive 95/17/EC of 19 June 1995 concerning the application by manufacturers for commercial confidentiality not to disclose the details of one or more ingredients in the ingredient list on the label of a cosmetic product.

When the details referred to in (d) or (g) cannot be indicated in the accompanying booklet due to size or shape, they may be printed on the label, tape or card accompanying the cosmetic product.

When soaps, bath bombs or other small packaged products cannot be marked with the details mentioned in (g) on ??labels, strips, tapes or cards or accompanying booklets due to their size or shape, the instructions should be marked near the container where the cosmetics are exposed when they are sold.

2. For products that are not pre-packaged but are packaged at the request of the purchaser at the time of sale or pre-packaged before sale

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For cosmetic products, Member States shall make detailed provisions for the labelling of the details referred to in paragraph 1.

3. Member States shall take all necessary measures to ensure that the words, names, trademarks, images, numbers or other symbols used in the labelling, marketing or advertising of cosmetic products do not suggest that the product has a function that it does not have.

In addition, a manufacturer or a distributor of the product in the Union may make a claim that it has not been tested on animals, provided that the manufacturer and its suppliers have not subjected the finished product, its samples or any of its ingredients to animal testing, nor have they, for the purpose of developing new cosmetic products, subjected the ingredients to animal testing by others. The guidelines to be adopted shall be in accordance with the procedure laid down in Article 10(2) and in the Official Journal of the European Union. The European Parliament shall receive copies of the draft measures prepared by the Commission.

104 Appendix 4:

[US Code of Federal Regulations]

[Volume 7, Title 21]

[Revised April 1, 2005]

[Citation: US Code of Federal Regulations Title 21 Part 701]

Part 701 Cosmetic Labeling

Subpart A? General

§ 701.1 Mislabeling

- (a) A cosmetic is mislabeled when a statement on the label of a cosmetic is a false or misleading statement about another cosmetic, food, drug, or device
- (b) A cosmetic containing two or more ingredients that is labeled with a name that includes or implies one or more, but not all, of the ingredients will be considered misleading for this reason (and for other reasons) even if all the ingredients are named elsewhere on the label.
- § 701.2 Labeling Requirement Format
- (a) Words, statements, or other information required or permitted by regulation to appear on a label may be considered not to comply with the conspicuousness and distinctiveness requirements of section 602(c) of the act if, among other reasons:
- (1) Such words, statements, or information are not displayed on a portion of the label or on a surface of the label that is displayed or presented in the ordinary course of purchase.
- (2) Such words, statements, or information are not displayed on two or more portions of the label or on a surface of the label, each of which contains sufficient space for such words, statements, or information and is designed to be displayed in the ordinary course of purchase.
- (3) The label does not cover the available space on the container or package, resulting in insufficient label space for the conspicuousness and distinctiveness of such words, statements, or information.
- (4) Insufficient space on the label (insufficient space to prominently display such words, statements, or information) due to the inclusion of any words, statements, designs, or devices not required or permitted under the Act.

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- (5) Insufficient space on the label due to the presence of other words, statements, information, designs, or graphics on the label (insufficient space to prominently display such words, statements, or information).
- (6) Such words, statements, or information do not contrast well with the background due to being too small or in a font size that obscures the design or text, or is crowded with other written or printed information or graphics.

(b)

- (1) All words, statements, and other information required or permitted by the Act to be displayed on the label must be in English, provided that if the product is sold only in the Commonwealth of Puerto Rico or in a territory where the dominant language is not English, the dominant language of the territory may be used in lieu of English.
- (2) If the label contains any foreign language statements, all words, statements, and other information required or permitted by the Act to be displayed on the label shall be in such foreign language.
- (3) If the label contains any statement in a foreign language, all words, statements, and other information required or permitted by the Act to appear on the label or label must appear in the foreign language.
- § 701.3 Naming of ingredients
- (a) The label on each package of a cosmetic product shall list the name of each ingredient in descending order of amount, except that flavors and fragrances shall be listed as flavors and fragrances. Ingredients that are both flavors and fragrances shall be named according to their respective functions unless such ingredients are identified by name. No ingredient shall be named as a flavor or fragrance unless such ingredient is commonly understood by consumers to mean a flavor or fragrance. If one or more ingredients are exempted from disclosure by the Food and Drug Administration in accordance with the procedures prescribed in § 720.8(a) of this chapter, the words ?and other ingredients? may be used at the end of the ingredient statement in lieu of the specific names of such ingredients.
- (b) The ingredient statement shall be presented in a manner that is conspicuous and legible to the average consumer under normal circumstances of purchase. The ingredient statement shall appear on any appropriate information display surface in a font not less than 1/16 inch in height without obscuring graphics or text. If there is insufficient space on the package to include the ingredient statement, or if the manufacturer or distributor desires to use a decorative container, the ingredient statement may be included on a label, tape, or card securely attached to the package. If there is insufficient space on the package to include the ingredient statement, and it is not possible to securely attach a label, tape, or card to the package, the Administrator may prescribe an acceptable alternative, such as a reduced font size, in accordance with applicable regulations. A request for the Administrator to prescribe such an alternative shall be submitted in accordance with part 10 of this chapter.

- 106 (c) The following names shall be used in the declaration of cosmetic ingredients:
- (1) The Commissioner shall identify the cosmetic ingredients pursuant to paragraph (e) of this section by the names that shall be used on the label of the ingredients specified in §701.30.
- (2) For ingredients not specified by name in §701.30, the names of the ingredients as used in subsequent editions and supplements of the following references shall be identified as sources:
- (i) CTFA (Cosmetic, Toiletries and Fragrance Association), Dictionary of Cosmetic Ingredients, 2nd edition, 1977 (obtainable from the CTFA, 1110 NW Vermont Avenue, Room 800, Washington, DC 20005, or at the National Archives and Records Administration (NARA), which is incorporated herein by reference except as noted below. (To determine whether NARA has this material, call 202-741-6030 or go to:

http://www.archives.gov/federal\_register/code\_of\_federal\_regulations/ibr\_locations.html.)

(a) The following names shall not be used on a cosmetic ingredient label:

Acid Black 58

Acid Black 107

Acid Black 139

Acid Blue 168

Acid Blue 170

Acid Blue 188

Acid Blue 209

Naphthylamine Brown 19

Naphthylamine Brown 30

Naphthylamine Brown 44

Naphthylamine Brown 45

107 Naphthylamine brown 46 Naphthylamine brown 48 Naphthylamine brown 224 Acid orange 80 Acid orange 85 Acid orange 88 Acid orange 88 Acid orange 89 Acid orange 116 Acid red 131 Acid red 213 Acid red 213 Acid red 252 Acid violet 73 Acid violet 73 Acid violet 76 Acid violet 76 Acid violet 89 Acid violet 89 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43 Oil-soluble pellow 63	Guidelines for the management of cosmetic labels in various countries	
Naphthylamine brown 48 Naphthylamine brown 224 Acid orange 80 Acid orange 85 Acid orange 86 Acid orange 88 Acid orange 89 Acid orange 89 Acid orange 116 Acid red 131 Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 73 Acid violet 76 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	107	
Naphthylamine brown 224 Acid orange 80 Acid orange 85 Acid orange 86 Acid orange 88 Acid orange 89 Acid orange 116 Acid red 131 Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 76 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Naphthylamine brown 46	ĺ
Acid orange 80 Acid orange 85 Acid orange 86 Acid orange 88 Acid orange 89 Acid orange 116 Acid red 131 Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 76 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Naphthylamine brown 48	ĺ
Acid orange 85 Acid orange 88 Acid orange 89 Acid orange 116 Acid red 131 Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Naphthylamine brown 224	ĺ
Acid orange 86 Acid orange 89 Acid orange 116 Acid red 131 Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 76 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid orange 80	ĺ
Acid orange 88 Acid orange 116 Acid red 131 Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble brown 43	Acid orange 85	ĺ
Acid orange 89 Acid orange 116 Acid red 131 Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 99 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble brown 43	Acid orange 86	ĺ
Acid orange 116 Acid red 131 Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid orange 88	ĺ
Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 99 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid orange 89	ĺ
Acid red 213 Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid orange 116	ĺ
Acid red 252 Acid red 259 Acid violet 73 Acid violet 76 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid red 131	ĺ
Acid red 259 Acid violet 73 Acid violet 76 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid red 213	ĺ
Acid violet 73 Acid violet 76 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid red 252	ĺ
Acid violet 76 Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid red 259	ĺ
Acid violet 99 Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid violet 73	ĺ
Acid yellow 114 Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid violet 76	ĺ
Acid yellow 127 Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid violet 99	ĺ
Direct yellow 81 Oil-soluble black 5 Oil-soluble brown 43	Acid yellow 114	ĺ
Oil-soluble black 5 Oil-soluble brown 43	Acid yellow 127	ĺ
Oil-soluble brown 43	Direct yellow 81	ĺ
	Oil-soluble black 5	ĺ
Oil-soluble yellow 63	Oil-soluble brown 43	ĺ
	Oil-soluble yellow 63	

108 Oil-soluble yellow 90

(b) The following names may be used in cosmetic ingredient labels, provided that the respective monographs have been amended to describe their chemical ingredients as disclosed by other means, or to more accurately describe their chemical ingredients, and such amended monographs were published before July 18, 1980, as a supplement to the second edition of the Cosmetic Ingredient Dictionary.

