

Attachment 1

Orange Book Listing for Olux[®] Foam
11 September 2006

Proprietary Name Search Results from "OB_Rx" table for query on "olux."

Appl No	TE Code	RLD Active	Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
<u>021142</u>		Yes	CLOBETASOL PROPIONATE	AEROSOL, FOAM; TOPICAL	0.05%	OLUX	CONNETICS

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Orange Book Data Updated Through July, 2006

Patent and Generic Drug Product Data Last Updated: September 11, 2006

Search results from the "OB_Rx" table for query on "021142."

Active Ingredient:	CLOBETASOL PROPIONATE
Dosage Form;Route:	AEROSOL, FOAM; TOPICAL
Proprietary Name:	OLUX
Applicant:	CONNETICS
Strength:	0.05%
Application Number:	021142
Product Number:	001
Approval Date:	May 26, 2000
Reference Listed Drug	Yes
RX/OTC/DISCN:	RX
TE Code:	

Patent and Exclusivity Info for this product: [View](#)

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Patent and Exclusivity Search Results from query on Appl No 021142 Product 001 in the OB_Rx list.**Patent Data**

Appl No	Prod No	Patent No	Patent Expiration	Drug Substance Claim	Drug Product Claim	Patent Use Code
021142	001	6126920	OCT 03,2017			U-484

Exclusivity Data

Appl No	Prod No	Exclusivity Code	Exclusivity Expiration
021142	001	I-374	DEC 20,2005

Additional information:

1. Patents are published upon receipt by the Orange Book Staff and may not reflect the official receipt date as described in 21 CFR 314.53(d)(5).
2. Patents submitted on FDA Form 3542 and listed after August 18, 2003 will have one to three patent codes indicating specific patent claims as submitted by the sponsor and are detailed in the above table.
3. Patents listed prior to August 18, 2003 are flagged with method of use claims only as applicable and submitted by the sponsor. These patents may not be flagged with respect to other claims which may apply.
4. *PED and PED represent pediatric exclusivity. Patents with pediatric exclusivity granted after August 18, 2003 will be indicated with *PED as was done prior to August 18, 2003. Patents with *PED added after August 18, 2003 will not contain any information relative to the patent itself other than the *PED extension. Information related specifically to the patent will be conveyed on the original patent only.
5. U.S. Patent Nos. RE36481 and RE36520 are being relisted for Zocor (NDA 19-766) pursuant to the decision and related order in Ranbaxy Labs. v. Leavitt, No. 05-1838 (D.D.C. April 30, 2006). The '481 and '520 patents will remain listed in Approved Drug Products with Therapeutic Equivalence Evaluations until any applicable periods of exclusivity pursuant to section 505(j)(5)(B)(iv) of the Federal Food, Drug, and Cosmetic Act have been triggered and run, unless the agency's appeal of the decision to the U.S. Court of Appeals for the District of Columbia is decided in the agency's favor before the exclusivity periods have expired. While the patents remain listed, any new or pending ANDA referencing Zocor must contain patent certifications to these patents. For additional information on this matter, please refer to Docket Nos. 2005P-0008 and 2005P-0046.

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Patent Use Codes

This page defines the patent use codes.

Code Definition

U-484 METHOD OF TREATING A SKIN DISEASE WITH A CORTICOSTEROID-CONTAINING PHARMACEUTICAL COMPOSITION

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