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RESEARCH**

APPLICATION NUMBER:

22-009

APPROVAL LETTER



NDA 22-009

NDA APPROVAL

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 31, 2007, received May 31, 2007, and submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for 2% avobenzone, 3% ecamsule, 10% octocrylene and 5% titanium dioxide cream. We note that you propose to market the product by the following distributors with the following trade names:

- Lancôme UV EXPERT 40
- La Roche-Posay ANTHELIOS 40
- Vichy CAPITAL SOLEIL 40

Per your November 30, 2007 request, ANTHELIOS 40 distributed by La Roche-Posay is designated as the primary trade name and reference drug for this application.

We acknowledge receipt of your submissions dated November 30, 2007, and February 8 and 26, 2008.

This new drug application provides for a nonprescription sunscreen cream containing 2% avobenzone, 3% ecamsule, 10% octocrylene and 5% titanium dioxide. This sunscreen has the following three uses:

- Helps prevent sunburn
- Higher SPF gives more sunburn protection
- Helps provide protection from UVA rays (short and long wavelengths)

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.

Submit the final printed labeling as soon as available, but no more than 30 days after printing. The final printed labeling (FPL) must be identical to the enclosed labeling (1.7 oz. tube and carton labels submitted May 31, 2007) and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for**

approved NDA 22-009.” Approval of this submission by FDA is not required before the labeling is used.

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.

If you intend to market this product under additional labeling (e.g., under a different trade name), you must submit a prior approval supplement.

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 waiving the pediatric study requirement for infants ages 0 to 6 months for this application.

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

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

We remind you that you must comply with reporting 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

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

/s/

Andrea Segal
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