CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 21-501

OTHER REVIEWS

OTC Drug Labeling Review Addendum for L'Oreal Sunscreens (NDA 21-501)

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

SUBMISSION DATES:	August 1 and September 20, 2006	**RECEIVED DATES:**	August 2 and September 21, 2006

REVIEW DATE: September 28, 2006

NDA/SUBMISSION TYPE: NDA 21-501

SPONSOR/CONTACT:

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

L'Oreal USA Products, Inc.
111 L'Oreal Way
Clark, NJ 07066
732-680-5562
732-909-2007 (FAX)

DRUG PRODUCT: Vichy CAPITAL SOLEIL 15
Lancôme UV EXPERT 15

ACTIVE INGREDIENTS:

Avobenzone, 2%
Ecamsule, 3%
Octocrylene, 10%

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 3.4 oz products:

- Vichy CAPITAL SOLEIL 15
- Lancôme UV EXPERT 15

REVIEWER: Michael L. Koenig, Ph.D.

BACKGROUND

This is an addendum to the labeling review for NDA 21-501 dated September 26, 2006. Dr. Ganley's memo dated July 21, 2006 and filed under NDA 21-502, stipulates that the sponsor submit a prior approval supplement if it decides to package sunscreen products ——— ——— ; in package sizes larger than 3.4 oz. This applies to products marketed under NDA 21-501 as well. b(4)

REVIEWER'S COMMENTS

The sponsor should be informed that the approval of these products applies only to the 3.4 oz package size.

RECOMMENDATIONS

In the approval letter, inform the sponsor that it must submit a prior approval supplement if it proposes to increase the package size of these products to a size greater than 3.4 oz.

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/s/

Michael Koenig
9/29/2006 02:50:53 PM
INTERDISCIPLINARY

Matthew Holman
9/29/2006 02:58:15 PM
INTERDISCIPLINARY

OTC Drug Labeling Review Addendum for L'Oreal Sunscreens (NDA 21-501)

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

SUBMISSION DATES:	August 1 and September 20, 2006	**RECEIVED DATES:**	August 2 and September 21, 2006

REVIEW DATE: September 25, 2006

NDA/SUBMISSION TYPE: NDA 21-501

SPONSOR/CONTACT:

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

L'Oreal USA Products, Inc.
111 L'Oreal Way
Clark, NJ 07066
732-680-5562
732-909-2007 (FAX)

DRUG PRODUCT: Vichy CAPITAL SOLEIL 15
Lancôme UV EXPERT 15

ACTIVE INGREDIENTS:

Avobenzone, 2%
Ecamsule, 3%
Octocrylene, 10%

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 3.4 oz products:

- Vichy CAPITAL SOLEIL 15
- Lancôme UV EXPERT 15

REVIEWER: Michael L. Koenig, Ph.D.

BACKGROUND

In response to a July 21, 2006, approvable letter recommending changes to the labeling for this NDA (21-501), the sponsor submitted revised labeling for two products on August 1, 2006:

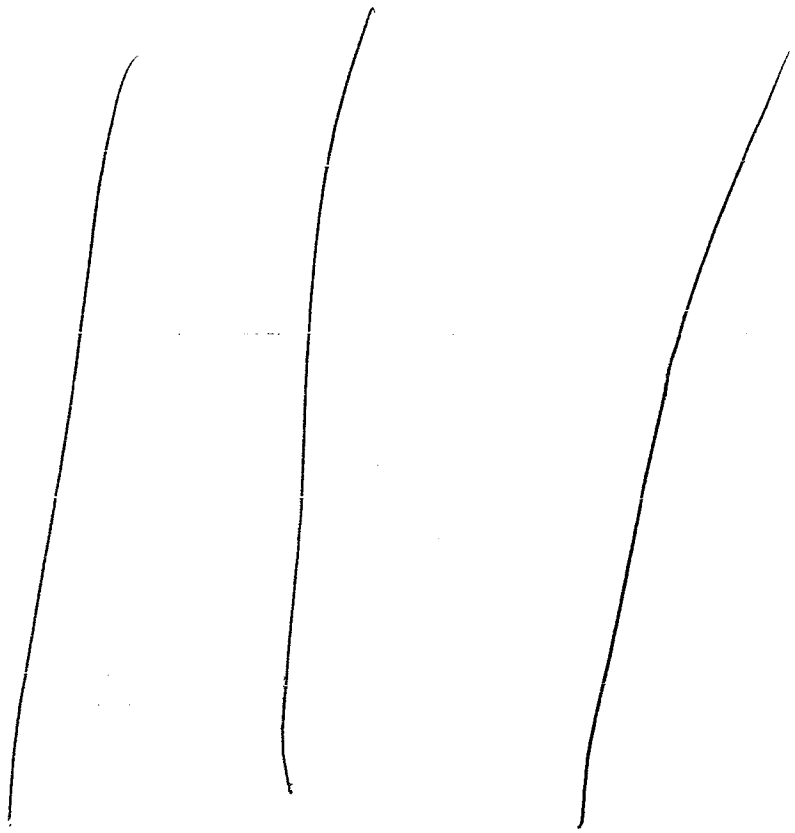
- Vichy CAPITAL SOLEIL 15
- Lancôme UV EXPERT 15

