



DEPARTMENT OF HEALTH AND HUMAN SERVICES

COPY

9136 Food and Drug Administration  
Rockville MD 20857 APR 19 2002

APR 19 2002

Ms. Beverly Ann Blatz, B.A.  
The Procter & Gamble Company  
11511 Reed Hartman Highway  
Cincinnati, Ohio 45241

Re: Docket No. ~~78N-183H~~ 75N-183H  
Comment No. CP8

Dear Ms. Blatz:

This letter concerns your citizen petition (CP) dated September 5, 2001. The petition is filed under Docket No. 78N-183H in the Dockets Management Branch. The petition requests that the agency recognize salicylic acid as a safe and effective OTC antibacterial (antiseptic) active ingredient for use as a consumer, food handler, and healthcare personnel handwash.

We have reviewed the information that you provided, which describes the marketing history of salicylic acid in the United States (U.S.). We note that salicylic acid has no U.S. marketing history as a consumer, food handler, and healthcare personnel handwash. We also note that you provided information on the use of salicylic acid in other parts of the world as an active ingredient in medicinal/antiseptic skin cleansers and in cosmetic products including facial cleansers, astringents, and moisturizers.

The agency has developed a process by which drugs without specific 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, 2002 (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)).

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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.

We look forward to reviewing your TEA upon submission.

Sincerely yours,

A handwritten signature in cursive script, appearing to read "Dennis E. Baker".

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

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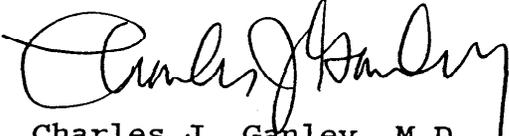
FROM: Director  
Division of OTC Drug Products, HFD-560

SUBJECT: Material for Docket No. 78N-183H

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. CPS

  
Charles J. Ganley, M.D.

Attachment