



NDA 21-471/S-004

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 August 2, 2007, received August 3, 2007, submitted pursuant to section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anthelios 20 (2% ecamsule, 2% avobenzone, 10% octocrylene, and 2% titanium dioxide) cream.

We acknowledge receipt of your submission dated September 24, 2007.

This supplemental application provides for an additional trade name, REVITALIFT UV 20, 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 and tube labeling submitted on September 24, 2007), 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 21-471/S-004.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the word "NEW!" from the principal display panel (PDP) after 180 days of marketing.

We recommend that you add the following warning included in the August 2007 sunscreen proposed rule (<http://www.fda.gov/OHRMS/DOCKETS/98fr/07-4131.pdf>):

UV exposure from the sun increases the risk of skin cancer, premature skin aging, and other skin damage. It is important to decrease UV exposure by limiting time in the sun, wearing protective clothing, and using a sunscreen.

According to the proposed rule, this warning should appear in bold font as the first warning under the Warnings section of the Drug Facts box. This warning contains important information that consumers should have available in the labeling. Also, inclusion of the Sun Alert would make the labeling associated with this new trade name consistent with other products approved under this NDA.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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

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

Joel Schiffenbauer
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