

Attachment B

**Electronic Orange Book listing for
Prometh w/ Codeine (Promethazine
Hydrochloride and Codeine Phosphate
Syrup, 6.25 mg and 10 mg/ 5 mL)**

Search results from the "OB_Rx" table for query on "088763."

Active Ingredient: CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE
Dosage Form;Route: SYRUP; ORAL
Proprietary Name: PROMETH W/ CODEINE
Applicant: ACTAVIS MID ATLANTIC
Strength: 10MG/5ML;6.25MG/5ML
Application Number: 088763
Product Number: 001
Approval Date: Oct 31, 1984
Reference Listed Drug: Yes
RX/OTC/DISCN: RX
TE Code: **AA**
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: January 29, 2007

Patent and Exclusivity Search Results from query on Appl No 088763 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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