

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-009

OTHER REVIEW(S)



**OTC Drug Labeling Review for
L'Oreal SPF 40 Sunscreens
(NDA 22-009): Amendment**

Office of Nonprescription Products
Center for Drug Evaluation and Research • Food and Drug Administration

SUBMISSION DATES: May 31, 2007 **RECEIVED DATES:** May 31, 2007

REVIEW DATE: March 17, 2008

NDA/SUBMISSION TYPE: NDA 22-009

SPONSOR/CONTACT: Jean R. Grieve
Assistant Vice President,
Research & Development Drug Approval
Group

L'Oreal USA Products, Inc.
30 Terminal Ave.
Clark, NJ 07066
732-680-5562
732-909-2007, 732-680-5502 (FAX)

DRUG PRODUCT:

- Lancôme UV EXPERT 40
- La Roche-Posay ANTHELIOS 40
- Vichy CAPITAL SOLEIL 40

ACTIVE INGREDIENTS:

- Avobenzone, 2%
- Ecamsule, 3%
- Octocrylene, 10%
- Titanium dioxide, 5%

INDICATIONS: Helps prevent sunburn; provides broad spectrum protection from UVA and UVB radiation

PHARMACOLOGICAL CATEGORY: Sunscreen (broad spectrum)

LABELING SUBMITTED:

Tube & carton labels for the following 1.7 oz products:

- UV EXPERT 40
- ANTHELIOS 40
- CAPITAL SOLEIL 40

REVIEWER:

Michael L. Koenig, Ph.D.

TEAM LEADER

Matthew R. Holman, Ph.D.

BACKGROUND

The sponsor submitted labeling for three SPF 40 sunscreen products on May 31, 2007 (NDA 22-009). We reviewed the labeling and posted our review in DFS on January 4, 2008. This is an amendment to that review.

REVIEWER'S COMMENT

To facilitate the safe and effective use of these products, this reviewer recommends that the sponsor implement the warnings and directions included in the 2007 UVA proposed rule (*Federal Register* vol. 72, p. 49070). The proposed warnings and directions are cited in proposed 21 CFR 352.50(c) and (d), respectively. If the sponsor implements these changes, it can remove the "Sun Alert" statement on the outer package side panels. The other labeling included in the proposed rule deals primarily with UVA labeling and testing proposals. Because we are likely to make revisions to these proposals, it does not seem prudent for the sponsor to incorporate these proposals in its labeling prior to publication of the final rule.

RECOMMENDATION

Inform the sponsor that, to facilitate the safe and effective use of these products, we recommend the sponsor consider revising the labeling at the time of next printing to incorporate the warnings and directions included in the 2007 sunscreen proposed rule (21 CFR 352.52(c) and (d); *Federal Register* vol. 72, p. 49113). The other labeling included in the proposed rule deals primarily with UVA labeling and testing proposals. These proposals may change significantly when we issue a sunscreen final rule.

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/s/

Michael Koenig
3/17/2008 11:40:55 AM
INTERDISCIPLINARY

Matthew Holman
3/17/2008 12:00:34 PM
INTERDISCIPLINARY



OTC Drug Labeling Review for L'Oreal SPF 40 Sunscreens (NDA 22-009)

Office of Nonprescription Products
Center for Drug Evaluation and Research • Food and Drug Administration

SUBMISSION DATES: May 31, 2007

RECEIVED DATES: May 31, 2007

REVIEW DATE:

January 4, 2008

NDA/SUBMISSION TYPE:

NDA 22-009

SPONSOR/CONTACT:

Jean R. Grieve
Assistant Vice President,
Research & Development Drug Approval
Group

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DRUG PRODUCT:

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ACTIVE INGREDIENTS:

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- Octocrylene, 10%
- Titanium dioxide, 5%

INDICATIONS:

Helps prevent sunburn; provides broad spectrum protection from UVA and UVB radiation

PHARMACOLOGICAL CATEGORY:

Sunscreen (broad spectrum)

LABELING SUBMITTED:

Tube & carton labels for the following 1.7 oz products:

- UV EXPERT 40
- ANTHELIOS 40
- CAPITAL SOLEIL 40

REVIEWER:

Michael L. Koenig, Ph.D.

TEAM LEADER

Matthew R. Holman, Ph.D.

BACKGROUND

In its submission (NDA 22-009) dated May 31, 2007, the sponsor includes labeling for three sunscreen products to be marketed by three different marketing divisions:

- UV EXPERT 40 (Lancôme)
- ANTHELIOS 40 (La Roche-Posay) (Reference listed drug)
- CAPITAL SOLEIL 40 (Vichy)

REVIEWED LABELING

b(4)

2 Page(s) Withheld

 Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

 Draft Labeling (b5)

 Deliberative Process (b5)

b(4)

REVIEWER'S COMMENTS

1. The trade names for these products are distinct from other sunscreen drug products included under L'Oreal NDAs 21-471, 21-501, and 21-502 because they include the SPF value (40). Therefore, these trade names are acceptable.

Distributor	NDA 22-009	NDA 21-471	NDA 21-501	NDA 21-502
Lancôme	UV EXPERT 40	UV EXPERT 20 ¹	UV EXPERT 15 ¹	UV EXPERT 15
La Roche Posay	ANTHELIOS 40	ANTHELIOS 20 ¹		ANTHELIOS SX ¹
Vichy	CAPITAL SOLEIL 40	CAPITAL SOLEIL 20 ¹	CAPITAL SOLEIL 15 ¹	UV ACTIV
Kiehl's		UV PROTECTIVE SUNCARE ¹		UV PROTECTIVE
Shu Uemura				UV DEFENDER

¹ Approved

2. The submitted labeling incorporates all aspects of labeling approved under NDA 21-471 for the SPF 20 products (containing the same four active ingredients) and is acceptable.

RECOMMENDATIONS

1. Send an approval letter for the 1.7 oz. (50 g) product with the following trade names:
 - UV EXPERT 40 (Lancôme)
 - ANTHELIOS 40 (La Roche-Posay)
 - CAPITAL SOLEIL 40 (Vichy)

2. Note that the sponsor has designated ANTHELIOS 40 distributed by LaRoche-Posay as the reference listed drug for this application.
3. In the approval letter, inform the sponsor that the application is approved for use as recommended in the agreed-upon labeling text and request final printed labeling (FPL). The FPL must be identical to the tube and carton labeling submitted on May 31, 2007.

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/s/

Michael Koenig
1/4/2008 09:59:27 AM
INTERDISCIPLINARY

Matthew Holman
1/4/2008 10:58:18 AM
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