FDA Cracks Down on Unapproved Rx Drugs

BY ALICIA AULT
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The Food and Drug Administration announced it is renewing efforts to remove all drugs currently sold by prescription either go through its formal approval process or be taken off the market.

The agency has periodically targeted some of these products using its existing authority. Now, the FDA has issued more formal guidance that spells out for manufacturers how it will prioritize enforcement, and what route they can take to prove safety and efficacy of their products.

There are many reasons why unapproved products are on the market, said Dr. Steven Galson, director of the FDA’s Center for Drug Evaluation and Research. “This is a very difficult market,” said Mr. Galson, “and we want manufacturers to understand if what they’re selling is marketed in the U.S. is effective and safe.”

Many of the unapproved drugs are listed in the Physicians’ Desk Reference. Some are advertised in medical journals.

Carbinoxamine Products Targeted

A part of a wider crackdown on the marketing of unapproved drugs, the Food and Drug Administration has notified manufacturers of many unapproved carbinoxamine-containing products that they must submit safety and efficacy data by September or be subject to enforcement action, which could include a forced recall.

The FDA said it was targeting carbinoxamine because of safety concerns, including 21 deaths since 1983 in children under age 2 that may be related to the ingredient. Infants and young children are vulnerable to adverse events with products containing carbinoxamine because there are so many differences, formulations, and combinations of active ingredients, according to the FDA.

Carbinoxamine, a sedating antihista-
mine, was first marketed in 1953. Four combinations of active ingredients, according to the FDA, were approved in 2003. “We are satisfied that these products meet the FDA approval requirements,” said Deborah M. Autor, FDA associate director for compliance policy, at a press briefing sponsored by the agency.

But as many as 120 carbinoxamine-containing drugs are being marketed without the agency’s approval, Ms. Autor said, adding that there may be more not listed with the FDA. Many are sold as prescription cough and cold formulations, but the FDA has not found carbinoxamine to be safe or effective for that indication. And they are often labeled for use in children under age 1, even as young as 1-3 months, said the agency.

Under the new directive, unap-
proved carbinoxamine products will be allowed to stay on pharmacy shelves through September, said Ms. Autor. But the companies must submit new drug applications by that time.

Before prescribing an unapproved carbinoxamine-containing preparation, physicians should consider the patient’s medical condition, previous response to the drug, and whether approved alternatives are more suitable, according to the FDA.

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Carbinoxamine Products Targeted

In-Office AIDS Test, Please

Americans would much prefer to be tested for AIDS in a physician’s office or clinic, instead of performing a home test, according to a survey of 2,500 adults by the Kaiser Family Foundation. Over all, 88% of respondents prefer a doctor’s office or clinic, compared with 26% who preferred home testing; only 10% said the location did not matter. However, respondents did think home testing should be an option; 65% said home tests help people who otherwise would not learn their HIV status. On the other hand, 27% agreed with the statement that home tests are “a bad idea” because people need counseling that is available only in a physician’s office or clinic. HIV testing should be treated like any routine screening and included as part of regular check-ups and exams, according to 65% of respondents. Slightly more than one-fourth (27%) of respondents disagreed; instead, they agreed with the statement that HIV testing is different and requires special procedures such as written permission from the patient.

MinuteClinic: Quality Council

MinuteClinic, the nation’s largest provider of retail-based health care, has created a National Clinical Quality Advisory Council. The eight-member council has five physicians, including a representative of the American Academy of Family Physicians. To develop its own standards, MinuteClinic has consulted with the American Academy of Pediatrics and the American Academy of Family Physicians. To develop its own standards, MinuteClinic has consulted with the American Academy of Pediatrics and the American Academy of Family Physicians.

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