Acid Black 2

Benzophenone-11

Carbomer 934

Carbomer 934P

Carbomer 940

Carbomer 941

Carbomer 960

Carbomer 961

CFC-11S

Dimethicone Copolyol

Disperse Red 17

Pigment Green 7

Polysaminoglycans condensate

Alcohol, denatured (all 27 alphanumeric names)

Sodium chondroitin sulfate

Synthetic beeswax

(c) The following names were used in cosmetic ingredient labels before January 19, 1981.

Amphoteric (all 20 numeric names)

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Quaternary Ammonium Salts (Full 49-digit Name)

(ii) United States Pharmacopeia, 19th Edition, 1975, and Appendix XIX of the United States Pharmacopeia and Second Supplement to Appendix XIV of the National Formulary, 1976 (Copies may be obtained from the United States Pharmacopeial Convention, 12601 Twain Brook Parkway, Rockville, Maryland 20852, or from the National Archives and Records Administration (NARA). For information on obtaining materials from NARA, call 202-741-6030 or visit:

http://www.archives.gov/federal\_register/code\_of\_federal\_regulations/ibr\_locations.html.)

(iii) National Formulary, 14th Edition, 1975, and Appendix XIX of the United States Pharmacopeia and the Second Supplement to Appendix XIV of the National Formulary, 1976 (Copies may be obtained from the United States Pharmacopeial Convention, 12601 Tweenbrook Parkway, Rockville, Maryland 2085 2, or may be viewed at the National Archives and Records Administration (NARA). Information on obtaining materials from NARA may be obtained by calling 202-741-6030 or visiting http://www.archives.gov/federal\_register/code\_of\_federal\_regulations/ibr\_locations.html.) (iv) Food Chemicals Codex, Second Edition, 1972, First Supplement, 1974, and Second Supplement, 1975, which are incorporated herein by reference. Copies may be obtained from the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Painted Branch Parkway, College Station, Maryland 20740, or from the National Archives and Records Administration (NARA). For information on obtaining materials from NARA, call 202-741-6030 or go to http://www.archives.gov/federal\_register/code\_of\_federal\_regulations/ibr\_locations.html.) (v) U.S. Drug Names and Pharmacopeial Dictionary, 1975 U.S. Drug Names, Cumulative List, 1961-1975. (Copies may be obtained from the United States Pharmacopeial Convention, 12601 Twainbrook Parkway, Rockville, MD 20852, or may be viewed at the National Archives and Records Administration (NARA). For information on obtaining materials from NARA, call 202-741-6030 or go to:

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- 110 http://www.archives.gov/federal\_register/code\_of\_federal\_regulations/ibr\_locations.html.?
- (3) If no such list exists, the name recognized by consumers shall be used.
- (4) If none of the above names exist, the chemical name or other technical name or description of the ingredient shall be used.
- (d) If a cosmetic is also an over-the-counter drug, the name of the drug active ingredient shall be listed as specified in §201.66(c)(2) and (d) of this chapter, and the name of the cosmetic ingredient shall be listed as specified in §201.66(c)(8) and (d) of this chapter.
- (e) An interested person may file a petition requesting that the Commissioner designate a specific name for a cosmetic ingredient in accordance with part 10 of this chapter. The Commissioner may also propose the designation of such a specific name on his or her own initiative.
- (f) Instead of arranging all ingredients in descending order of presence, the ingredients may be grouped and listed in the following order:
- (1) All ingredients except colorants present in an amount greater than 1 percent may be grouped in descending order of presence, then
- (2) All ingredients except color additives present in an amount not exceeding 1 percent may be grouped in any order, regardless of presence, then
- (3) All color additives may be grouped in any order, regardless of presence. The ingredients described in paragraph (f)(2) of this section may also be included in the ingredients described in paragraph (f)(1) of this section, grouped in descending order of presence.
- (g) An ingredient statement may include an ingredient that is not present in the product, provided that the ingredient is preceded by the word ?may contain? and
- (1) the ingredient is a color additive that is added to multiple batches of the product for color matching; or
- (2)
- (i) the same ingredient statement is also used in other products that contain similar ingredients and have the same intended use, including multiple products that contain similar ingredients and have the same intended use; and
- (ii) the product is a ?contouring? product, which is a category listed in §720.4(c)(3), (7), and (8)(v) of this chapter; and

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- (iii) all products with the same ingredient statement are sold under the same trade name or brand name, and no non-shared trade name or brand name appears on any label of those products; and
- (iv) the ingredient is a color additive.
- (h) Instead of labeling the color additive ingredients of each product individually, a single ingredient list may be compiled for the color additives of various cosmetics sold together in the same package. The ingredient list must not contain misleading information and must indicate that the list applies to all products.
- (i) If the total surface area of ?? the package is less than 12 square inches, the ingredient statement may be marked on a label attached to the product (such as a liner or package insert) in font height not less than 1/16 inch if the total surface area of ?? the package is less than 12 square inches. This paragraph does not apply to any cosmetic that has both an inner package and an outer container (such as a folding carton). In addition, this paragraph applies only to cosmetics that meet any of the following requirements:
- (1) The cosmetic is placed or displayed for sale on closely spaced pallets or shelves. The label carrier containing the ingredient statement shall be attached to the display unit; or
- (2) The cosmetic is a "contouring" product, which is a category listed in §720.4(c)(3), (7), and (8)(v) of this chapter, and is placed or displayed on closely spaced pallets or shelves. The label carrier containing the ingredient statement shall be attached to a display that contains a color sample of the product to be displayed to the purchaser. Such a display shall be constructed and designed to ensure that it can be used for continuous display, such as on a counter, and is designed primarily to display a color sample of the product.
- (j) A package containing an ingredient statement label used as specified in paragraph (i) of this section shall be attached to a display unit or display and shall meet one of the following conditions:
- (1) The label is located on the front of the display unit or display and is visible to the purchaser from the front of the display unit or display under normal retail conditions.
- (2) The label is located on the front of the display unit or display and is partially visible. The front of the display unit or display contains a conspicuous reminder indicating the location of the label in a font not less than 3/16 inch high, such as "Ingredients List See Above", which is visible to the purchaser when the display unit or display is facing the front under normal retail conditions. The reminder may also be used as specified in paragraph (k)(3) of this section, but the reminder must always be conspicuous; or

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- 112 (3) The label is located on the side of the display unit or display, but not on the top, back, or bottom, and a conspicuous reminder indicating the location of the label is affixed to the front of the display unit or display in font not less than 3/16 inch high, such as "ingredients list located on right side", which should be visible to the purchaser when facing the display unit or display in normal retail conditions.
- (k) The use of a display unit or display with a label complying with paragraph (i) of this section shall comply with the following requirements:
- (1) For labels containing ingredient statements and used in conjunction with any display unit or display, all terms of the label shall be identical and shall indicate the ingredient statement of all products sold with the display unit or display, the ingredient statement prepared in accordance with paragraph (i) of this section:
- (2) Any display unit or display intended for such use shall be shipped with the label intended to be attached thereto.
- (3) Each display unit or display and/or labeling system shall be designed to ensure that the words "FEDERAL LAW REQUIRES A POSTING OF INGREDIENTS LIST HERE" in a font not less than 3/16 inch in height are either (i) conspicuously visible when no ingredient statement is present and the last ingredient statement has been removed, or (ii) conspicuously displayed at all times adjacent to the location where the ingredient statement is to be affixed.
- (4) Any label containing an ingredient statement reflecting a formulation change and not shipped with the display unit or display shall be dated. When a label containing an ingredient statement is required to be used on products made with both the new and old formulations because of a formulation change, the label shall identify the ingredients in the new and old formulations separately in a manner that is not misleading and enables the purchaser to determine which ingredient statement is on each package, or shall clearly inform the consumer that the formulation has changed and that both ingredient statements are applicable.
- (5) Each shipment of a cosmetic product shall be accompanied by a sufficient number of ingredient statements to allow the purchaser to obtain a copy with each purchase. Display units and replacement labels for display units shall be provided to retailers for their information. Compliance with this requirement shall constitute compliance with this section. The ingredient statement shipped with the replacement shall be accompanied by the corresponding designated replacement terms or packaged with the corresponding designated replacement terms in a container that does not contain other cosmetics.
- (6) In accordance with §701.12, the company whose name is marked on the product shall promptly mail an ingredient statement to the person who requests it.
- (7) Under normal retail conditions, the display unit or display should be designed and placed so that the front side of the display faces the

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The labels are easily visible to their buyers.

