CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-282

PHARMACOLOGY REVIEW

HFD-570: DIVISION OF PULMONARY AND ALLERGY DRUG PRODUCTS
REVIEW AND EVALUATION OF PHARMACOLOGY AND TOXICOLOGY DATA
Original Review

Reviewer: C. Joseph Sun, Ph.D.

Review Completion Date: April 9, 2001

NDA 21282

Date/type of submission: Original, June 29, 2000 and Correspondence, Jan. 5, 2001

Information to be conveyed to Sponsor: Yes ( ) No (x)

Sponsor: Adams Laboratories, Inc

Drug Name: Guaifenesin Extend Release (ER) 600 mg.

Chemical name:

Class: expectorant

Indication: Helps loosen phlegm and thin bronchial secretion in patient with stable chronic bronchitis.

Clinical formulation:

Guaifenesin	
(guaifenesin & hydroxypropyl methyl cellulose)	
Microcrystalline Cellulose	
Sodium Starch Glycolate	
Hydroxypropyl Methylcellulose	
Carbomer 934P	
Magnesium Stearate	
Total	

Route of administration: Oral (tablet)

Proposed recommended dosage:

Adults and adolescents 12 years of age and over: one or two 600 mg tablets every 12 hrs, not to exceed 2400 mg in a 24-hr period.

Introduction and drug history:

Guaifenesin is an active ingredient of approved OTC cough drug products (21CFR 341.18). It is a well-known expectorant and has been used widely in the United States and is generally recognized as safe and effective. It has undergone regulatory review through the monograph process and the monograph for expectorant drug products was published. Currently guaifenesin is approved for immediate release tablets dosed every four hours or six times a day. Patient compliance with this is known to be poor. This ER formulation is intended to facilitate patient compliance with a twice-daily dosage.

Studies reviewed: No preclinical studies were submitted.

Overall summary and evaluation:

Guaifenesin is considered to be an expectorant active ingredient. It enhances the output of respiratory tract fluid by reducing adhesiveness and surface tension, facilitating the removal of viscous mucus. It provides symptomatic relief of respiratory conditions characterized by dry nonproductive cough.. It is generally recognized as safe and effective. A monograph for the OTC immediate release formulation has been published (CFR 341.18).

The recommended dosage of the proposed extended release formulation is the same as the currently approved immediate release product (CFR 341.78).

Animal studies to assess the carcinogenic and mutagenic potential or the effect on fertility in animals have not been performed. Animal reproductive studies to assess it developmental or teratogenic effects have not been conducted. Thus, a pregnancy category C is an appropriate designation.

The labeling of the product is in compliance with 21 CFR 341.78 labeling of expectorant drug products.

Recommendation:

The product is approvable from a preclinical perspective.

C. Joseph Sun, Ph. D.

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/s/

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