



NDA 22-009/S-002

SUPPLEMENT APPROVAL

L'Oreal USA
Attention: Jean Grieve
Assistant Vice President, Research & Development
30 L'Oreal Way
Clark, NJ 07066

Dear Ms. Grieve:

Please refer to your supplemental new drug application (sNDA) dated September 17, 2008, received December 29, 2008, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Anthelios 40 (3% ecamsule, 2% avobenzone, 10% octocrylene, and 5% titanium dioxide) cream.

We acknowledge receipt of your submissions dated December 1, 2008, and February 9, May 6, 8, and 15, July 13, September 3, and 25, and October 29, 2009.

This supplemental new drug application proposes a change in (b) (4)

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.

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling (1.7 oz (50 g) ANTHELIOS 40, UV EXPERT 40, CAPITAL SOLEIL 40, AND UV SHIELD carton labels submitted September 3, 2009), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable. We request that you also submit the tube labels for the referenced SKUs as part of the FPL even though no revisions were made to these labels as part of this supplement.

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/S-002.**” Approval of this submission by FDA is not required before the labeling is used.

REQUIRED PEDIATRIC ASSESSMENTS

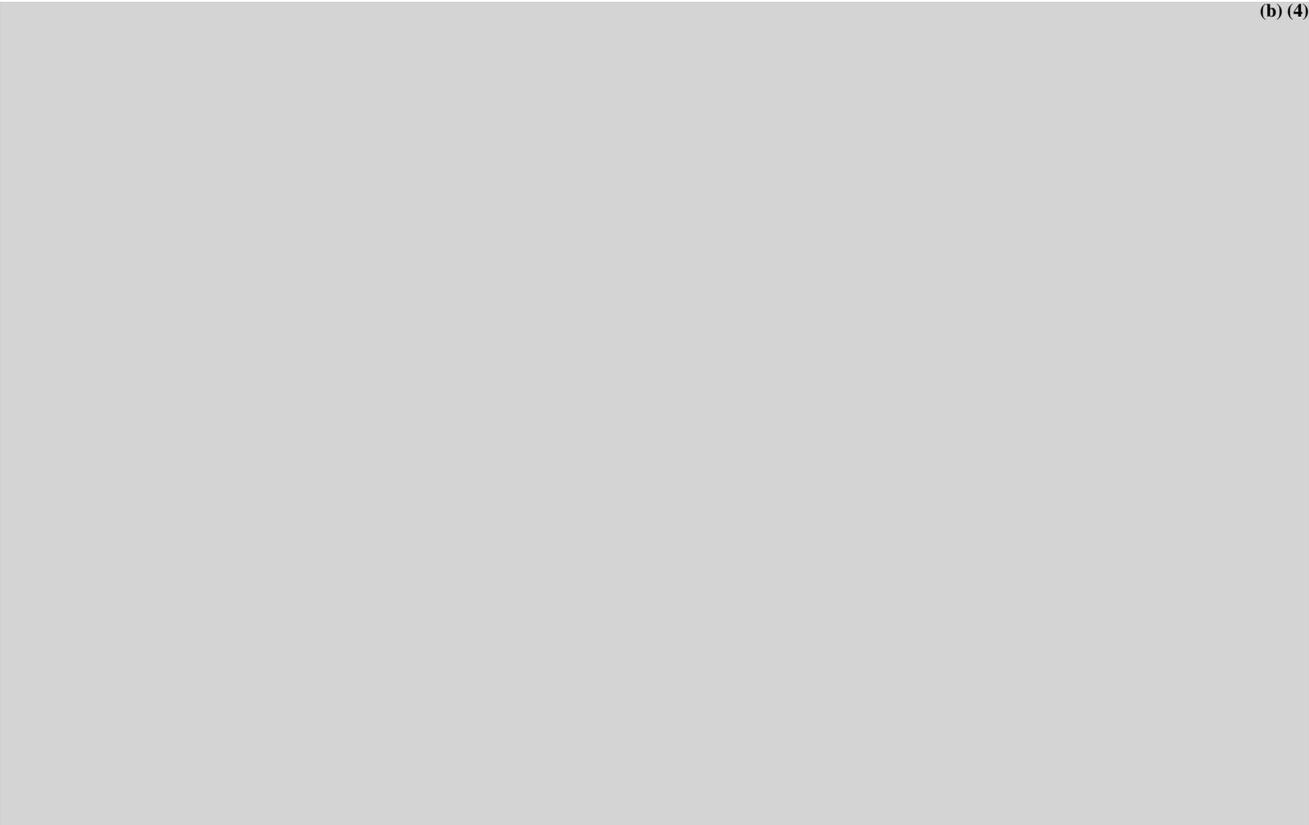
Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

This product is appropriately labeled for use in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

POSTMARKETING COMMITMENTS SUBJECT TO THE REPORTING REQUIREMENTS OF SECTION 506B

We acknowledge your written commitment to conduct the following postmarketing studies as described in your submission dated October 29, 2009, and as outlined below:

(b) (4)



Submit the protocol to your IND for this product, with a cross-reference letter to this NDA. Submit all final report(s) to your NDA. Use the following designators to prominently label all submissions, including supplements, relating to this postmarketing study commitment, as appropriate:

- **POSTMARKETING STUDY COMMITMENT PROTOCOL**
- **POSTMARKETING STUDY COMMITMENT FINAL REPORT**
- **POSTMARKETING STUDY COMMITMENT CORRESPONDENCE**

In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of each commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study.

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 Michelle Poindexter, Regulatory Project Manager, at (301) 796-4795.

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

Enclosure: Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22009	SUPPL-2	LOREAL USA PRODUCTS INC	AVOBENZENE/ECAMSULE/OCT OCRYLENE/TITANIUM

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

/s/

CHARLES J GANLEY on behalf of ANDREA LEONARD SEGAL
10/29/2009
Signing for Andrea Leonard Segal