- (1) In accordance with the provisions of this section, non-essential ingredients that are present in very small amounts in cosmetics and do not have any technical or functional effects on the cosmetics need not be listed. The ?non-essential ingredients? mentioned in this paragraph are:
- (1) Substances that are added to the cosmetics as a result of the addition of a cosmetic ingredient but do not have any technical or functional effects on the cosmetics.
- (2) Processing excipients, as follows:
- (i) Substances that are added to the cosmetics during the processing of the cosmetics but are removed from the cosmetics in accordance with good manufacturing practices before the finished product is packaged;
- (ii) Substances that are added to the cosmetics during the processing of the cosmetics because of their technical or functional effects on the processing technology, which are converted into substances identical to the listed ingredients during the processing and do not significantly increase the concentration of these ingredients.
- (iii) Substances that are added to the cosmetics during the processing of the cosmetics because of their technical or functional effects on the processing technology, which are present in very low amounts in the finished product and do not have any technical or functional effects on the cosmetics.
- (m) If an immediate or anticipated shortage of a cosmetic ingredient affects the availability of certain ingredients in the ingredient statement required by this section, substitute ingredients shall be identified. Substitute ingredients shall be stated: (1) immediately following the normally used ingredient for which they are substituted, followed by the word ?or? after the normally used ingredient and any other substitute ingredients, or (2) after a list of all normally used ingredients, in which case the substitute ingredients shall be listed in descending order of their presence or in accordance with paragraph (f) of this section and shall be identified by the words ?may also contain.? This paragraph shall not apply to any ingredient mentioned in an advertisement or to any ingredient not included in an ingredient statement required by this section. (n) If a cosmetic formulation change is necessary because of a shortage of a cosmetic ingredient, packaging with the old formulation labelled may be used provided that the revised ingredient statement appears on (1) a tag, tape, card, sticker or similar accessory firmly attached to the package and the words ?NEW INGREDIENTS LIST? are prominently displayed on such accessory in font not less than 1/16 inch in height, or (2) a label inside an unsealed package and the words ?NEW INGREDIENTS LIST INSIDE? are prominently displayed on such sticker or similar label in font not less than 1/16 inch in height.

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- 114 (o) Products containing similar ingredients and intended for the same use may be labeled with ingredient statements as follows:
- (1) For different types of products sold together in the same package (e.g., different shades of eye shadow), the ingredients common to all products may be listed in a single list in descending order of their cumulative presence, or as provided in paragraph (f) of this section, accompanied by a statement describing the other ingredients in clear and non-misleading terms and indicating which products contain them. In addition, all color additive ingredients contained in the product (whether or not they are common to all products) may be listed in a single list (without indicating which products contain the color additive ingredients) attached to the above ingredient list.
- (2) For products that are sold together in the same package and that are different in appearance (e.g., different shades of eye shadow), the ingredients may be listed in a single list in descending order of cumulative amount if the surface of the package is large enough to accommodate a label that is less than 12 square inches, or as specified in paragraph (f) of this section. For purposes of this paragraph, a package surface that is not labelable shall be considered label-proof if the physical characteristics of the package surface (e.g., decorative relief) make it impractical to label the package surface.
- (3) For products that are packaged individually but share a label with other products as specified in paragraph (g)(2) of this section (e.g., a lipstick in a line of lipsticks), the ingredients common to all products may be listed in a single list in descending order of cumulative amount, or as specified in paragraph (f) of this section. A statement describing the other ingredients in clear and non-misleading terms and identifying the products that contain them shall be included. Color additive ingredients shall be labeled as provided in paragraph (g) of this section.
- (4) For a product that shares a label with other products as provided in paragraph (g)(2) of this section (e.g., one of a line of powder compacts), the ingredients common to all products may be listed in descending order of cumulative concentration or as provided in paragraph (f) of this section. A statement identifying the other ingredients in clear and non-misleading terms and indicating which products contain them shall be included. Color additive ingredients shall be labeled as provided in paragraph (g) of this section.
- (p) If the surface of the package available for labeling is less than 12 square inches, the ingredient statement need not be less than 1/16 inch in height and shall be no less than 1/32 inch in height. For purposes of this paragraph, a package shall be deemed to be a package that has physical features (e.g., decorative relief) that make it impractical to label the package.

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Surfaces that are not amenable to labeling.

- (q) Containers within a multi-component or multi-component retail cosmetic package may be made without an ingredient statement if the label on the package complies with all of the requirements of this section and the containers are not routinely and expectedly separated from the retail package for retail sale.
- (r) If a cosmetic is sold to consumers by direct mail, the ingredient statement may be made, instead of on the information display, on a label accompanying the mailed cosmetic in font not less than 1/16 inch in height or on a label that is given to the consumer for personal use and that serves as a source of information about the cosmetic being ordered (such as a direct mail sales catalog or brochure), provided that the following additional requirements are met:
- (1) The ingredient statement must be conspicuous and presented in a manner that enables the consumer to determine the ingredients contained in each cosmetic.
- (2) Products mailed to consumers must be accompanied by a notice that is visible to the consumer upon opening the package. The notice may appear on the outside of the package, on the top of the package, on the product inside the package, or on the surface of the packaging material that is used to secure the product. The notice shall include the following information in fonts not less than 3/16 inches high:
- (i) The location of the ingredient statement: such as in an accompanying brochure or in the sales catalog used to order the product;
- (ii) A statement that a copy of the ingredient statement will be mailed to any person who requests it; and
- (iii) The name and business address of the mail order distributor.
- (3) The mail order distributor shall promptly mail the ingredient statement to any person who requests it.

[39 F.R. 10056, March 15, 1974, as amended in 40 F.R. 8922, March 3, 1975; 40 F.R. 18426, April 28, 1975; 42 F.R. 4718, January 25, 1977; 42 F.R. 15676, March 22, 1977; 42 F.R. 24255, May 31, 1977; 42 F.R. 46516, September 16, 1977; 42 F.R. 61257, December 2, 1977; 45 Federal Register, p. 3577, January 18, 1980; 47 Federal Register, p. 9397, March 5, 1982

116 Federal Register, 54, p. 24900, June 12, 1989; Federal Register, 64, p. 13297, March 17, 1999; Federal Register, 69, p. 18803, April 9, 2004]

## § 701.9 Exemptions from labeling requirements

- (a) Except as provided in paragraphs (b) and (c) of this section, a cosmetic that is to be processed, labeled, or repackaged in bulk at a location other than the location where it was originally processed or packed, as is the case in commerce, is exempt from the labeling requirements of sections 601(a) and 602(b) of the Act when it is shipped or otherwise delivered while such cosmetic is being distributed across state lines and while such cosmetic is stored at such location, provided that:
- (1) or (2) if the person who sells such cosmetics interstate is not the operator of an establishment at which such cosmetics are processed, labeled, or repackaged, such shipments are shipped to such place in accordance with a written agreement signed by such person and operator and containing their postal addresses and including instructions for processing, labeling, or repackaging, as the case may be, to ensure that, if such instructions are followed, the cosmetics will not become adulterated or misbranded as defined in the Act after such processing, labeling, or repackaging. Such person and operator shall each retain a copy of such agreement for a period of 2 years after the date on which such cosmetics were finally shipped or delivered from such place of processing, labeling, or repackaging and shall, upon request by the appropriate authority and within a reasonable time, furnish a copy of such agreement to the appropriate officer or employee for review. (b) If such cosmetics contain an adulterated or misbranded product as defined in the Act at the time they are removed from such processing, labeling, or repackaging location, the exemption from labeling requirements in paragraph (a)(1) of this section will be ineffective as of the time such cosmetics are removed from such processing, labeling, or repackaging location in whole or in part.
- (c) If a person who sells such cosmetics across state lines refuses to provide a copy of the agreement for review as required by the provision, the exemption from labeling requirements in paragraph (a)(2) of this section will be ineffective as of the time such person refuses to provide a copy of the agreement for review.
- (d) The exemption from labeling requirements in paragraph (a)(2) of this section will be ineffective as of the date on which the exemption occurs:

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- (1) If such cosmetic is adulterated or misbranded as defined in the Act at the time it is removed from such processing, labeling, or repacking location, the exemption from labeling requirements of paragraph (a)(2) of this section will be ineffective as of the time such cosmetic is removed from such processing, labeling, or repacking location in whole or in part.
- (2) If the operator of such processing, labeling, or repacking location refuses to provide a copy of the agreement for review as required by the provision, the exemption from labeling requirements of paragraph (a)(2) of this section will be ineffective as of the time such refusal occurs.

