

L'ORÉAL  
USA

John D. Sullivan  
General Counsel

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February 12, 2001

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

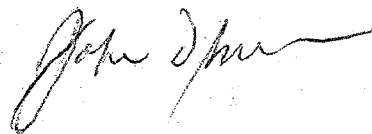
**Re: Final monograph for sunscreen drug products; For over-the-counter human use;  
Dockets # 98N-0337, 96N-0420, 95N-0259, 90P-0201, 78N-0038;  
Application of OTC drug labeling regulations to sunscreens**

Dear Sir or Madam:

We wish to make these comments concerning the above-referenced OTC drug labeling regulations for sunscreens. L'Oréal USA is the US subsidiary of L'Oréal SA, the world's largest beauty company. L'Oréal USA develops, markets, distributes, and manufactures beauty care products throughout the United States under brands such as L'Oréal, Lancôme, Maybelline, Laboratoires Garnier, Redken 5<sup>th</sup> Avenue NYC, Ralph Lauren Fragrances, Giorgio Armani Perfumes, Biotherm, Helena Rubinstein, Kiehl's, Dermablend, and La Roche Posay. A significant portion of L'Oréal USA's products contain sunscreens which includes all types of sunscreen products from those whose primary purpose is the protection of consumers against the effects of solar energy to those whose primary purpose is cosmetic (including beautification and moisturization), in which case the sunscreens have a secondary role.

L'Oréal USA supports the comments of the Cosmetic, Toiletry and Fragrance Association (CTFA) filed in these dockets, including those dated January 5, 2001. L'Oréal USA is in accord with CTFA's position that sunscreens are fundamentally different than other OTC drugs and their labeling requirements should reflect their unique position and encourage their use. In addition, the company believes that there is a rational and beneficial purpose in expanding the accommodations already made for sunscreens used in small areas of the face to all facial makeup and face and hand lotions and moisturizers containing sunscreens in packaging containing less than two ounces. We support the rationale provided by CTFA and believe it is the consensus position of our industry. The adoption of this proposal will benefit consumers by promoting the widespread and regular use of sunscreens.

Respectfully submitted,



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