



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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Carl D. D'Ruiz, M.P.H.
Director, Product Stewardship & Regulatory Affairs
Ciba Specialty Chemicals
Consumer Care & Colors
4090 Premier Drive
P.O. Box 2444
High Point, North Carolina 27261-2444

APR 19 2002

Re: Docket No. 78N-0038
Comment No. CP13

Dear Mr. D'Ruiz:

This letter concerns your citizen petition (CP) dated September 5, 2000. The petition is filed under Docket No. 78N-0038 in the Dockets Management Branch.

The agency has developed a process by which drugs without any marketing experience in the United States could become eligible for consideration in the agency's over-the-counter (OTC) drug review. We are pleased to inform you that the process is now being implemented.

This process is described in a final rule entitled "Additional Criteria and Procedures for Classifying Over-the-Counter Drugs as Generally Recognized as Safe and Effective and Not Misbranded," which was published in the Federal Register of January 23, 2001 (67 FR 3060). A copy is enclosed for your information. This final rule is effective on February 22, 2002.

The final rule requires the submission of a Time and Extent Application (TEA) (see § 330.14(c)) to request consideration under the OTC drug review. The required information and format for a TEA are set out in the final rule (see § 330.14(c)). Three copies of the TEA are to be submitted to the Central Document Room (see § 330.14(d)).

If you wish to pursue inclusion in the OTC drug monograph system of an OTC drug product or active ingredient that was the subject of your CP, please submit a TEA in the required format. We do not intend to take further action on your CP.

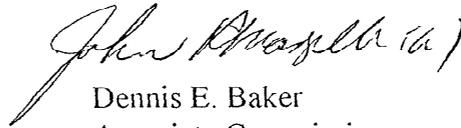
As stated in comment 20 of the final rule that established the TEA process, the agency will give priority to TEA's associated with pending CP's if those CP's are converted to TEA's that are submitted within 120 days after publication of that final rule.

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We look forward to reviewing your TEA upon submission.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "John Maxwell (u)", is written over the typed name.

Dennis E. Baker
Associate Commissioner
for Regulatory Affairs

Enclosure

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: 4-26-02
FROM: Director
Division of OTC Drug Products, HFD-560
SUBJECT: Material for Docket No. 78N-0038
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. CP13


Charles J. Ganley, M.D.

Attachment