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## Deadlines set for unapproved drugs

By Rita Rubin, USA TODAY

WASHINGTON — The Food and Drug Administration on Friday announced it is giving manufacturers of unapproved cough and cold remedies containing timed-release guaifenesin, an expectorant, until Aug. 27 to stop making their products. They have until Nov. 26 to stop shipping such products across state lines.

Because the companies never sought approval for the products, "FDA has not determined that they are safe and effective as formulated and manufactured," Deborah Autor, director of the Office of Compliance at the FDA's Center for Drug Evaluation and Research, said at a press conference.

About 20 companies make timed-release products that combine guaifenesin with a cough suppressant or other drug, and 65 distribute them, Autor said. Among the biggest sellers, she said, are Guaifenex, from Ethex Corp.; Crantex, from Breckenridge Pharmaceutical; and Amibid, from Acavis.

The move, part of a stepped-up effort to crack down on unapproved drugs, does not affect products that contain guaifenesin in immediate-release form, such as Robitussin. Since 1959, though, Autor said, the FDA has had a regulation stating that timed-release products are new drugs requiring agency approval. The FDA wants to make sure that timed-release pills really work as long as their manufacturers claim they do, she said.

As 2,000 or more prescription products sold in the U.S. are unapproved, the FDA has estimated. They are sold in drugstores and are listed in the *Physicians Desk Reference*, so many doctors who prescribe them are unaware that they are not FDA-approved.

"We're doing extensive outreach on this with the health care community," Michael Levy, director of the Division of New Drugs and Labeling Compliance in Center for Drug Evaluation and Research, said Friday.

In February, the agency sent warning letters to 20 makers of unapproved headache remedies containing ergotamine. And last June, the FDA ordered makers of unapproved products containing carbinoxamine, a sedative, to take them off the market. The agency said it had received 21 reports of deaths in children under 2 years of age who had taken an unapproved carbinoxamine product.

The only FDA-approved timed-release products containing guaifenesin are the Mucinex line, made by Adams Respiratory Therapeutics in Chester, N.J. After the FDA approved Mucinex, whose only ingredient is timed-release guaifenesin, in 2002, the agency told makers of unapproved versions to stop selling their products by Dec. 1, 2003.

Adams received FDA permission to market Mucinex DM, a timed-release product containing guaifenesin and dextromethorphan, a cough suppressant, in 2004, and Mucinex D, a timed-release product containing guaifenesin and pseudoephedrine, a decongestant, in 2005. But hadn't taken action against the unapproved combination products until now.

In a statement, Adams CEO Michael J. Valentino, commented: "We are extremely pleased with the FDA announcement today. Our initial review of this regulatory action is underway and we expect to be able to serve the additional market demand for our products as it develops."