Subpart B?Packaging

§701.10 Principal Display Panel

As used in this part with respect to the packaging of a cosmetic, the term ?principal display panel? means the portion of the package on which the label is most likely to be displayed, presented, visible, or inspected under ordinary retail sales conditions. The principal display panel shall have sufficient space to clearly and prominently display all the mandatory label information required by this part, without any blurred design or text or crowded fonts. If there are alternating principal display panels on the package, the information required to be displayed on the principal display panel shall be repeated on each principal display panel. In order to ensure that the quantity of goods in all packages of approximately the same volume is indicated in a uniform font size, "principal display panel area" means the area of ??one side or surface that contains the principal display panel, specifically:

- (a) If it is a rectangular container and the entire side can be regarded as the principal display panel, the principal display panel area = the height of the side × the width of the side.
- (b) If it is a cylindrical or nearly cylindrical container, the principal display panel area = (container height × 40%) × circumference.
- (c) For containers of other shapes, the principal display surface area = the total surface area of ??the container × 40%, but if the container contains a distinct "principal display surface", such as the top of a triangular or round container, then the principal display surface area is the total surface area of ??the top.

When determining the area of ??the principal display surface, the top, bottom, top and bottom flanges of the can, and the shoulder and neck of the bottle or jar should be excluded. If it is a cylindrical or nearly cylindrical container,

the information required by this part to be marked on the principal display surface should be marked on the 40% of the circumference that is most likely to be displayed, presented, displayed or inspected under normal retail conditions.

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118 §701.11 Information on product characteristics on the label

- (a) The principal display panel of a packaged cosmetic product shall display a statement of the characteristics of the product as a principal feature of that principal display panel.
- (b) Such statement of characteristics shall include:
- (1) the common or usual name of the cosmetic product; or
- (2) an appropriate descriptive name, or (if the nature of the cosmetic product is obvious) a fictitious name that is understandable to the public; or
- (3) an appropriate pictorial or textual description of the intended use of the cosmetic product.
- (c) The statement of characteristics shall appear on the principal display panel in boldface type, of a size that reflects the most prominent printed information on the principal display panel, and in lines that are approximately parallel to the package display support.
- §701.12 Name and business address of the manufacturer, packer, or distributor
- (a) The name and business address of the manufacturer, packer, or distributor shall be prominently displayed on the label of a packaged cosmetic product.
- (b) If the manufacturer, packer, or distributor is a corporation, only its actual corporate name shall be indicated, preceded or followed by the name of the specific division. Abbreviations such as "Corporation," "Limited Licensing Corporation," etc. may be used, and the definite article "The" may be omitted. If the manufacturer, packer, or distributor is an individual, partnership, or corporate association, the name used in the course of its business shall be used.
- (c) If the cosmetic is not manufactured by the individual named on the label, a qualifier shall be used to indicate the relationship between the individual and the cosmetic, such as "manufactured by," "distributed by," or other similar expressions.
- (d) The business address shall include the street, city, state, and zip code, except that the street address may be omitted if the business address is currently recorded in a city directory or telephone directory. The zip code shall be required only on consumer product labels prepared or modified after the effective date of this section. In the case of non-consumer packaging, the postal code should be indicated on the product label or other documentation (including invoices).
- (e) If a person manufactures, packs or distributes cosmetics at a location other than his principal place of business,

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Then, if it is not misleading, the address of the principal place of business may be indicated on the label instead of the address of the actual production, packaging or distribution location of such cosmetics.

# §701.13 Net Content Statement of Products

- (a) The net content of the product shall be indicated on the label of packaged cosmetics. The net content of the product shall be expressed in weight, volume, quantity, or both quantity and weight, or quantity and volume. Liquid cosmetics shall be expressed in liquid units; solid, semi-solid, viscous or a combination of solid and liquid cosmetics shall be expressed in weight. If there is a fixed consumer general usage and relevant trade practice, that is, the net content of cosmetics is expressed in quantity, length units or area units, these specific terms may also be used. If there is a fixed consumer general usage and relevant trade practice, that is, the net content of liquid cosmetics is expressed in weight, or the net content of solid, semi-solid or viscous cosmetics is expressed in liquid units. If the Commissioner determines that the current practice of expressing the net contents of a packaged cosmetic by weight, volume, count, or a combination of these does not facilitate value comparisons by consumers, the Commissioner shall prescribe appropriate units of measure, subject to regulatory provisions.
- (b) Weights shall be expressed in avoirdupois pounds and ounces. Liquid units shall be the U.S. gallon (equivalent to 231 cubic inches) and its derivatives, quarts, pints, and fluid ounces; volumes shall be measured at 68 degrees Fahrenheit (20 degrees Celsius).
- (c) If the number, length, or area of ??a packaged cosmetic is not sufficient to accurately reflect the number of cosmetics contained in the package, the weight, volume, or size of the unit, or the total weight or volume of the cosmetics, shall be supplemented to accurately reflect the net contents of the cosmetic.
- (d) Values ??may contain fractions or decimals. Fractions shall be expressed as one-half, one-quarter, one-eighth, one-sixteenth, or one-thirty-second, but net contents of a particular article may be expressed in other fractions if there is established common consumer usage and relevant trade practices. Fractions shall be expressed in the most simplified form. Decimal values ??shall be rounded to two decimal places. Ounces containing decimals shall be treated as if the tolerance allowed was less than that allowed for whole ounce values.
- (e) The net quantity statement shall appear on the principal display panel of the label and, if there are alternating principal display panels on the package, shall be repeated on each principal display panel, except that:
- (1) The principal display panel of a cosmetic packaged and sold in a "boudoir" type container (including decorative "cartridge," "mini-car," "compact," or "pencil" containers and containers that do not hold more than 1/4 ounce) shall appear on the principal display panel of the label.

Guidelines for the Labeling of Cosmetics in Various Countries

- 120 The main display surface of a cosmetic product may be deemed to be a tear-off label or tape attached to a decorative container and contain the mandatory label information required by this part, but the size of the font used to indicate the net content of the cosmetic product will depend on the size of the decorative container; and
- (2) If the cosmetic product is sold on a display stand and the inner container is fixed to the display stand, the main display surface of such cosmetic product may be deemed to be the display surface of the display stand, and the size of the font used to indicate the net content of the cosmetic product will depend on the size of the display stand.
- (f) The net content statement shall be prominently displayed on the main display surface and shall be separated from any printed information above or below it (by a spacing of at least the height of the font used in the net content statement) and from any other printed information to its left or right (by a spacing of at least twice the width of the letter "N" used in the net content statement). Units of weight, volume, or quantity shall not be preceded by any qualifier (e.g., "large pint" or "full quart") that would exaggerate the net quantity of the cosmetic in the container. The declaration shall be placed on the bottom of the principal display surface in an area equal to 30% of the display surface, with the text generally parallel to the display support, except that:
- (1) If the principal display surface of the package does not exceed 5 square inches, the net quantity statement of the cosmetic need not comply with the above provisions regarding the location of the net quantity statement if the net quantity statement of the cosmetic meets the other requirements of this part;

and

- (2) If the cosmetic is sold in inner and outer retail containers that bear the mandatory labeling information specified in this part and the inner containers are not sold separately, such inner containers may be exempted from the applicable provisions of this section regarding the location of the net quantity statement.
- (g) The net quantity statement shall accurately reflect the amount of the cosmetic product contained in the package (excluding external packaging and other packaging materials), except that
- (1) if the cosmetic product is packaged in a container designed to be shipped under pressure, the net quantity of the product that will be released when the instructions for use on the container are followed shall be stated. The net quantity statement shall include the net quantity of the propellant; and
- (2) if all components of the package constitute a kit and the package is designed to ship components that are combined for a particular purpose (e.g., a home curling kit), the net quantity of the product shall be indicated by stating the number of uses for which the kit can be used when the instructions for use on the container are followed.
- (h) The net quantity statement shall be in a manner that contrasts with the packaging (by typography, layout, color, etc.).

