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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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er sunscreen ingredient, TINOSORB® M (bisoctrizole and 4 inactive ingredients), to the sunscreen monograph. In our April 2002 response letter, FDA stated that the applicant should use the newly developed TEA format (67 FR 3060, January 23, 2002) rather than a petition to add these ingredients to the monograph. As directed by the FDA, the applicant submitted a TEA for both TINOSORB® M and TINOSORB® S on May 21, 2002. On July 15, 2002, FDA informed the applicant that we could not find either ingredient eligible for the OTC drug review, because neither ingredient had been “marketed for a minimum of five continuous years,” as required in 21 CFR 330.14(b)(2). Both ingredients had only been marketed for 2.5 years at that time. The applicant submitted the current TEAs on April 11, 2005, because bemotrizinol (and bisoctrizole) have now been marketed for 5 continuous years.

**REVIEWER’S COMMENTS**

The applicant has provided basic information about bemotrizinol including a detailed 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.

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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** |