CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-501

APPROVABLE LETTER(S)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 21-501

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 16, 2005 received May 16, 2005, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for 2% avobenzone, 3% ecamsule, and 10% octocrylene cream. We note that you propose to market the product by the following distributors with the following trade names:

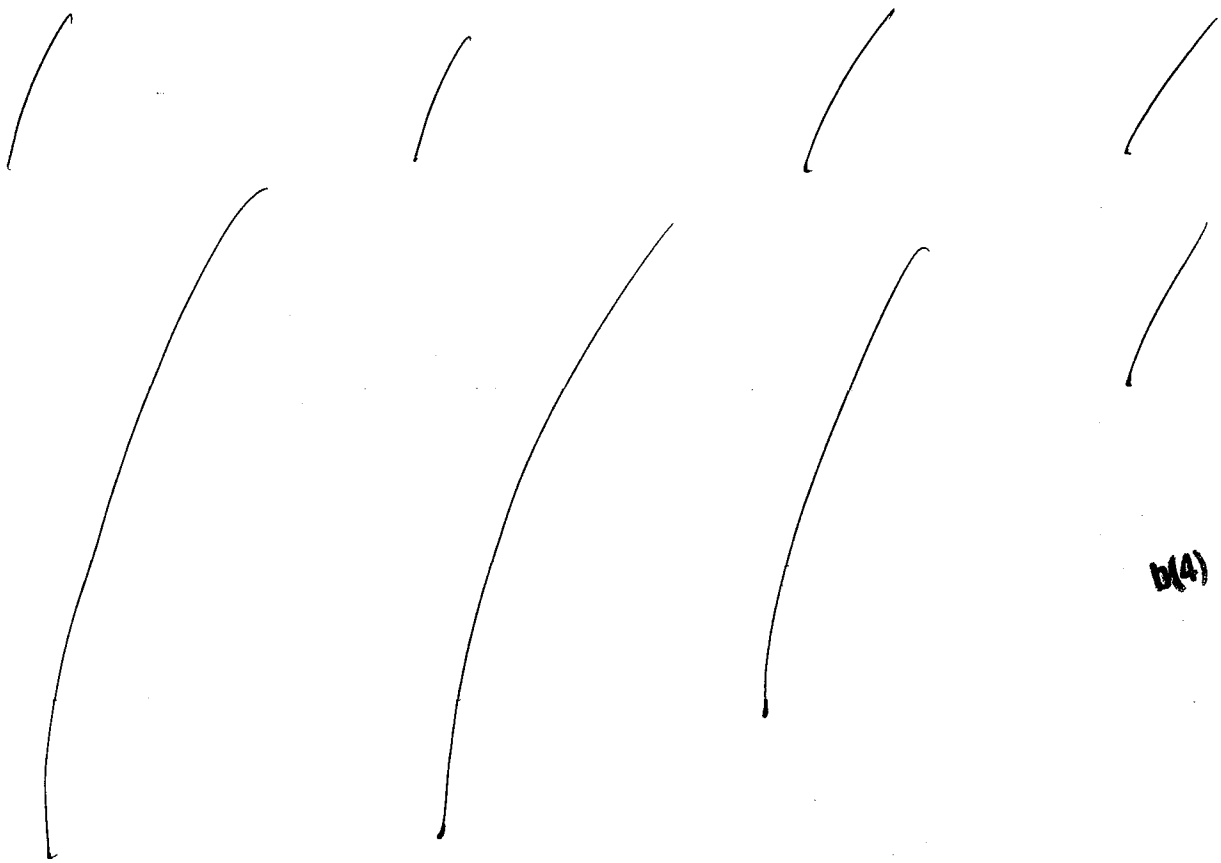
- b(4)
- Vichy CAPITAL SOLEIL 15
- LaRoche-Posay ANTHELIOS 15
- Lancome UV EXPERT 15
- b(4)

We acknowledge receipt of your submissions dated April 12, May 18, June 22 and 23, and July 10 and 12, 2006.

The May 18, 2006 submission constituted a complete response to our March 10, 2006 action letter.

This new drug application is indicated for the prevention of sunburn.

We have completed our review of this application, as amended, and it is approvable. Before this application may be approved, however, you must submit draft labeling revised as follows: b(4)



If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all non-clinical and clinical studies of the drug under consideration regardless of indication, dosage form, or dose level.