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However, if all label information is marked on the surface of glass or plastic by blow molding, embossing or molding, the net content statement can also be marked in the same way. The requirements of "eye-catching and easy to read" include the following aspects:

- (1) The height/width ratio of (font) shall not exceed 3 (that is, the height shall not exceed 3 times the width).
- (2) The height of letters is appropriate for uppercase letters. If uppercase and lowercase letters are mixed or all lowercase letters are used, the lowercase letter "o" or a letter with the same height and width as the lowercase "o" shall meet the minimum standard.
- (3) If a fraction is used, both the numerator and denominator shall reach half of the minimum height standard.
- (i) The size of the letters and numbers in the net quantity statement shall be determined based on the principal display area of ??the package. The size of the letters and numbers on all packages of approximately the same volume shall be uniform, as follows:
- (1) The height of the letters and numbers on packages with a principal display area of ??not more than 5 square inches shall not be less than 1/16 inch.
- (2) The height of the letters and numbers on packages with a principal display area of ??more than 5 square inches but not more than 25 square inches shall not be less than 1/8 inch.
- (3) The height of the letters and numbers on packages with a principal display area of ??more than 25 square inches but not more than 100 square inches shall not be less than 3/16 inch.
- (4) The height of the letters and numbers on packages with a principal display area of ??more than 100 square inches shall not be less than 1/4 inch, but if the principal display area of ??the package is greater than 400 square inches, the height of the letters and numbers on the package shall not be less than 1/2 inch.

If the net quantity statement is blown, stamped, or molded on a glass or plastic surface rather than printed, printed, or colored, the font size specified in paragraphs (i)(1) through (4) of this section shall be increased by 1/16 inch.

- (j) If the package contains less than 4 pounds or 1 gallon and the label is marked by weight or liquid units:
- (1) In both cases, the net quantity statement shall be in ounces, by weight or liquid units, and, when necessary (1 pound or 1 pint or more), shall be followed by the weight in pounds, with the remainder expressed in ounces or in fractional or decimal pounds (see paragraphs (m)(1) and (2) of this section).

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- 122); if it is a liquid unit, it shall be expressed in the largest whole unit (quart, quart plus pint, pint, as appropriate), and the remainder shall be expressed in fluid ounces or fractional or decimal pints or quarts (see paragraphs (m)(3) and (4) of this section). Net weight or liquid units less than 1 ounce shall be expressed in fractional or decimal ounces rather than dram.
- (2) The net content statement may be indicated on multiple lines. When indicating the net weight of the product, "net weight" shall be used. When indicating liquid units or quantities, "net" or "net content" may also be used. Avoirdupois ounces and fluid ounces shall be distinguished by a combination of words, such as "net weight 6 ounces" or "6 ounces net weight", "net content 6 fluid ounces" or "6 fluid ounces".
- (k) If the contents are 4 pounds or 1 gallon or more and are expressed in weight or fluid units, the net quantity statement shall state the weight in pounds with the remainder in ounces or in decimal or fractional pounds. If the contents are in fluid units, the statement shall be in the highest whole unit (gallons followed by fractions or decimals of a gallon or the next highest whole unit (quart, quarts, or pints)) with the remainder in fluid ounces or in fractions or decimals of pints or quarts (see paragraph (m)(5) of this section).
- (1) (Reserved)
- (m) Examples:
- (1) A quantity of 1.21 pounds shall be stated as ?net 24 ounces (1 lb 8 oz)?, ?net 24 ounces (1.21 pounds)?, or ?net 24 ounces (1.5 pounds)?.
- (2) The net weight of a cargo with an avoirdupois weight of 43 pounds shall be expressed as "net weight 12 ounces".
- (3) The net quantity of a liquid cargo with a capacity of 1 quart shall be expressed as "net content 32 fluid ounces (1 quart)".
- (4) The net quantity of a liquid cargo with a capacity of 1
- 43 quart shall be expressed as "net content 56 fluid ounces (1

quart 1

- 21 pints)" or "net content 56 fluid ounces (1 quart 1 pint 8 ounces)", but quarts and ounces shall not be combined to form the following expression, such as "net content 56 fluid ounces (1 quart 24 ounces)".
- (5) The net quantity of a liquid cargo with a capacity of 2
- 21 gallons may also be expressed as "net content 2 gallons 2 quarts" instead of "2 gallons 4 pints".

	- 1
123	İ
(n) When expressing the quantity of goods, the following abbreviations must be used (periods and plural forms are allowed):	İ
Weight wt.	İ
Square sq.	İ
Liquid fl.	İ
Yard yd.	ĺ
Feet ft.	İ
Inch in.	İ
Gallon gal.	İ
Quart qt.	İ
Pint pt.	İ
Ounce oz	İ

(o) If the label on the package is expressed in units of length, the net quantity statement shall be expressed in both inches and (if the length is more than 1 foot) the greatest whole unit (yards and feet). The value expressed in the greatest whole unit shall be in parentheses immediately following the inch value, and the remainder shall be expressed as a fraction or decimal of inches or feet or yards. For example, "86 inches (2 yards 1 foot 2 inches)", "90 inches (2

21 yards), "30 inches

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(2.5 feet)", etc.

Pound lb.

(p) If the package is labeled in terms of area, the net quantity statement shall be expressed in square inches and

(if the area is 1 square foot or more) in the highest whole square units (square yards and square feet).

The value expressed in the highest whole unit shall be immediately followed by the value expressed in square inches in parentheses, and the remainder shall be expressed as a fraction or decimal of the square inch or square foot or square yard, such as "158 square inches (1 square foot 14 square inches)", etc.

(q) This section shall not be construed to prohibit the inclusion of a supplemental statement of net quantity in non-deceptive language in a location other than the principal display panel of the label, provided that such supplemental statement shall not be in the form of a statement of weight, volume, or other unit of weight.

- 124 Units or quantity units shall be preceded by any qualifier that may exaggerate the net quantity of the cosmetic in the package, such as "large pint" and "full quart". Dual statements or combined statements (e.g., net weight and quantity) indicated in accordance with paragraphs (a), (c), and (j) of this section are not supplemental net quantity statements and must be indicated on the principal display panel.
- (r) Net quantity stated in metric units alone is not supplemental net quantity statements and may be indicated on the principal display panel or other display panels when the net quantity is accurately expressed in metric weight units or volume units.
- (s) The net quantity statement shall accurately reflect the net quantity of the product in the package. Reasonable deviations due to moisture loss or gain in compliance with good distribution practices or unavoidable deviations in compliance with good manufacturing practices are acceptable deviations. However, the deviation between the actual net quantity and the declared net quantity shall be kept within a reasonable range.

Subpart C?Labeling Requirements for Certain Ingredients

§701.20 Cleansing Substances Other Than Soap Intended for Personal Hygiene

- (a) The Federal Food, Drug, and Cosmetic Act specifically excludes soap from the definition of ?cosmetic.? ?Soap? is not defined elsewhere in the Act. In implementing the Act, the Food and Drug Administration defines ?soap? as a product that:
- (1) The majority of the nonvolatile matter in the product consists of alkali metal salts of fatty acids and the cleansing properties of the product are derived from the basic fatty acid compounds; and
- (2) The product is labeled, sold, and described solely as a soap.
- (b) Products intended for personal hygiene that do not meet the definition of ?soap? in paragraph (a) of this section are cosmetics and are therefore subject to the provisions of the Act and the associated regulatory requirements. For example, one requirement for bar products is that the weight of the product be accurately stated in avoirdupois pounds or ounces in a prominent and conspicuous location on the product label so that purchasers and consumers are likely to see that information under ordinary circumstances of purchase and use.
- §701.30 Requirements for the names of ingredients on cosmetic ingredient labels The Commissioner, pursuant to paragraph (e) of section 701.3, requires the following names for ingredients listed on cosmetic labels:

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Chemical Name or Description Chemical Expression Required Label Name

Trichlorofluoromethane CCI 3F Chlorofluorocarbon 11.

Trichlorofluoromethane and 0.3% nitromethane CCI 3F+CH 3NO 2 Chlorofluorocarbon 11 S.

Dichlorodifluoromethane CCI 2F2 Chlorofluorocarbon 12.

Monochlorodifluoromethane CHCIF 2 Hydrofluorochlorocarbon 22.

