Our STN: BL 101376/5054

NOTIFICATION
SAFETY LABELING CHANGE
January 12, 2023

Allergy Laboratories, Inc.
Attention: Katie Tucker
1005 S.W. 2nd Street
Oklahoma City, OK 73109

Dear Katie Tucker:

Please refer to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Multiple Products: Non-standardized Allergenics.

Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA) authorizes FDA to require holders of approved drug and licensed biological product applications to make safety related labeling changes based upon new safety information that becomes available after approval of the drug or biological product.

Since your license for Multiple Products: Non-standardized Allergenics, was approved on June 14, 1930, we have become aware of increased postmarketing adverse event reporting of false negative skin test results with another manufacturer's Non-standardized Peanut (*Arachis hypogaea*) Allergenic Extract. Some of these reports of false negative test results have been associated with anaphylaxis from subsequent exposure to peanut. For additional information please see CBER safety communication at 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 | FDA and a posting under *Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS)* for Allergenic Extract – Peanut (*Arachis hypogaea*) – For Diagnostic Use Only, manufactured by ALK Abelló, Inc, available at July - September 2022 | Potential Signals of Serious Risks/New Safety Information Identified by the FDA Adverse Event Reporting System (FAERS). We consider this information to be "new safety information" as defined in section 505-1(b)(3) of the FDCA. Furthermore, we consider the risk of anaphylaxis following false negative food allergen skin test results to be applicable to all allergenic extracts used for diagnosis of food allergies.

In accordance with section 505(o)(4) of the FDCA, we are notifying you that based on the new safety information described above, we believe that the new safety information should be included in the labeling for all allergenic extracts used for diagnosis of food allergies. For Allergenic Extracts, we believe that the new safety information should be included in the labeling as follows:

1. In the Warnings section of the Prescribing Information (PI), addition of a new subsection to follow the existing information on immediate severe allergic reactions (i.e., include a second subsection):

   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.

2. Please include new subsection titles for the existing paragraphs on immediate allergic reactions and reasons to temporarily withhold diagnostic testing and immunotherapy (e.g., Severe Allergic Reactions and Withholding Diagnostic Testing or Immunotherapy/Dose Reduction, respectively).

In accordance with section 505(o)(4), within 30 calendar days of the date of this letter, you must submit a supplement proposing changes to the approved labeling in accordance with the above direction or notify FDA that you do not believe a labeling change is warranted and submit a rebuttal statement detailing the reasons why such a change is not warranted. If you submit a supplement that includes only language identical to that specified above, the supplement may be submitted as a changes being effected (CBE-0) supplement. If the supplement includes proposed language that differs from that above, submit a prior approval supplement (PAS).

Under section 505(o)(4), if you fail to submit a response within 30 calendar days, you would be in violation of the FDCA that may deem your product to be misbranded under section 502(z) and may subject you to enforcement action, including civil monetary penalties under section 303(f)(4)(A) and an order to make whatever labeling changes FDA deems appropriate to address the new safety information.

Please submit your safety labeling submission to STN 101376/5054.

Prominently identify the submission with the following wording in bold capital letters at the top of the first page of the submission, as appropriate:

SAFETY LABELING CHANGES UNDER 505(o)(4) - PRIOR APPROVAL SUPPLEMENT

OR

SAFETY LABELING CHANGES UNDER 505(o)(4) – CHANGES BEING EFFECTED

OR

SAFETY LABELING CHANGES UNDER 505(o)(4) – REBUTTAL (CHANGE NOT WARRANTED)."

Prominently identify subsequent submissions related to the safety labeling changes supplement with the following wording in bold capital letters at the top of the first page of the submission:

SAFETY LABELING CHANGES UNDER 505(o)(4) - AMENDMENT

If you have any questions, please contact the Regulatory Project Manager, Margaret Dayhoff-Brannigan, PhD, by email at Margaret.dayhoff-brannigan@fda.hhs.gov.

Sincerely,

Narayan Nair, MD
Director
Division of Pharmacovigilance
Office of Biostatistics and Pharmacovigilance
Center for Biologics Evaluation and Research