DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-501/S-003

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 January 8, 2007, received January 9, 2007, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Capital Soleil 15 (2% avobenzone, 3% ecamsule, and 10% octocrylene) cream.

We acknowledge receipt of your submission dated May 17, 2007.

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

We have completed our review of this supplemental application, as amended. This application is approved, 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 (carton back and side panels and tube back panel submitted on January 8, 2007, and carton and tube front panels submitted on May 17, 2007), and must be formatted in accordance with the requirements of 21 CFR 201.66. We note that the font color as originally proposed in the January 8, 2007 submission is acceptable.

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 21-501/S-003**." Approval of this submission by FDA is not required before the labeling is used.

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
5515 Security Lane
HFD-001, Suite 5100
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}*

Joel Schiffenbauer, M.D.
Deputy 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 this page is the manifestation of the electronic signature.**

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/s/

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Joel Schiffenbauer

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