- 1, 2-Dichloro-1, 1, 2, 2-tetrafluoroethane CCIF 2CCIF 2 Chlorofluorocarbon 114.
- 1-Chloro-1, 1-difluoroethane CH 3CCIF 2 Hydrofluorochlorocarbon 142 B.
- 1, 1-Difluoroethane. CH 3CHF 2 Hydrofluorocarbon 152A.

Ethyl esters of hydrolyzed animal proteins are ethanol esters and hydrolysis products of collagen or other animal proteins obtained by acid, enzymatic or other forms of hydrolysis. Ethyl esters of hydrolyzed animal proteins

[42 Federal Register, p. 24255, May 13, 1977, as amended in 45 Federal Register, p. 3577, January 18, 1980]

126 Appendix 5:

[US Code of Federal Regulations]

[Volume 7, Title 21]

[Revised April 1, 2005]

[Citation: US Code of Federal Regulations Title 21 Part 740]

Cosmetic Warning Statements

Subpart A --- General

§740.1 Warning Statements

- (a) Cosmetic labels shall contain warning statements that are necessary or appropriate to prevent the product from being harmful to the health of consumers.
- (b) The Commissioner of the Food and Drug Administration may, on his own initiative or on behalf of any interested party who submits a petition, publish a proposal to prescribe or amend regulations for cosmetic warning statements in accordance with subpart B of this part.

Such a petition shall state a sufficient factual basis and shall be in the form required by part 10 of this chapter, and if the proposed regulation is justified, it shall be published for comment.

[40 FR 8917, March 3, 1975, as amended in 42 FR 15676, March 22, 1977]

§740.2 Conspicuity of warning statements

- (a) Warning statements shall appear on the product label in a manner that is conspicuous and prominent relative to other words, statements, designs, or graphics, in boldface type, against a contrasting background, and sufficiently large to be legible and understandable by the average consumer under ordinary conditions of purchase and use, with letters and/or numbers not less than 1/16 inch in height, except as provided in paragraph (b) of this section for exemptions therefrom.
- (b) If the label on a cosmetic package does not contain sufficient space to carry the information required by this section, the Commissioner may, by regulation, prescribe an acceptable alternative, such as type less than 1/16 inch in height.

A petition for the promulgation of such a rule to supplement this section shall be submitted to the Office of the Administrator in a format consistent with the requirements of part 10 of this chapter.

[40 Federal Register, p. 8917, March 3, 1975, reproduced in 42 Federal Register, p.

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Revised at 15676, March 22, 1977; 69 FR 13717, March 24, 2004]

Subpart B?Warning Statements

§740.10 Labeling Requirements for Cosmetics for Which Safety Has Not Been Fully Demonstrated

(a) Each ingredient in a cosmetic and a finished cosmetic product must be marketed only after its safety has been fully demonstrated. Any ingredient or product marketed before its safety has been fully demonstrated will be considered misbranded unless the product label contains the following prominent statement on the principal display panel:

Warning? The safety of this product has not been determined.

(b) Any new information about a cosmetic or an ingredient or product that has been used in a cosmetic for a certain period of time may raise doubts about its safety, even if such new information is not convincing on its own.

An ingredient or product that meets the following conditions shall be exempt from the warning statement required by paragraph (a) of this section.

- (1) the safety of the ingredient or product was adequately established before the new information became known;
- (2) the new information does not indicate that the ingredient or product is hazardous to human health; and
- (3) adequate studies are being conducted to adequately establish the safety of the ingredient or product.
- (c) Nothing in paragraph (b) of this section shall be construed to grant an exemption from the adulteration provisions of the Act or any other provision of the Act or this chapter.

[40 Fed. Reg. 8917, Mar. 3, 1975]

§740.1 1 Cosmetics in self-pressurized containers

(a)

(1) Cosmetics that are packaged in self-pressurized containers and that are extruded by pressure from the container shall carry the following warning on the label:

Warning?Do not spray in eyes. Container contents are under pressure. Do not puncture or incinerate. Store at 120 degrees Fahrenheit or below. Keep out of reach of children.

(2) If the product is intended for children, the warning statement required by paragraph (a)(1) of this section may be

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- 128 Add "must be used under adult supervision" after the last sentence.
- (3) If the product is packaged in a glass container, the word "puncture" in the warning required by paragraph (a)(1) of this section may be replaced with "break".
- (4) If the product is not in the form of a spray, the word "beware of spraying into eyes" in the warning required by paragraph (a)(1) of this section may be deleted.

(b)

- (1) If a cosmetic is packaged in a self-pressurized container and the propellant in the package is composed entirely or partially of halogenated hydrocarbons or hydrocarbon compounds, in addition to the warning required by paragraph (a)(1) of this section, the following warning shall be displayed on the product label:
- Warning Please follow the instructions for use carefully. Intentional concentration and inhalation of this product may be harmful to health or even fatal.
- (2) Products that meet the following conditions may be exempted from the warning required by paragraph (b)(1) of this section.
- (i) The product is extruded in the form of foam or cream and the propellant content in the container is less than 10%.
- (ii) The product container has a safety design to prevent the propellant from spilling during use.
- (iii) The net content of the product is less than 2 ounces, and each squeeze of the valve releases a fixed amount of product.
- (iv) The net content of the product is less than 1/2 ounce.
- (c) The labeling requirements for cosmetics packaged in self-pressurized containers or using chlorofluorocarbons or other ozone-depleting substances specified by the Environmental Protection Agency as propellants are found in Title 40 of the United States Code of Federal Regulations Part 82.
- [40 Federal Register, p. 8917, March 3, 1975, as amended in 42 Federal Register, p. 22033, April 29, 1977; 54 Federal Register, p. 39640, September 27, 1989; 61 Federal Register, p. 20101, May 3, 1996]

§740.12 Spray deodorants for women

- (a) For purposes of this section, the term ?spray deodorant for women? means a spray deodorant product that is labeled or suggested to be used on the female genital area or on the entire body.
- (b) The label of a spray deodorant for women shall contain the following information:

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Warning - For external use only. This product should be used at least 8 inches from the skin. Do not use on broken, irritated, or itchy skin. If unusual odor or discharge persists, consult a physician. If rash, irritation, or discomfort occurs, discontinue use immediately.

If the product container does not contain a liquefied gas propellant (such as a halogenated hydrocarbon or hydrocarbon compound propellant), the above warning "This product should be used at least 8 inches from the skin" may be omitted.

(c) If such a product is labeled with the words "health care" or "health care" or similar words, the product will be considered a misbranded product as defined in section 602(a) of the Federal Food, Drug, and Cosmetic Act.

If such a product is labeled with a statement or implication that the product has a medical effect, the product will be considered a misbranded product as defined in section 502(a) of the Act and a new drug that is illegally marketed in violation of section 505 of the Act.

[40 Fed. Register 8929, Mar. 3, 1975]

§740.17 Foaming bath products

- (a) For purposes of this section, a ?foaming bath product? means a product that is added to bath water to produce a foam that contains a surfactant as a detersive or lathering ingredient.
- (b) A foaming bath product as defined in paragraph (a) of this section must carry on its label instructions for safe use and the following warning, unless the product is labeled as intended for adults only.

Warning? Follow the directions for use carefully. Excessive use or prolonged contact with this product may cause irritation to the skin and urinary tract. Discontinue use if rash, redness, or itching occurs. If irritation persists, consult a physician. Keep out of reach of children.

(c) If the product is intended for children, the words ?Use only under adult supervision? may be added to the end of the last sentence of the warning required by paragraph (b) of this section.

[51 Fed. Register 20475, June 5, 1986]

§740.18 Coal tar hair dyes that present a risk of cancer

(a) A coal tar hair dye product that contains any ingredient listed in paragraph (b) of this section shall contain the following information on the principal display panel of the label and on any accompanying labels and instructions as specified in §740.2:

WARNING? This product contains a skin-penetrating ingredient that has been shown to cause cancer in laboratory tests on animals.

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130 (b) Hair dyes containing any of the following ingredients shall be subject to the provisions of this section: (1) 4-methoxy-m-phenylenediamine (2,4-diaminoanisole); (2) 4-methoxy-m-phenylenediamine sulfate (2,4-diaminoanisole sulfate).

[44 Federal Register, p. 59522, October 16, 1979]

Effective Date Note: Section 740.18 was suspended as of February 23, 1982, in the Federal Register, p. 7829, pending further notice, and became effective on September 18, 1980.

