|  |  |  |
| --- | --- | --- |
| **CONDITIONS** | Bemotrizinol, at a maximum concentration of 10 percent, as a single active ingredient and in combination with other sunscreen active ingredients | |
|  |  | |
| **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 | |

|  |  |
| --- | --- |
| **Region** | **Estimated total sales**  **(million dosage units)** |
| Europe (6 countries) | 99.8 |
| South America (1 country) | 20.3 |
| **Total** (7 countries) | **120.1** |

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