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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. |
|  | |  |

motrizinol. 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 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 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** |