

Food and Drug Administration
Rockville, MD 20857

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RE: Docket No. 96N-0277

Ciba Specialty Chemicals Corporation
Home and Personal Care (USA)
Attention: Carl D. D'Ruiz, MPH
Head, Product Safety, Regulatory Affairs & GMP
4090 Premier Drive
P.O. Box 2444
High Point, North Carolina 27261-2444

Dear Mr. D'Ruiz:

Please refer to your May 21, 2002 Time and Extent Application (TEA) submitted under 21 CFR 330.14 (Additional criteria and procedures for classifying OTC drugs as generally recognized as safe and effective and not misbranded). Your application requests the agency to consider including two new active ingredients (Tinosorb M and Tinosorb S) to the list of UV filters currently allowed for use under the Final Monograph for Sunscreen Drug Products for Over-the-Counter Human Use (21 CFR part 352).

We have reviewed your application for Tinosorb M and Tinosorb S and note your statement that "both products [ingredients] are currently being sold in more than five countries, but we have only 2.5 years of continuous use data in most of these countries." As you know, in order to be eligible for consideration under the TEA process, the condition must meet certain criteria which include that "the condition must have been marketed over-the-counter (OTC) for a minimum of 5 continuous years in the same country and in sufficient quantity" (21 CFR 330.14(b)(2)). As a result, these ingredients are not eligible for consideration under the TEA process at this time because you have not demonstrated that the ingredients have been marketed for a material time and a material extent.

We note your desire to commence an open dialogue regarding appropriate testing and other technical issues. The appropriate mechanism to do so at this time is under an Investigational New Drug Application (IND), as these ingredients are currently considered new drugs as defined in the Federal Food, Drug, and Cosmetic Act. (See 21 U.S.C. 321(p) and 355.) We invite you to submit your ingredients to the Division of Dermatological and Dental Drug Products for review as a part of the normal IND/NDA process. If you wish to schedule a pre-IND meeting, please contact Mary Jean Kozma-Fornaro of that Division at (301)-827-2020. Your questions can be addressed at that time.

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If you have any questions regarding this letter, please call Walter Ellenberg, Ph.D. Regulatory Project Manager, at (301) 827-2279.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Jonca Bull". The signature is fluid and cursive, with a large initial "J" and "B".

Jonca Bull, M.D.
Director, Office of Drug Evaluation V
Center for Drug Evaluation and Research

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 7-10-02

FROM: Director
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 96N-0277

TO: Dockets Management Branch, HFA-305

The attached material should be placed on public display under the above referenced Docket No.

This material should be cross-referenced to Comment No. _____


Charles J. Ganley, M.D.

Attachment