The sponsor did not submit revised labeling for:

- [redacted] b(4)
- [redacted]
- La Roche Posay ANTHELIOS 15

FDA reviewed the submitted labeling and informed the sponsor, on September 14, 2006, that revisions would be necessary. The sponsor made the recommended revisions and resubmitted the labeling to FDA on September 20, 2006.

REVIEWED LABELING



b(4)

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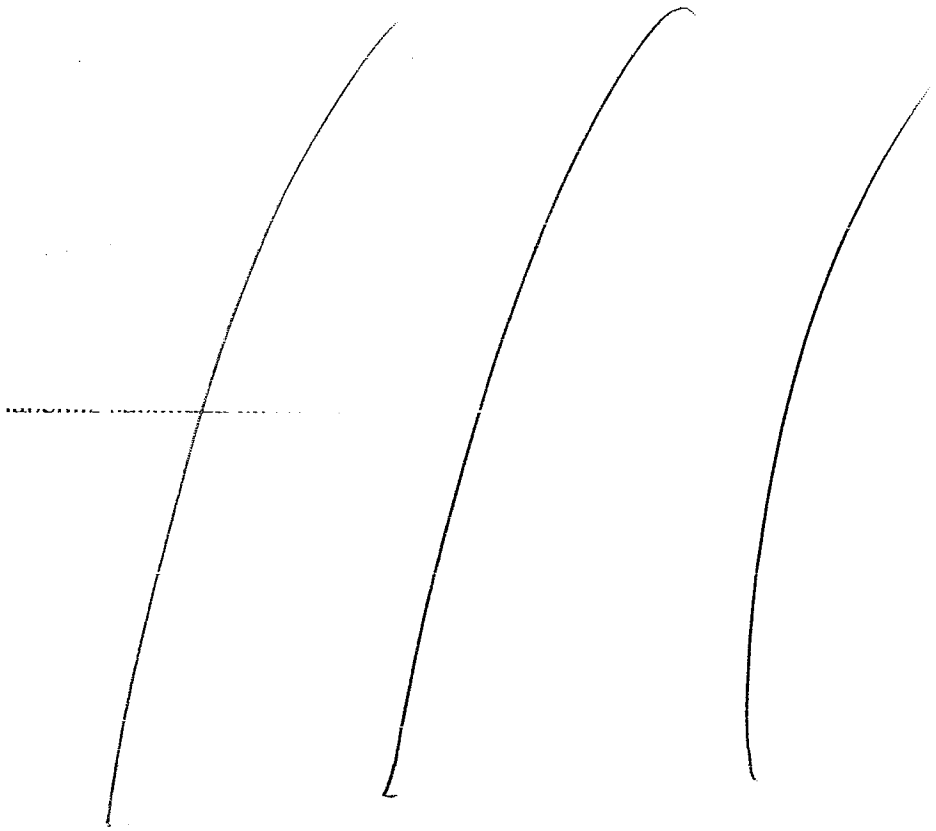
_____ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)



b(4)

e

RECOMMENDATIONS

Send an approval letter indicating that the final printed labeling must be identical to the tube and carton labels submitted on September 20, 2006, for the 3.4 oz packages of Vichy CAPITAL SOLEIL 15 and Lancôme UV EXPERT 15. Ask the sponsor to submit final printed labeling when available.

