DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-502/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 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Anthelios SX (2% avobenzone, 2% ecamsule and 10% octocrylene) cream.

This supplemental application provided for an additional trade name, UV DEFENDER, and associated labeling for the product.

We also refer to our approval letter of your supplement dated January 12, 2007. This letter had incorrect labeling attached. We will be sending you a replacement approval letter with the correct labeling attached. The date of your approval action will be unchanged; however the signature time will be one minute later than the original signature time to permit differentiation between the letters.

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 this page is the manifestation of the electronic signature.

/s/

Joel Schiffenbauer

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