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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 |
|  | |  |
| **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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| |  |  | | --- | --- | | **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 | |

rizinol 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 The applicant also states that sunscreen products containing bemotrizinol have not been withdrawn from the market in any country.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** |