§740.19 Tanning products

Tanning products that do not contain a sunscreen must carry the following warning statement on their labels: "WARNING? This product does not contain a sunscreen and does not protect the skin from sunburn. Do not repeatedly expose unprotected skin to the sun while using this product. Doing so may increase the risk of skin aging, skin cancer, and other adverse consequences, even if the skin does not burn." For purposes of this section, "tanning products" means gel-type, cream-type, liquid-type, or other type of topical product (such as moisturizing or conditioning products) that, when used, will cause the skin to become bronzed by exposure to ultraviolet light, or gel-type, cream-type, liquid-type, or other type of topical product that, when used, causes the skin to become tanned by the use of an approved colorant (such as dihydroxyacetone) without exposure to ultraviolet light.
"Tanning products" do not include products that provide sun protection or that can affect the structure or any function of the body.

[64 Federal Register, p. 27693, May 21, 1999]

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Appendix 6:

(USA)

Cosmetic Labeling Guidelines

Contents

- ·Summary of Cosmetic Labeling Management Regulations for Cosmetics Sold in the United States
- ·Cosmetic Labeling Regulations (included in 21 CFR Parts 701, 704 and other relevant parts)
- ·Cosmetic Labeling Guidelines

Summary of Cosmetic Labeling Management Regulations for Cosmetics Sold in the United States

Cosmetics sold in the United States, whether domestically produced or imported from overseas, must comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act), the Fair Packaging and Labeling Act (FP&L Act), and regulations promulgated under these laws.

Regulations promulgated by the Food and Drug Administration are compiled in 21 CFR (CFR).

The regulations applicable to cosmetics are stated in 21 CFR Parts 700 to 740 (21 CFR 700 to 740). The color additive regulations applicable to cosmetics are in 21 CFR 73, 74, 81, and 82.

The FD&C Act defines cosmetics as products that are applied to the human body for cleansing, beautification, attractiveness, or improvement of appearance without affecting the structure or function of the human body. Products that meet this definition include skin creams, lotions, perfumes, lipsticks, nail polishes, eye and facial makeup, shampoos, perms, hair dyes, toothpastes, deodorants, and any other substance used as an ingredient in cosmetics. For purposes of this regulation, soap products that are primarily made of alkaline salts of fatty acids and that only claim to cleanse the body on the label are not considered cosmetics.

Products that are cosmetics and can also be used to treat or prevent disease or affect the structure or function of the human body are also considered drugs and must comply with the regulations for drugs and cosmetics in this regulation. Examples of products that are both drugs and cosmetics are anti-caries toothpaste (e.g., fluoride toothpaste), hormone creams, sunscreen products used to prevent sunburn, antiperspirants that are also deodorants, and anti-dandruff shampoos.

132 The most commonly sold cosmetics that are also drugs are over-the-counter drugs (OTC drugs). Some are new drugs, and distributors must prove their safety and effectiveness before they are allowed to be sold. New drugs are drugs that have not yet been widely recognized by experts as safe and effective under the conditions of intended use, or drugs that have not yet been used for a specific range or time.

The regulatory requirements for drugs are more extensive than those for cosmetics. For example, the FD&C Act requires drug manufacturers to register with the FDA annually and update the drug production list twice a year. In addition, drug production must comply with current good manufacturing practice regulations (covered in 21CFR 210 and 211).

## · Adulterated and Misbranded Cosmetics

The FD&C Act prohibits the spread of adulterated and misbranded cosmetics. A cosmetic product is considered adulterated if it contains a substance that would render it hazardous to consumers under ordinary conditions of use; contains foul, corrupted, or spoiled matter; is likely to have been contaminated by impurities due to manufacture or storage under insanitary conditions, or is injurious to consumers; or is not a hair dye but contains a prohibited color additive.

Coal tar hair dyes are exempt from adulteration even if they are irritating to the skin or hazardous to humans if they are labeled with the required warning statement and a "patch test" recommendation. This exemption does not include eyelash and eyebrow tinting products. All eyelash and eyebrow tinting products must be approved by the FDA for use in this purpose.

A cosmetic product is considered misbranded if its label is false or misleading, or if it does not contain required label information, or if the container is fraudulently manufactured or filled.

# · Cosmetic Labeling

Cosmetics distributed in the United States must comply with FDA labeling regulations promulgated by the FD&C Act and the FP&L Act. Labeling means all labels and other written, printed, or illustrated material on a product or in the product's packaging. Label claims required under the FD&C Act must be made on both the inner and outer containers and packaging. FD&C Act requirements, such as ingredient labeling and net contents statement, are required only on the principal display panel of the outer package label. Labeling requirements are contained in 21 CFR 701 and 740. Cosmetics that are labeled with false or misleading labeling claims or that are not labeled as required by law may be considered misbranded cosmetics and subject to regulatory action.

The principal display panel is the portion of the label that is most likely to be displayed or examined under normal display conditions at the time of sale.

The product name must be included on the principal display panel, which may be a descriptive name or a pictorial description of the product's properties or uses.

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The net quantity of the cosmetic contents in the package must be accurately stated by weight, volume, number, or both number and weight or volume. The statement must be clearly marked on the bottom of the display panel, usually parallel to the bottom of the package, and the font size must be commensurate with the size of the container. The net quantity of solid, semisolid, and viscous cosmetics is stated in weight units - pounds and ounces; liquid volumes are stated in U.S. gallons (equivalent to 231 cubic inches), quarts, pints, and fluid ounces derived therefrom. If the net quantity is 1 pound or 1 pint or more, it must be stated in ounces followed by parentheses () stating the largest unified unit (i.e., pounds and ounces or quarts, pints, and ounces). Alternatively, the net quantity may be stated in metric units of weight or volume.

The name and business address of the selling company must be marked on the information display panel of the label (21 CFR

701.12). The address must state the street address, city, state, and zip code. The street address may be omitted if the company is included in a current city or telephone directory. If the distributor is not the manufacturer or packer, this fact must be stated on the label by the descriptive phrase "Made by" or "Distributed by" or similar appropriate wording.

The Tariff Act of 1930 requires that all imported goods be labeled with the English name of the country of origin.

· Ingredient Statements

Cosmetics manufactured or distributed for retail sale to consumers for personal care must be labeled with an ingredient statement (21 CFR 701.3). Cosmetics that are not normally sold for retail sale, such as hair or makeup products that professionals use on their premises for customers, and cleansers and moisturizers that are used by people in the workplace, are exempt from this requirement if the products are not sold to consumers for use at home in the professional or workplace setting.

The ingredient statement must be prominent so that it can be easily read at the time of purchase. If the inner container is packaged in a folding carton or box-type packaging material, the ingredient statement may be marked on any display surface of the package or on a securely attached label, tape, or card. The height of the letters shall not be less than 1/16 inch (21 CFR 701.3 (b)). If the total package surface area available for labeling is less than 12 square inches, the height of the letters shall not be less than 1/32 inch (21 CFR 701.3 (b)). If the cosmetic is presented on closely spaced trays or racks and is not contained in a folding carton, ingredient labeling is permitted outside the package when the package surface area is less than 12 square inches (21 CFR 701.3(i)).

134 Ingredients must be listed in descending order of content. Color additives (21 CFR 701.3(f)(3)) and ingredients present at 1% or less (21 CFR 701.3(f)(2)) may be listed in any order. Ingredients must be listed by the names established or adopted by regulation (21 CFR 701.3(c)); ingredients exempted from disclosure by FDA must state: "and other ingredients".

Cosmetics that are also drugs must first list the drug ingredients as "active ingredients" before listing the cosmetic ingredients.

All labeling statements required by regulation must be in English and prominently displayed on the label or sticker so that consumers can easily notice and understand them under normal purchasing conditions.

## · Label warnings

For cosmetics that may be harmful to consumers if used incorrectly, appropriate warnings and adequate safe use instructions must be placed on the label. These statements should be prominent. Some cosmetics must carry a warning on the label as required by the regulation (21 CFR 740). For example, cosmetics in self-pressurized containers (aerosol products), women's deodorant sprays, and children's bubble bath products are required to have such a statement. Although the FD&C Act does not require cosmetic manufacturers or sellers to demonstrate the safety of their products, FDA strongly recommends that cosmetic manufacturers conduct any toxicity or other tests that are appropriate to demonstrate the safety of their cosmetics. If the safety of a cosmetic product has not been fully demonstrated, the following statement must be placed on the label: WARNING--THE SAFETY OF THIS PRODUCT HAS NOT BEEN DETERMINED. Failure to do so will be considered misbranding of the cosmetic and will be subject to regulatory action. Tamper-resistant packaging Liquid oral care products (e.g., mouthwashes, fresheners) and cosmetic vaginal products (e.g., douches, tablets) must be sold in tamper-resistant packaging. A package is considered tamper-resistant if it has an access indicator or barrier (e.g., shrink or band seal, sealed carton, sealed tube, sealed bag, aerosol container) that, if torn or missing, alerts the consumer that the package has been tampered with. The design (fragile cap, blister) and appearance (trademark, vignette, or other illustration) of the indicator must be distinctive to prevent substitution. The tamper-resistant feature may include the inner container or the outer container or both. The package must be prominently marked with a statement alerting the consumer to the tamper-resistant feature. The statement must remain intact even if the tamper-resistant feature is torn or missing. (Sec. 21 CFR 700.25.)

