



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

2723 '00 MAR -6 A9:45  
MAR 2 2000

T.S. Elliott, Ph.D., MPH  
The Procter & Gamble Company  
11511 Reed Hartman Highway  
Cincinnati, Ohio 45241

RE: Docket No. 78N-0038  
Comment No. CP10

Dear Dr. Elliott:

We refer to your citizen petition dated May 26, 1998. The petition requests the Commissioner of the Food and Drug Administration (FDA) to amend the tentative final monograph (TFM) for over-the-counter (OTC) drug products to include a provision for formulating combination products with active ingredients at less than the proposed minimum concentrations, provided that companies have supporting data which show a significant contribution to ultraviolet (UV) radiation protection for those active ingredients formulated at less than the proposed minimum concentrations.

For the reasons given below, the agency considers action on the petition completed.

In the final rulemaking for OTC sunscreen drug products published in the Federal Register of May 21, 1999 (64 FR 27666 at 27687 and 27688) (copy of these pages enclosed), the agency removed the minimum concentration requirement for sunscreen active ingredients proposed in § 352.20 and added the requirement that: (1) The concentration of each active sunscreen ingredient used in a combination product must be sufficient to contribute a minimum sun protection factor (SPF) of not less than 2 to the finished product, and (2) the finished product must have a minimum SPF of not less than the number of the sunscreen active ingredients used in combination multiplied by 2.

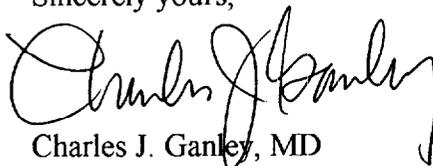
Accordingly, this petition has been granted.

78N-0038

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If you have any questions regarding the petition, please refer to the docket and comment numbers above, and submit all inquiries in triplicate, to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Charles J. Ganley". The signature is fluid and cursive, with a large initial "C" and "G".

Charles J. Ganley, MD

Director

Division of OTC Drug Products

Center for Drug Evaluation and Research

Enclosure