Writing Sample 2 - Regulatory Guide

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This writing sample was an exercise in writing for regulated environments. The prompt was to create a short guide for an imagined team of science, medical, and health writers. The guide was to relay all the necessary regulatory information related to a particular regulated document. I chose to build an introductory guide to the labeling requirements for non-pharmaceutical skin lotions. This tool is created for technical writers with previous knowledge of regulatory labeling conditions for pharmaceutical and medicated skin creams.

Regulatory Guide

Non-Pharmaceutical Skin Lotions & Creams

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Overview

As a producer of medicated creams for psoriasis and eczema, we must understand the different regulatory conditions for our new product line of non-medicated lotions (Nutrition, 2020). This guide aims to inform technical writers, with previous pharmaceutical labeling experience, of the required labeling considerations for skin lotions and creams that are not considered drugs.

Lotion: a Cosmetic or Drug?

The FDA considers all non-pharmaceutical skin creams and lotions a cosmetic product. A cosmetic is defined as "a product (excluding pure soap) intended to be applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance" (Nutrition, 2020). Cosmetic products do not need to be approved by the FDA before they go to market. However, the ingredients must be considered safe for cosmetic use, listed clearly on a label, and not misrepresented. Any claim that these lotions treat disease or otherwise affect the structure of any body function will define the product as a drug, thus subject to additional FDA regulations.

Submitting to the Professional VCRP

The Voluntary Cosmetic Registration Program is the reporting system used by manufacturers, packers, and distributors of commercial cosmetic products in the United States. Submitting to the VCRP is highly recommended when a new product is released (*Voluntary Cosmetic Registration Program | FDA*, n.d.). The Cosmetic Ingredient Review (CIR), an independent, industry-funded panel of scientific experts, uses this system to contribute to their assessments of ingredient safety.

Customer Ingredient Review (CIR) and Ingredients Lists

The CIR has a record of all cosmetic ingredients that are approved, unapproved, or in a varying state of approval. Use these lists to help you confirm spellings or the need for potential warnings (*CIR Findings | Cosmetic Ingredient Review*, n.d.).

Safe as Used	Safe with Qualifications	Zero Uses	Insufficient Data	Prohibited & Restricted	Unsafe

Labeling Requirements

Label Type - Principal Display Panel (PDP)

The "principal display panel" is the part of the label most likely to be examined under the customary conditions of retail sale. The label is usually placed on the front panel of the outer package (Nutrition, 2020).

Content Type	Description
Identity Statement	Establishes the nature and use of the product. This could include a common name, a descriptive name, a fanciful name understood by the public, or an illustration.
Statement of net quantity of contents	Weight, measure, numerical count, or a combination.

Label Type - Information Panel

Back and side panels are generally considered information panels. Information panels must be prominent and conspicuous.

Content Type	Description
Name and place of business	The street address, city, state, and ZIP code of the manufacturer, packer, or distributor.
Distributor statement	If the name and address are not those of the manufacturer, the label must say "Manufactured for..." or "Distributed by...," or similar wording expressing the facts.

Material facts	Failure to reveal material facts is one form of misleading labeling and therefore makes a product misbranded.
Warning and caution statements	The FD&C Act and related regulations specify warning and caution statements related to specific products. Cosmetics that may be hazardous to consumers must bear appropriate label warnings.
Ingredients	If the product is sold on a retail basis to consumers, even if it is labeled "For professional use only" or words to that effect, the ingredients must appear on an information panel, in descending order of predominance. Remember, if the product is also a drug, its labeling must comply with the regulations for both OTC drug and cosmetic ingredient labeling, as stated above., see "Ingredient Names," "Color Additives and Cosmetics," "Fragrances in Cosmetics," and "'Trade Secret' Ingredients.

References

CIR Findings | Cosmetic Ingredient Review. (n.d.). Retrieved April 21, 2020, from https://www.cir-safety.org/cir-findings

Nutrition, C. for F. S. and A. (2020, March 19). Cosmetics. FDA; FDA. https://www.fda.gov/cosmetics

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