FDA Demands Approval Data on Carbinoxamine

BY ALICIA AULT
Associate Editor, Practice Trends

As 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 the drug because there are so many different strengths, formulations, and combinations of active ingredients, according to the FDA.

Carbinoxamine, a sedating antihistamine, was first marketed in 1953. Four products are FDA-approved to treat allergic reactions: Palgic Carbinoxamine Maleate Oral Solution (4 mg/5 mL), PamLab LLC; Palgic Carbinoxamine Maleate Tablets (4 mg), PamLab LLC; Carbinox Maleate Solution, Physicians Total Care; and Palgic Carbinoxamine Maleate Tablets USP (4 mg), Physicians Total Care. All four are manufactured by Mikart Inc. of Atlanta, and 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 2, even as young as 1-3 months, said the agency.

Under the new directive, unapproved 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 preparation, physicians should consider the patient's medical condition, previous response to the drug, and whether approved alternatives might be more suitable, according to the FDA.

Physicians, patients, and pharmacists can continue to check the FDA's Web site (www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm) to see if more products have been approved. ■

Apply Now for New Identifier, Physicians Urged

Physicians need to apply now for a national provider identifier number in order to start using them in May 2007, according to the Centers for Medicare and Medicaid Services.

The national provider identifier (NPI) is a 10-digit number that does not expire or change; it is used to speed claims processing. The Health Insurance Portability and Accountability Act mandates that the NPI be used for all standard health care transactions involving both public and private payers starting on May 23, 2007. Small health plans, defined as having annual receipts of $5 million or less, are given an additional year to comply.

A physician needs only one NPI, regardless of the number of specialties, licenses, or practice locations he or she may have. Once assigned to the physician, that number will stay with him or her through job changes and relocations.

Physicians will need to have several numbers on hand before applying, such as their health care license number or certificate number and any "legacy identifiers," such as a unique physician identification number (UPIN).

Numbers issued by Medicaid and other health plans also need to be included in the application.

—Nancy Nickell

Apply online for an NPI at https://NPPES.cms.hhs.gov; or call 800-465-3203 for a paper application. For more information, go to www.cms.hhs.gov/apps/npi/01_overview.asp.