

September 27, 2000

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

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**Re: Sunscreen Drug Products for Over-the-Counter Human Use; Monograph; Extension of Effective Date; Reopening of Administrative Record, FDA Docket No. 78N-0038 ✓**

Dear Sir/Madam:

The purpose of this letter is to explain the position of the undersigned major sun care companies concerning the August 30, 2000, submission of the Schering-Plough Corporation. Specifically, Avon Products Inc., Playtex Products Inc. and The Procter and Gamble Company do not support the proposal for UVA testing and labeling presented in the Schering-Plough document. As such, the Schering-Plough submission does not represent the opinions of the whole sun care industry.

In the document submitted by Schering-Plough HealthCare Products and accompanied by letters from Bath and Body Works, Estee Lauder Companies, Johnson & Johnson, L'Oréal USA, and Mary Kay Inc, a proposal for testing and labeling sunscreen products offering UVA protection is presented. To position the support for this proposal, it is stated that *"These companies are responsible for the development, manufacture and sale of a majority of the Branded sunscreen-containing products that make SPF and UVA protection label claims"*.

We believe it is important that the Agency understands that the proposal presented by Schering-Plough is not supported by all major companies in the sun care business. Specifically, the undersigned companies, global leaders in the mass and direct marketing of products containing sunscreens, including seasonal, skincare and makeup products, are opposed to the test methods and labeling proposed by Schering-Plough and the supporting companies.

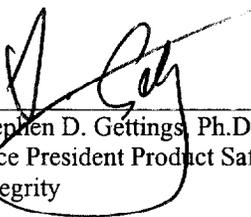
In our individual submissions, we have provided data and comments supportive of a singular threshold or "pass/fail" label indicating the presence of UVA protection, based on determination of the critical wavelength using the 1996 CTFA consensus method. We strongly believe this to be in the best interest of consumers because it assures protection against longwave UVA which is complimentary and commensurate with SPF and communicates such protection to consumers in a simple, uncomplicated label. As well, determination of the critical wavelength provides industry with a reproducible and standardized method that minimizes the advancement of misleading claims regarding product efficacy.

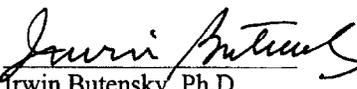
In summary, the proposal presented in the Schering-Plough letter is not supported by all the major sun care companies. We would be happy to meet with the Agency at any time to addresses concerns or clarify our positions as presented in the individual submissions.

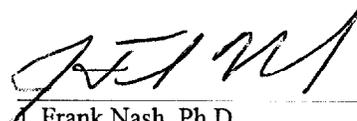
Respectfully,  
AVON PRODUCTS INC.

PLAYTEX PRODUCTS, INC.

THE PROCTER & GAMBLE  
COMPANY

  
Stephen D. Gettings, Ph.D., JD  
Vice President Product Safety &  
Integrity

  
Irwin Butensky, Ph.D.  
Senior Vice President Biomedical  
& Administrative Svcs.  
Research & Development

  
J. Frank Nash, Ph.D.  
Senior Scientist  
Research & Development

c/ FDA Desk Copies  
C Ganley, M.D., HFD-560  
L. Katz, M.D., HFD-560

J. Wilkin, M.D., HFD-540  
J. Lipnicki, HFD-560

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