Questions and Answers about FDA's Enforcement Action Against Unapproved Timed-Release Products Containing Guaifenesin

FDA has developed these questions and answers (Q & A's) to help consumers, health care practitioners, and the general public understand FDA's actions regarding unapproved timed-release products containing guaifenesin. These Q & A's are not intended to be used, and cannot be used, to determine whether a particular product is covered by the action that is the subject of this document or to determine how to comply with the law and FDA policies regarding timed-release products containing guaifenesin.

Q. What action is FDA taking concerning timed-release drug products containing guaifenesin?

A. The U.S. Food and Drug Administration (FDA) has ordered companies to stop marketing unapproved drug products in timed-release dosage forms that contain guaifenesin, an expectorant commonly used in medicines to relieve cough and cold symptoms. FDA took the action as part of its effort to ensure that all drugs marketed in the United States have the required FDA approval and that they are safe, effective, of good quality, and are appropriately labeled.

The notice applies to any drug product in a timed-release form containing guaifenesin, including combination drug products in which the guaifenesin is in immediate release form but another ingredient in the combination drug product is in timed-release form.

Manufacturers must stop making these products within the next 90 days, and stop shipping the products interstate within the next 180 days. After these dates, only FDA-approved timed-release drug products containing guaifenesin may be manufactured and shipped interstate.

The FDA estimates that about 20 companies manufacture unapproved timed-released drug products containing guaifenesin, and that about 65 others distribute these products under their own name but do not manufacture them. Unapproved timed-release drug products containing guaifenesin may be marketed under many different trade names or may simply be identified by the active ingredient(s).

This action is outlined in 72 *Federal Register* 29517 of May 29, 2007.

Q. What is guaifenesin?

A. Guaifenesin is an expectorant, a drug taken by mouth that promotes or facilitates the removal of secretions from the respiratory airways. It is used in both prescription and over-the-counter medicines. Many products containing guaifenesin are intended to relieve multiple cold symptoms and contain other active ingredients that, for instance, relieve nasal congestion, reduce fever, suppress cough, or relieve pain. Drugs that contain guaifenesin are indicated to loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus, drain bronchial tubes, and make coughs more productive.

Q. Why is FDA taking this action?

A. When drugs lack required FDA approval, consumers and health care providers cannot be assured that those drugs are safe, effective, accurately labeled, and properly manufactured. For products in timed-release form, FDA approval is also necessary to ensure that the product is made so that the active ingredients are released at the correct rate. Improperly manufactured timed-release products may release the active ingredients too quickly, too slowly, or not at all, making the product unsafe or ineffective. FDA has stated in a regulation since 1959 that drugs in this form need to be reviewed and approved by the FDA.

Q. What are timed-release products?

A. Timed-release products are medicines that release their active ingredient(s) over a period of time, rather than all at once, so that they can be taken less frequently than immediate release products. Medicines in timed-release form are often labeled as extended-release, controlled-release, sustained-release, or long-acting, or with the initials ER, CR, SR, or LA.

Q. Will FDA allow any timed-release drug products containing guaifenesin to remain on the market?

This action does not affect the six FDA approved timed-release drug products containing guaifenesin. These six products are manufactured by Adams Respiratory Therapeutics, Inc., formerly known as Adams Laboratories, Inc. Some of the Adams products contain guaifenesin only; some contain guaifenesin in combination with dextromethorphan, a cough suppressant; and others contain guaifenesin in combination with pseudoephedrine, a nasal decongestant. The Adams products are sold over-the-counter (OTC) under the names Mucinex and Humibid. The chart below shows the six approved Adams products with their active ingredients and strengths. (Products marked with an asterisk (*) are not marketed at this time; consumers interested in these products may contact Adams for further information.)

Trade Name	Active Ingredient(s)
Mucinex	Guaifenesin, 600 mg
Humibid	Guaifenesin, 1200 mg
Mucinex DM	Guaifenesin, 600 mg, Dextromethorphan, 30 mg
Mucinex DM	Guaifenesin, 1200 mg, Dextromethorphan, 60 mg *
Mucinex D	Guaifenesin, 600 mg, Pseudoephedrine, 60 mg
Mucinex D	Guaifenesin, 1200 mg, Pseudoephedrine, 120 mg *

Under today's action, previously-manufactured unapproved timed-release drug products containing guaifenesin may still be found on pharmacy shelves and in consumers' homes for a short period of time. Consumers should talk to their health care provider about whether or not to use unapproved timed-release drug products.

Q. Does the action affect products containing guaifenesin that are not in timed-release form?

A. There are many legally marketed, over-the-counter immediate release products containing guaifenesin, both as guaifenesin alone and in combination with other ingredients to treat the

symptoms of coughs and colds. Immediate release drug products containing guaifenesin are unaffected by today's action and will remain on the market.

Q. The approved timed-release drug products containing guaifenesin are marketed over-the-counter, while many of the unapproved products are marketed by prescription only and are therefore covered by some health insurance plans. Why are the approved products available only over-the-counter?

A. When FDA approved the Adams timed-release drug products containing guaifenesin, the agency concluded that these products met the legal criteria for over-the-counter sale. These products can be used safely and effectively by consumers without the supervision of a health care practitioner, if the drugs are used as directed in the labeling. The FDA realizes that some consumers take unapproved prescription timed-release drug products containing guaifenesin that are covered by their health insurance, and that insurance reimbursement may no longer be available. The lack of reimbursement for these consumers is likely to be offset because the consumers will no longer need to pay to see a health care provider to get a prescription for these products.

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