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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 | |
|  | |  |
| **MONOGRAPH** | | OTC Sunscreen Drug Products (21 CFR part 352) |
|  | |  |
| **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 |
|  | |  |
| **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 | |

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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** |

**RECOMMENDATION**

I recommend that bemotrizinol, up to a maximum concentration of 10 percent, be considered eligible for the OTC drug review. Bemotrizinol should be eligible as a single active ingredient and in combination with other active ingredients in the OTC sunscreen monograph (21 CFR Part 352). Bemotrizinol has been marketed, primarily in combination, “for a material time” and “to a material extent” in 1 South American and 4 European countries. The demographics of these countries, especially when considered in combination with other countries in which this ingredient has been marketed as a component in sunscreens, adequately reflects the diversity of the U.S. population. At least 30 million dosage units of sunscreens containing bemotrizinol have been sold in 7 selected countries on 2 continents during 2000-2004. Furthermore, over 32 million dosage units have been sold in 31 countries on every continent except Antarctica. The applicant states that no serious adverse drug experiences have been reported for sunscreen products containing bemotrizinol. The sponsor should be advised of the following:

an official or proposed USP monograph must be included with data and information demonstrating the safety and effectiveness of this ingredient, in accordance with 21 CFR 330.14(i)

safety and effectiveness data are required for bemotrizinol as a single active ingredient and bemotrizinol in combination with GRASE active ingredients