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| **CONDITIONS** | Bemotrizinol, at a maximum concentration of 10 percent, as a single active ingredient and in combination with other sunscreen active ingredients | |
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| **PHARMACOLOGICAL CLASS** | UVA and UVB sunscreen | |
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| **MONOGRAPH** | | OTC Sunscreen Drug Products (21 CFR part 352) |
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| **APPLICANT** | | Ciba Specialty Chemicals Corporation  Home and Personal Care Business Line |
|  | | 4090 Premier Drive |
|  | | High Point, NC 27265 |
|  | |  |
| **SUBMISSION DATE** | | April 11, 2005 |
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| **RECEIVED DATE** | | April 12, 2005 |
|  | |  |
| **REVIEW DATE** | | April 17, 2005 |
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| **REVIEWER** | | Michael L. Koenig, Ph.D. |
|  | |  |
| **TEAM LEADER** | | Matthew R. Holman, Ph.D. |
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chemical description as required in 21 CFR 330.14(c)(1)(i). Although bemotrizinol is not included in the U.S. Pharmacopeia (USP)-National Formulary (NF), the applicant submitted a draft monograph to the USP on July 23, 2004. According to the applicant, USP is currently reviewing the draft monograph.

Bemotrizinol has been marketed for varying lengths of time in 31 countries on every continent except Antarctica and for at least 5 continuous years in 5 of these countries. The applicant has selected 7 countries to serve as the basis of the TEA, because these 7 countries represent the greatest volume of sales: Brazil, France, Germany, Greece, Italy, Spain, and Switzerland (bold print in Table 1). Bemotrizinol has been marketed for 5 continuous years in Brazil, France, Germany, Greece, and Switzerland. One of the selected countries (Switzerland) is listed in section 802(b)(1)(A)(i) of the Federal Food, Drug, and Cosmetic Act (the act) and 5 others (France, Germany, Greece, Italy, and Spain which are part of the European Union) are listed in section 802(b)(1)(A)(ii) of the act. The applicant states that, in all 31 countries, sunscreen products containing bemotrizinol are sold directly to consumers without a prescription and are “not regulated as drugs.” However, FDA notes that sunscreens are regulated as OTC medicines by the Therapeutic Goods Administration in Australia.

**TABLE 1.** **Countries in which bemotrizinol has been marketed (7selected countries appear in bold print)**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | **Continent** | **Countries** | | Africa | South Africa | | Asia | China, Hong Kong, India, Indonesia, Korea, Malaysia, Philippines, Taiwan, Thailand | | Australia | Australia | | Europe | Austria, Belgium, **France1**, **Germany1**, **Greece1**, Israel, **Italy**, Poland, Slovenia, **Spain**, Sweden, **Switzerland1**, United Kingdom | | North America | Mexico | | South America | Argentina, Bolivia, **Brazil1**, Chile, Columbia, Ecuador | |

1 Bemotrizinol has been marketed for 5 continuous years in these countries.

The applicant indicates that bemotrizinol is most commonly marketed in combination with other sunscreen active ingredients. Formulations marketed in different countries include bemotrizinol and other monograph active ingredients (e.g. avobenzone, titanium dioxide) and/or other active ingredients under consideration for inclusion in the sunscreen monograph (e.g. amiloxate, enzacamene).

Detailed information about the population demographics in each of the 7 selected countries is provided in Appendix 1 of the TEA. Considering these 7 countries together with the other countries listed in Table 1, the population demographics appears to reflect the diversity of the U.S. population.

The applicant reports that it is unaware of any adverse drug experiences (ADEs) in any of the countries in which bemotrizinol-containing sunscreens have been marketed. The applicant also states that sunscreen products containing bemotrizinol have not been withdrawn from the market in any country.

Examples of labeling are provided for product sold in Europe (23 labels), South America (7 labels), and Asia (1 label). The indications, warnings, and directions included in the labeling from these countries are comparable to those outlined in 21 CFR 352.52(b), (c), and (d) respectively.

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| **Region** | **Estimated total sales**  **(million dosage units)** |
| Europe (6 countries) | 99.8 |
| South America (1 country) | 20.3 |
| **Total** (7 countries) | **120.1** |