1. Describe in detail any significant changes or findings in the safety profile.

2. When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:

   - Present new safety data from the studies for the proposed indication using the same format as the original NDA submission.
   - Present tabulations of the new safety data combined with the original NDA data.
   - Include tables that compare frequencies of adverse events in the original NDA with the retabulated frequencies described in the bullet above.
   - For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.

3. Present a retabulation of the reasons for premature study discontinuation by incorporating the drop-outs from the newly completed studies. Describe any new trends or patterns identified.

4. Provide case report forms and narrative summaries for each patient who died during a clinical study or who did not complete a study because of an adverse event. In addition, provide narrative summaries for serious adverse events.

5. Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original NDA data.

6. Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.

7. Provide English translations of current approved foreign labeling not previously submitted.

Within 10 days after the date of this letter, you are required to amend these applications, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw these applications under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

These drug products may not be legally marketed until you have been notified in writing that these applications are approved.

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Office of Nonprescription Products
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Acting Director
Office of Drug Evaluation III
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/

Susan Johnson
10/2/2006 03:01:16 PM

Susan Walker
10/2/2006 03:03:03 PM

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

/s/

Susan Walker
7/21/2006 04:11:15 PM
Signed for Dr. Julie Beitz

Susan Johnson
7/21/2006 04:44:42 PM
Susan Johnson signing for Charles Ganley

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-501
NDA 21-502

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 applications (NDA) dated May 12, 2005 received May 12, 2005 (NDA 21-502) and dated May 16, 2005 received May 16, 2005 (NDA 21-501), submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for 2% avobenzone, 3% ecamsule, and 10% octocrylene cream (NDA 21-501), and 2% avobenzone, 2% ecamsule, and 10% octocrylene cream (NDA 21-502).

These products are indicated for the prevention of sunburn.

We acknowledge receipt of your submissions dated August 5, September 8 (NDA 21-502), September 9 (NDA 21-501), and December 19, 2005, and January 11, February 16 (NDA 21-502), and February 17, 2006 (NDA 21-501).

We have completed our review of these applications, as amended, and they are approvable. Before these applications may be approved, however, you must submit draft labeling revised as follows:

2 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

/ / / / b(4)

Before these applications may be approved, FDA must conduct an inspection of the manufacturing facilities referenced in the applications to determine satisfactory compliance with cGMPs. The cGMP inspection for a facility which manufactures one of the drug substances has not been completed as of this date.

In addition, we are still reviewing the multiple trade names for your formulations.

If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

When you respond to the above deficiencies, include a safety update as described at 21 CFR 314.50(d)(5)(vi)(b). The safety update should include data from all non-clinical and clinical studies of the drug under consideration regardless of indication, dosage form, or dose level.

1. Describe in detail any significant changes or findings in the safety profile.

2. When assembling the sections describing discontinuations due to adverse events, serious adverse events, and common adverse events, incorporate new safety data as follows:

   - Present new safety data from the studies for the proposed indication using the same format as the original NDA submission.
   - Present tabulations of the new safety data combined with the original NDA data.
   - Include tables that compare frequencies of adverse events in the original NDA with the retabulated frequencies described in the bullet above.
   - For indications other than the proposed indication, provide separate tables for the frequencies of adverse events occurring in clinical trials.

3. Present a retabulation of the reasons for premature study discontinuation by incorporating the drop-outs from the newly completed studies. Describe any new trends or patterns identified.

4. Provide case report forms and narrative summaries for each patient who died during a clinical study or who did not complete a study because of an adverse event. In addition, provide narrative summaries for serious adverse events.

5. Describe any information that suggests a substantial change in the incidence of common, but less serious, adverse events between the new data and the original NDA data.

6. Provide a summary of worldwide experience on the safety of this drug. Include an updated estimate of use for drug marketed in other countries.

7. Provide English translations of current approved foreign labeling not previously submitted.

Within 10 days after the date of this letter, you are required to amend these applications, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw these applications under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

These drug products may not be legally marketed until you have been notified in writing that these applications are approved.

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Office of Nonprescription Products
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Julie Beitz, M.D.
Acting Director
Office of Drug Evaluation III
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/

Stanka Kukich
3/9/2006 05:01:50 PM
Signing off for Dr. Julie Beitz, Acting Director Office of Drug Evaluation III

Andrea Segal
3/10/2006 09:33:57 AM
I am signing on behalf of Dr. Charles Ganley.