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February 17, 2025

Jay E. Slater, MD
Division of Bacterial, Parasitic, & Allergenic Products
Office of Vaccine Research and Review
Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: Ensuring Access to Allergen Extracts for Patch Testing in Dermatology

Dear Dr. Slater,

On behalf of the American Academy of Dermatology Association (Academy), I would like to thank you for the opportunity to meet with the Food and Drug Administration (FDA) Office of Compliance and Biologics Quality (OCBQ), and the Office of Vaccines Research and Review (OVRR) to discuss the importance of patch testing in dermatology, the impact of Import Alert 57-15¹, and additional opportunities to collaborate to maintain patient access to allergenic products. **The Academy supports FDA's efforts to ensure safe and effective haptens for patch testing and urges that the agency work collaboratively with the Academy to address regulatory challenges and safeguard patient access to these essential diagnostic tools.**

As the leading society in dermatological care, representing nearly 17,500 dermatologists nationwide, the Academy is committed to excellence in the medical and surgical treatment of skin disease, advocating for high standards in clinical practice, education, and research in dermatology and dermatopathology; and driving continuous improvement in patient care and outcomes while reducing the burden of disease.

Patch testing is an important tool used in dermatology to assist in diagnosing allergic contact dermatitis, one of the most common occupational diseases caused by the workplace.² Timely diagnosis of allergic

¹ See Food and Drug Administration, "Detention Without Physical Examination of Unlicensed Allergenic Products" (Oct. 30 2024). https://www.accessdata.fda.gov/cms_ia/importalert_154.html

² Matthew Elias, Iltefat Hamzavi, Benjamin Stoff, American Academy of Dermatology, "Eczema Types: Contact Dermatitis Causes" (Dec. 14 2020). <https://www.aad.org/public/diseases/eczema/types/contact-dermatitis/causes>

CORRESPONDENCE

PO Box 1968
Des Plaines, IL 60017-1968

EMAIL: mrc@aad.org
WEB: aad.org

ROSEMONT, IL OFFICE

9500 W Bryn Mawr Avenue, Suite 500
Rosemont, IL 60018-5216

MAIN: (847) 330-0230
FAX: (847) 240-1859

WASHINGTON, DC OFFICE

1201 Pennsylvania Avenue, NW, Suite 540
Washington, DC 20004-2401

MAIN: (202) 842-3555
FAX: (202) 842-4355

reactions is essential to reducing unnecessary healthcare costs and improving patient outcomes as well as quality of life, particularly among vulnerable patient populations and workers with frequent exposure to common allergens.

The effectiveness of patch testing relies on the consistent availability of haptens for the diagnosis of allergic contact dermatitis. However, a limited number of allergen extract manufacturers can pose challenges for the physicians and patients who rely on these products. Supply disruptions may restrict patients' access to high-quality care, delaying diagnoses and increasing the risk of complications. The Academy recognizes that limited availability of allergen extracts can result in prolonged allergen exposure, worsening symptoms, unnecessary treatments, and a diminished quality of life for affected patients.

The Academy supports the FDA's ongoing initiatives to enhance access to safe and effective allergens, and urges that the agency engage in regular, ongoing dialogue with the Academy to ensure that patients have continued access to these important products. The Academy highly recommends establishing policies that promote stable access to new and existing allergenic products that support patient care, improve patients' health outcomes, and alleviate the burden caused by undiagnosed or untreated allergic skin disease. Additionally, we would greatly appreciate any updates regarding the timing of the FDA Patch Testing Workshop, as we look forward to the opportunity to contribute to this important discussion.

Thank you again for the opportunity to meet with your office to discuss the importance of allergenic products in dermatology. The Academy remains a resource to the FDA in ensuring patient access to safe and effective allergenic products. Please do not hesitate to reach out to Nija Chappel, JD, MPH, Manager, Regulatory Policy, at nchappel@aad.org if you have any questions or need additional information. Thank you for your time and consideration.

Sincerely,

A handwritten signature in cursive script that reads "Seemal R. Desai MD FAAD".

Seemal R. Desai, MD, FAAD
President, American Academy of Dermatology Association

CC: Melissa Mendoza, Office of Compliance and Biologics Quality, CBER