

We are notifying members about a recent safety alert from the FDA, regarding allergen extracts used for food allergy skin testing.

On March 3, 2023, the FDA released a safety communication entitled: FDA Requires Warning about Anaphylaxis Following False Negative Food Allergen Skin Test Results in the Prescribing Information for All Allergenic Extracts for Diagnosis of Food Allergy (available at: <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-requires-warning-about-anaphylaxis-following-false-negative-food-allergen-skin-test-results>).

The FDA had identified four lots of peanut extract from ALK-Abello that were associated with several cases of subsequent peanut anaphylaxis (false negative tests), and these lots were recalled.

The FDA determined that the risk of anaphylaxis following false negative food allergen skin test results is applicable to all allergenic extracts for the diagnosis of food allergies. Therefore, the FDA initiated safety labeling changes for all allergenic extracts for the diagnosis of food allergy to include a warning regarding anaphylaxis following possible false negative food allergen skin test results.

The label warning is:

Anaphylaxis Following False Negative Food Allergen Skin Test Results

False negative skin test results associated with anaphylaxis from subsequent exposure to the allergen have been reported during postmarketing diagnostic use of some food allergenic extracts. Based on the patient's clinical history and the index of suspicion, healthcare providers should consider confirming negative skin testing with serologic testing by measuring specific serum IgE or with a medically-supervised oral food challenge.

The FDA also posted information for patients and healthcare providers as follows:

Information for Patients

- Some people who have had false negative food allergen skin test results, have experienced anaphylaxis after subsequent exposure to the food allergen.
- Discuss negative food allergen skin test results with your healthcare provider to determine if any further testing is needed to evaluate for food allergy.
- Symptoms of a severe allergic reaction (including anaphylaxis) that may require emergency treatment can include:
 - Difficulty breathing
 - Swelling of the face and throat
 - A fast heartbeat
 - A bad rash all over the body
 - Dizziness and weakness

Information for Healthcare Professionals

- Some people who have had false negative food allergen skin test results, have experienced anaphylaxis after subsequent exposure to the food allergen.
- Based on the patient's clinical history and the index of suspicion, healthcare providers may wish to confirm negative skin testing with serologic testing for peanut-specific IgE or a medically-supervised oral food challenge.
- Do not use product from the four lots voluntarily withdrawn by the manufacturer that are listed on the FDA website: [Voluntary Lot Withdrawals of Allergenic Extract – Peanut \(*Arachis hypogaea*\)- For Diagnostic Use Only, Manufactured by ALK-Abelló, Inc. for Increased Reports of False Negative Test Results](#).

While the ACAAI and AAAAI appreciate that the FDA is being proactive, and is also acknowledging the role of the clinical history and the healthcare professional's clinical judgment, we are concerned that labeling all food extracts for skin testing in this manner is unnecessary. We believe the new label statement could as well be applied to food-specific serum IgE testing or any test in medicine where the result could on any occasion not match an expectation within clinical judgment, and where a clinician may wish to choose an alternative test.

In this case, we anticipate that the new labeling could be over-interpreted, resulting in over-testing, over-diagnosis, reduced quality of care, and increased health care costs.

With these multiple potential negative consequences, the ACAAI and AAAAI are requesting further discussion with FDA to remove or revise these new statements.