

Attachment E

**Electronic Orange Book listing for
Tussionex® Pennkinetic®
*(hydrocodone polisterex and
chlorpheniramine polistirex) Extended
Release Suspension***

and

***Codeprex™ Pennkinetic® (codeine
polisterex and chlorpheniramine
polistirex) Extended Release
Suspension***

Search results from the "OB_Rx" table for query on "019111."

Active Ingredient: CHLORPHENIRAMINE POLISTIREX; HYDROCODONE POLISTIREX
Dosage Form;Route: SUSPENSION, EXTENDED RELEASE; ORAL
Proprietary Name: TUSSIONEX PENNKINETIC
Applicant: UCB INC
Strength: EQ 8MG MALEATE/5ML;EQ 10MG BITARTRATE/5ML
Application Number: 019111
Product Number: 001
Approval Date: Dec 31, 1987
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

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FDA/Center for Drug Evaluation and Research

Office of Generic Drugs

Division of Labeling and Program Support

Update Frequency:

Orange Book Data - **Monthly**

Generic Drug Product Information & Patent Information - **Daily**

Orange Book Data Updated Through December, 2006

Patent and Generic Drug Product Data Last Updated: February 06, 2007

Patent and Exclusivity Search Results from query on Appl No 019111 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
019111	001	4762709	AUG 09,2005			

Exclusivity Data

There is no unexpired exclusivity for this product.

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. RE 36481 and RE 36520 were 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 remained 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 were triggered and run. For additional information on this matter, please refer to Docket Nos. 2005P-0008 and 2005P-0046. Patents were subsequently delisted in the December 2006 Orange Book update as the exclusivity periods have triggered and run to expiration.

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Search results from the "OB_Rx" table for query on "021369."

Active Ingredient: CHLORPHENIRAMINE POLISTIREX; CODEINE POLISTIREX
Dosage Form;Route: SUSPENSION, EXTENDED RELEASE; ORAL
Proprietary Name: CODEPREX
Applicant: UCB INC
Strength: EQ 4MG MALEATE/5ML;EQ 20MG BASE/5ML
Application Number: 021369
Product Number: 001
Approval Date: Jun 21, 2004
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code:
Patent and Exclusivity Info for this product: [View](#)

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Patent and Generic Drug Product Data Last Updated: February 06, 2007

Patent and Exclusivity Search Results from query on Appl No 021369 Product 001 in the OB_Rx list.

Patent Data

There are no unexpired patents for this product in the Orange Book Database.

[Note: Title I of the 1984 Amendments does not apply to drug products submitted or approved under the former Section 507 of the Federal Food, Drug and Cosmetic Act (antibiotic products). Drug products of this category will not have patents listed.]

Exclusivity Data

There is no unexpired exclusivity for this product.

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