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To enforce this regulation, FDA tests and inspects products, inspects production or storage sites, and seizes adulterated (harmful) or mislabeled (false or deceptive labeling or filling) cosmetics. Adulterated or mislabeled foreign products may be refused entry into the United States. To prevent further shipment of adulterated or mislabeled products, FDA requires federal district courts to issue a restraining order prohibiting the production and sale of cosmetics that violate the requirements.

FDA also initiates criminal prosecution against those who violate this regulation. Products seized in recent years include nail products containing methyl methacrylate or formaldehyde, various eyebrow and eyelash dyeing products containing banned coal tar dyes, and products contaminated by harmful microorganisms.

Further questions regarding regulatory requirements for marketed cosmetics may be addressed to the Food and Drug Administration, Center for Food Safety and Nutrition, Office of Colors and Cosmetics (HFS-100), 5100 Paint Branch Parkway, College Park, MD 20740, (301) 436-1130. Questions regarding marketed products that are also drugs may be addressed to the Drug Information Division, 5600 Fishers Lane, HFD-240, Rockville, MD 20857; telephone: (301) 827-4570; email: druginfo@cder.fda.gov; website: http://www.fda.gov/cder/Off fices/DDI/default.htm. · Notes

The Code of Federal Regulations may be purchased by check or cash from the Government Printing Office, Washington, DC 20402, telephone: (202) 512-1800. Current prices may be obtained by contacting the Government Printing Office directly.

For general regulations implementing the Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act, as well as color additive regulations, order 21 CFR Parts 1 through 99.

For regulations applicable to cosmetics, including labeling regulations, order 21 CFR Parts 600 through 799.

21 CFR is updated each April, and new regulations published that year are included in the Federal Register.

136 Appendix 7:

"ASEAN Cosmetics Technical Document"

Appendix II

ASEAN Cosmetic Labeling Requirements

A. Purpose

- 1. This document provides guidance on labeling requirements for cosmetic products and is applicable to Article 5 of the ASEAN Cosmetic Directive (05/01/ACCSQPWG).
- B. Scope and Definitions
- 1. In this document, the following terms are defined:

Name of cosmetic product means the name given to a certain cosmetic product, which may be a specially invented name used together with the trademark or manufacturer's name;

Inner packaging means the container or other form of packaging that is in direct contact with the cosmetic product;

Outer packaging means the packaging used to hold the inner packaging;

Label means the written information, printed information or diagram on the inner packaging, outer packaging or any form of appendix;

Registration holder means the authorized holder of the cosmetic product.

- B. Labels of cosmetics
- 1. The following details should be displayed on the outer packaging of the cosmetics, or on the inner packaging of the cosmetics if there is no outer packaging.
- a) The name and efficacy of the cosmetics, except those that can be clearly understood from the product description;
- b) Instructions for use of the cosmetics, except those that can be clearly understood from the product name or description;
- c) A complete list of ingredients. The various ingredients should be described in detail using the terms specified in the latest version of the reference standard (see Appendix A). Plant raw materials and extracts should be labeled with the family and genus to which they belong, where the family can be represented by abbreviations;

However, the following items should not be considered as ingredients:

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- Impurities in raw materials;
- Excipients used in production but not in the finished product;
- Substances used as solvents or carriers for flavors or aromatic substances and whose use is strictly controlled.
- d) Country of production;
- e) Name and address of the company or person responsible for placing the product on the local market;
- f) Content by weight or volume, in metric and imperial units or in metric units;
- g) Manufacturer's batch number;
- h) The date of production or expiration date of the product in clear terms (e.g. month/year);
- i) Special precautions that must be observed during use, especially those precautions that must be displayed on the label listed in the column "Conditions or uses and warnings that must be printed on the label according to the Appendix", as well as any special warning information on the cosmetic product.

ASEAN Member States may require specific warnings according to local needs, such as: animal-derived ingredient declarations. In this case:

- (i) the presence of ingredients of animal origin must be declared on the product label (in any form);
- (ii) for ingredients of bovine and porcine origin, the exact animal origin must be declared;
- (iii) ingredients derived from human placenta must be specifically declared on the product label.
- j) country of origin registration number.
- 2. If the size, shape or characteristics of the container or packaging do not allow the display of the detailed information referred to in paragraph 1 (a) to
- (i), it should be allowed to use additional pages, booklets, labels, display boards, shrink-wraps, etc.

However, small inner packaging should at least show the following details:

- a) the name of the cosmetic product;
- b) the manufacturer's batch number.
- 3. The details mentioned in paragraphs 1 and 2 should be legible, understandable and indelible.
- 4. The details listed in paragraph 1 should be in English and/or the national language and/or the consumer language of the place where the product is sold.

138 Language that can be understood.

Annex A

Citation Standards for Cosmetic Ingredient Terms

- 1. International Cosmetic Ingredient Dictionary
- 2. British Pharmacopoeia
- 3. United States Pharmacopoeia
- 4. Chemical Abstracts Service
- 5. Japanese Cosmetic Ingredient Standards
- 6. Japanese Cosmetic Ingredient Codex

Appendix III

**ASEAN Cosmetic Claims Guidance** 

This document provides product claim guidance for the classification of cosmetics/drugs.

Determining whether a product is a "drug" or a "cosmetic" depends on two major factors:

- the ingredients of the product, and
- the intended use of the product (++).

Ingredients - The ingredients of a product do not necessarily determine its classification. However, an ingredient or the concentration of an ingredient may make the product unsuitable for classification as a cosmetic.

Intended Use - Based on the definitions of the terms "drug" and "cosmetic" under the relevant laws, the key consideration for the classification of a drug is its intended use. Indicate to consumers the intended use of the product through claims in package inserts, advertisements and especially on product labels.

In general, cosmetics can only make cosmetic claims, not medical or therapeutic claims. Any cosmetic efficacy claims should be consistent with internationally accepted efficacy claims and their effectiveness should be demonstrated through technical data and/or the cosmetic formula or product raw materials themselves. Manufacturers/product holders are allowed to prepare technical data using their scientifically recognized procedures/designs, but they must justify the reasons for using such procedures/designs.

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Appendix 8:

List of Source Institutions for Cosmetics Regulations and Industry Information in Relevant Countries or Regions

Institution Name Website

Ministry of Commerce of the People's Republic of China www.mofcom.gov.cn

General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China www.aqsiq.gov.cn

Ministry of Health of the People's Republic of China www.moh.gov.cn

State Administration for Industry and Commerce of the People's Republic of China www.saic.gov.cn

China WTO/TBT-SPS Notification and Consultation Website www.tbt-sps.gov.cn

China Association of Flavors and Fragrances www.caffci.org

European Commission ec.europa.eu

European Cosmetics, Toiletries and Fragrances Association (COLIPA) www.colipa.com

U.S. Food and Drug Administration (FDA) www.fda.gov

Cosmetics, Toiletries and Fragrances Association (formerly CTFA) www.personalcarecouncil.org

Ministry of Health, Labor and Welfare of Japan www.mhlw.go.jp/english

Japan Fair Trade Commission www.jftc.go.jp

Japan Cosmetics Industry Association Trademark Naming Committee (JCIA) www.jcia.org

Korea Food and Drug Administration www.kfda.go.kr

Ministry of Health and Welfare of Korea www.mohw.go.kr

Association of Southeast Asian Nations www.aseansec.org

Drug Administration of Taiwan Department of Health www.doh.gov.tw

Saudi Arabian Standards Organization (SASO) www.saso.org.sa

Health Canada Consumer Safety Branch Cosmetics Division www.hc-sc.gc.ca/cosmetics

Russian State Committee for Standardization, Metrology and Certification (GOST) www.gost.ru

Australian Legal Information Institute (AustLII) www.austlii.edu.au