Division of Over-The-Counter Drug Products (HFD-560)

Center for Drug Evaluation and Research Food and Drug Administration

Rockville MD 20857

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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 |
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| **SUBMISSION DATE** | | April 11, 2005 |
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| **RECEIVED DATE** | | April 12, 2005 |
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| **REVIEW DATE** | | April 17, 2005 |
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| **REVIEWER** | | Michael L. Koenig, Ph.D. |
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| **TEAM LEADER** | | Matthew R. Holman, Ph.D. |
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**BACKGROUND**

The applicant requests addition of bemotrizinol, up to 10 percent*,* as a single active ingredient and in combination with other sunscreen active ingredients, to the monograph for OTC sunscreen drug products (21 CFR part 352). This TEA does not request any changes (e.g., labeling or testing) to the sunscreen monograph other than the addition of bemotrizinol. It is important to note that the applicant claims bemotrizinol protects against both UVA and UVB radiation.

Before submitting the TEA, the applicant submitted a citizen petition (CP13 in Docket Number 1978N-0038) in September 2000. The petition requested the addition of TINOSORB® S (bemotrizinol) to the sunscreen monograph. The petition also requested the addition of another 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 info

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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** |

ient 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