(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 |
|  | |  |
| **SUBMISSION DATE** | | April 11, 2005 |
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| **RECEIVED DATE** | | April 12, 2005 |
|  | |  |
| **REVIEW DATE** | | April 17, 2005 |
|  | |  |
| **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®

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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** |