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/s/

Michael Koenig
9/25/2006 09:25:10 AM
INTERDISCIPLINARY

Matthew Holman
9/25/2006 09:32:59 AM
INTERDISCIPLINARY

OTC Drug Labeling Review Addendum for L'Oreal Sunscreens (NDAs 21-501 and 21-502)

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

SUBMISSION DATES:	May 16, 2005 and May 18, 2006 (NDA 21-501) May 12, 2005 and May 18, 2006 (NDA 21-502)	**RECEIVED DATES:**	May 16, 2005 and May 22, 2006 (NDA 21-501) May 12, 2005 and May 22, 2006 (NDA 21-502)

REVIEW DATE: June 6, 2006

NDA/SUBMISSION TYPE: NDAs 21-501 and 21-502 (N-000/BL)

SPONSOR/CONTACT:

Jean R. Grieve
Assistant Vice President – Drug Approval Group
Research & Development Division
L'Oreal USA Products, Inc.
111 L'Oreal Way
Clark, NJ 07066
732-680-5562
732-909-2007 (FAX)

DRUG PRODUCT:

NDA 21-501: SPF 15 Water Resistant Sunscreen Cream
NDA 21-502: Moisturizer with SPF15 Sunscreen Cream

ACTIVE INGREDIENTS:

NDA 21-501:
- Avobenzone, 2%
- Ecamsule, 3%
- Octocrylene, 10%

NDA 21-502:
- Avobenzone, 2%
- Ecamsule, 2%
- Octocrylene, 10%

INDICATIONS: Prevention of sunburn [redacted] due to sun exposure by providing broad spectrum protection from UVB and UVA radiation b(4)

PHARMACOLOGICAL CATEGORY: Sunscreen (broad spectrum)

LABELING SUBMITTED: Carton & immediate container labels for the following products:

NDA 21-501

[redacted] b(4)

- Vichy CAPITAL SOLEIL 15
- LaRoche-Posay ANTHELIOS 15
- Lancome UV EXPERT 15

NDA 21-502

[redacted] b(4)

All products are 3.4 oz. (100 g) tubes unless noted above.

REVIEWER: Michael L. Koenig, Ph.D.

TEAM LEADER: Matthew Holman, Ph.D.

BACKGROUND

In response to a March 10, 2006, approvable letter recommending changes to the labeling for NDAs 21-501 and 21-502, the sponsor submitted revised labeling on May 18, 2006. A total of 11 labels were resubmitted for the two sunscreens (5 for NDA 21-501 and 6 for NDA 21-502).

[redacted] b(4)

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_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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/s/

Michael Koenig
6/13/2006 08:58:16 AM
INTERDISCIPLINARY

Matthew Holman
6/13/2006 09:10:23 AM
INTERDISCIPLINARY

OTC Drug Labeling Review for L'Oreal Sunscreens (NDAs 21-501 and 21-502)

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

SUBMISSION DATE:	May 16, 2005 (NDA 21-501) May 12, 2005 (NDA 21-502)	**RECEIVED DATE:**	May 16, 2005 (NDA 21-501) May 12, 2005 (NDA 21-502)
REVIEW DATE:	February 21, 2006		
NDA/SUBMISSION TYPE:	NDAs 21-501 and 21-502 (N-000)		
SPONSOR/CONTACT:	Jean R. Grieve Assistant Vice President – Drug Approval Group Research & Development Division L'Oreal USA Products, Inc. 111 L'Oreal Way Clark, NJ 07066 732-680-5562 732-396-7051 (FAX)		
DRUG PRODUCT:	NDA 21-501: SPF 15 Water Resistant Sunscreen Lotion NDA 21-502: SPF15 Sunscreen Lotion		
ACTIVE INGREDIENTS:	NDA 21-501: Avobenzone, 2% Ecamsule, 3% Octocrylene, 10% NDA 21-502: Avobenzone, 2% Ecamsule, 2% Octocrylene, 10%		
INDICATIONS:	Prevention of sunburn [redacted] due to sun exposure by providing broad spectrum protection from UVB and UVA radiation		b(4)

PHARMACOLOGICAL CATEGORY: Sunscreen (broad spectrum)

LABELING SUBMITTED:

NDA 21-501

Vichy CAPITAL SOLEIL[1]
LaRoche-Posay ANTHELIOS[1]
Lancome UV EXPERT[1]

b(4)

NDA 21-502

b(4)

[1] 100 ml tube
[2]

REVIEWER: Michael L. Koenig, Ph.D.

TEAM LEADER: Matthew Holman, Ph.D.

BACKGROUND

As part of NDAs 21-501 and 21-502, the sponsor submitted labeling for two sunscreens to be

7 Page(s) Withheld

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_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

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/s/

Michael Koenig
2/21/2006 11:12:47 AM
INTERDISCIPLINARY

Matthew Holman
2/21/2006 11:18:32 AM
INTERDISCIPLINARY