DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-501

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 new drug application (NDA) dated May 16, 2005, received May 16, 2005, and submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for 2% avobenzone, 3% ecamsule, and 10% octocrylene cream. We note that you propose to market the product by the following distributors with the following trade names:

- Vichy CAPITAL SOLEIL 15
- Lancôme UV EXPERT 15

Per your September 29, 2006 request, CAPITAL SOLEIL 15 distributed by Vichy is designated as the reference listed drug for this application.

We acknowledge receipt of your submissions dated August 1, September 20 and 29, 2006.

The August 1, 2006 submission constituted a complete response to our July 21, 2006 action letter.

This new drug application is indicated to help prevent sunburn and to help provide protection from UVA and UVB rays.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revision listed below. This change can be made at the time of next printing or at 180 days, whichever occurs earlier.

Replace the phrase "oil-free" with the term "non-greasy" in every occurrence on the labels.

The final printed labeling (FPL) must include the revision listed above, be otherwise identical to the enclosed labeling (tube and carton labels submitted September 20, 2006), and must be in the "Drug Facts" format (21 CFR 201.66). These revisions are terms of the NDA approval for the 3.4 oz. (100 g) product. Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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**." Approval of this submission by FDA is not required before the labeling is used.

If you intend to market this product under additional labeling (e.g., under a different trade name) or increase the package size from 3.4 oz. (100 g), you must submit a prior approval supplement.

The Agency is evaluating further the appropriate labeling statements for OTC sunscreen drug products. We will inform you of any additional changes to the labeling of these products that the Agency deems necessary in the future.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for under the age of 6 months until July 22, 2009.

Your deferred pediatric study required under section 2 of the Pediatric Research Equity Act (PREA) is considered a required postmarketing study commitment. The status of this postmarketing study shall be reported annually for each NDA according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the prevention of sunburn in pediatric patients under the age of 6 months.

   Final Report Submission: July 22, 2009

Submit final study reports to NDA 21-501. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

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

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

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

Sincerely,

{See appended electronic signature page}

Susan Johnson, Ph.D.
Associate Director
Office of Nonprescription Products
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Susan Walker, M.D.
Director
Division of Dermatologic and Dental Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Susan Johnson
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