

FDA Approval Of Guaifenesin Products Denied

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With one exception, timed-release drug products available in the United States that contain the expectorant guaifenesin have not been approved by the Food and Drug Administration and should be taken off the market, according to an agency announcement.

About 20 companies manufacture these products, most of which are by prescription only. They include Guaifex (manufactured by Ethex Corp.), Crantex and Guaifen (Breckenridge Pharmaceutical Inc.), Amibid and Amitex (Actavis Group), Duraphen (Proethic Pharmaceuticals Inc.), Wellbid (Prasco), Ambi (Ambi Pharmaceuticals Inc.), and Maxifed (MCR American Pharmaceuticals Inc.). Many include other active ingredients, said the FDA.

The agency ordered manufacturers of these unapproved products to stop making them no later than Aug. 27 and to cease interstate shipment by Nov. 25, although some inventory will remain in pharmacies after that time. The action does not affect immediate-release formulations of guaifenesin, only timed-release formulations, which are also described as extended release, long acting, or sustained release.

The only timed-release products containing guaifenesin that have been formally approved by the FDA are those marketed over the counter as Mucinex or Humibid, by Adams Respiratory Therapeutics. Beside Mucinex and Humibid, which contain only guaifenesin, the company makes Mucinex-D, which also contains pseudoephedrine, and Mucinex-DM, which also contains dextromethorphan.

Timed-release products must be approved because the FDA needs to ensure that "the product releases its active ingredients safely and effectively, sustaining the intended effect over the entire time in which the product is intended to work," said the FDA statement. Dose dumping is a major concern with these products, Deborah M. Autor, an attorney and director of the office of compliance in the FDA's Center for Drug Evaluation and Research (CDER), said in a telebriefing. The FDA did not look into whether there were any reports of adverse events linked to the unapproved guaifenesin products; adverse event reports did not spur this action, she said.

The guaifenesin products are the latest target of an FDA effort, announced in June 2006, to get unapproved, potentially dangerous drugs off the market. The first products targeted were unapproved prescription products containing the antihistamine carbinoxamine, which had been linked to 21 deaths in children under age 2. Others targeted since then include unapproved products containing quinine (December 2006), and unapproved products containing ergotamine (March 2007). ■

The FDA's Web site on unapproved drugs is available at www.fda.gov/cder/drug/unapproved_drugs/default.htm.

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