



NDA 22-009/S-001

L'Oreal USA Products, Inc.  
Attention: Jean R. Grieve  
Assistant Vice President, Drug Approval Group  
30 L'Oreal Way  
Clark, NJ 07066

Dear Ms. Grieve:

Please refer to your supplemental new drug application dated April 18, 2008, received April 22, 2008, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for ANTHELIOS 40 (3% ecamsule, 2% avobenzone, 10% octocrylene, and 5% titanium dioxide) cream.

This supplemental application provides for an additional trade name, UV SHIELD, and associated labeling for the product.

We have completed our review of this supplemental application. This application is approved, for the UV Shield 50-gram package size, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the submitted labeling (50-gram carton and tube labels submitted on April 18, 2008), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved NDA 22-009/S-001.**" Approval of this submission by FDA is not required before the labeling is used.

Because there are other OTC sunscreens with trade names containing "UV Shield," we recommend that you include the active ingredients on the principal display panel. Doing so will distinguish this product from the other "UV Shield" products.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

*{See appended electronic signature page}*

Andrea Leonard-Segal, M.D.  
Director  
Division of Nonprescription Clinical Evaluation  
Office of Nonprescription Products  
Center for Drug Evaluation and Research

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Andrea Segal  
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