



NDA 022009/S-004

SUPPLEMENT APPROVAL

L'ORÉAL PRODUCTS, Inc.

Attention: Jean R. Grieve

Assistant Vice President, Research & Development – Drug Approval Group

30 L'Oreal Way

Clark, NJ 07066

Dear Ms. Grieve:

Please refer to your November 17, 2009 Supplemental New Drug Application (sNDA), received November 18, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Anthelios 40 (3% ecamsule, 2% avobenzone, 10% octocrylene, and 5% titanium dioxide) cream.

This “Prior Approval” supplemental new drug application provides for the addition of a new 100 g package size and the associated labeling for the ANTHELIOS 40, UV EXPERT 40, CAPITAL SOLEIL 40, AND UV SHIELD products.

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling (FPL) as soon as it is available, but no more than 30 days after it is printed. The FPL must be identical to the enclosed labeling (3.4 oz (100 g) ANTHELIOS 40, UV EXPERT 40, CAPITAL SOLEIL 40, AND UV SHIELD carton and immediate container (tube) labels submitted on November 17, 2009), 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 022009/S-004.**” Approval of this submission by FDA is not required before the labeling is used.

LETTERS TO HEALTH CARE PROFESSIONALS

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
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

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 Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22009	SUPPL-4	LOREAL USA PRODUCTS INC	Avobenzone/ECAMSULE/OCTO CRYLENE/TITANIUM

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

/s/

ANDREA LEONARD SEGAL
04/09/2010