

Allergic reactions associated with food

X Do you routinely check the inactive ingredients of a drug product? Do you routinely ask patients about food allergies in addition to drug-related allergies? If you answered *no* to these questions, then you may not be aware that some patients with food allergies may have allergic reactions to ingredients in some drug products.

The Food & Drug Administration has received reports that patients with severe allergies to milk protein reacted to traces of this ingredient contained in some products. An article in the *Journal of Allergy and Clinical Immunology* cited a report of an asthmatic patient with severe milk allergy who experienced a serious allergic reaction following administration of Advair Diskus, a lactose-containing product. The article stated that the reactions were attributed to milk protein in the lactose filler. Additionally, the authors indicated that the amount of milk protein might vary from batch to batch. This was evident, as the patient previously received Advair without experiencing any allergic reaction.

Lactose, as well as other excipients in these products, is controlled by the FDA and is required to meet manufacturing specifications. Some variation in content within these specifications is acceptable. A small number of milk protein-sensitive patients may be extraordinarily sensitive, and some of these individuals may react to milk protein in the lactose excipient. However, the amount of milk protein in the lactose excipient is low enough that Advair is tolerated by many patients with milk protein allergy. Other currently marketed dry powder inhalers that contain milk protein include Serevent Diskus and Foradil Aerolizer. The package inserts of these inhalers mention the presence of lactose, which is derived from milk, in the

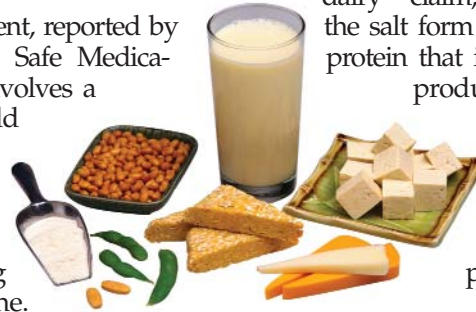
Description section as well as the Adverse Reactions section of the labeling.

Another incident, reported by the Institute for Safe Medication Practices, involves a soy-allergic child whose mother had purchased Benadryl Fast-melt, a product containing diphenhydramine.

Loading the child's backpack, the mother noticed that "soy protein isolate" was listed in the ingredients section of the side panel of the label. This product might have been given to the child had the parent not noticed the inactive ingredients.

Some healthcare practitioners and consumers may not be familiar with the terminology used to describe an ingredient that may cause an allergic reaction in patients with food allergies. Do you know what the inactive ingredient *casein* is? Casein is one of the two main allergens found in milk protein. The FDA received one report in which a child with a preexisting allergy to dairy products suffered an allergic reaction following ingestion of Chewable Calcium 600 with Vitamin D, manufactured by Mason Vitamin. The child was taken to the emergency room and treated with Benadryl. The product's container label states that the product is "Free of starch, yeast, soy, wheat, dairy, gluten, egg, fragrance, artificial colors, and preservatives." However, the Other Ingredients sec-

tion of the label lists the ingredient *sodium caseinate*. Despite the "free of ... dairy" claim, sodium caseinate, the salt form of casein, is a milk protein that is usually added to products like creamers and cheese and may cause allergic reactions in patients with allergies to dairy products.



Recommendations

Avoidance is the treatment of choice for food allergy. However, some clinical judgment is involved in the choice of drug treatment for these patients. Consultation with an allergist may be helpful, as many patients with a mild protein allergy can tolerate the low amount of milk protein found in products such as Advair. Healthcare practitioners should routinely ask patients for drug allergies as well as food allergies. Patients should be instructed to read all product labels and be familiar with milk protein-related terminology; not all labels clearly indicate allergens. If patients are unsure whether a particular ingredient may be an allergen, they should ask their pharmacist or healthcare provider for assistance before administration.

All patients with food allergies who have a severe allergic reaction should carry an Epi-pen, because an antihistamine alone is not sufficient. To better improve their chances of early intervention, it is also helpful to warn patients about the possible symptoms associated with an allergic reaction and/or when to seek emergency treatment.

By
Alina R. Mahmud, R.Ph., M.S.,
 and
Carol Holquist, R.Ph.



LCDR Alina R. Mahmud is Team Leader and Carol Holquist is Director of the Division of Medication Errors and Technical Support, Office of Drug Safety, at the Food & Drug Administration. The authors wish to acknowledge the assistance of pharmacy intern Emmanuel Testfaye.

Photos: PhotoDisc

To report a problem with an FDA-regulated product, please call 1-800-FDA-1088.