American Academy of
Allergy Asthma & Immunology

December 7, 2017

Scott Gottlieb, MD
Commissioner
Food and Drug Administration (FDA)
c/o Dockets Management Staff (HFA-305)
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

In Re: Docket No. FDA–2017–N–5101, Review of Existing Center for Drugs Evaluation and Research Regulatory and Information Collection Requirements

Submitted electronically at www.regulations.gov

Dear Dr. Gottlieb:

The American Academy of Allergy, Asthma, and Immunology (AAAAI) thanks the Food and Drug Administration (FDA or Agency) for soliciting information related to providing appropriate regulatory relief. Established in 1943, AAAAI is a professional organization with more than 7,000 members in the United States, Canada, and 72 other countries. This membership includes board certified allergist/immunologists, other medical specialists, allied health and related healthcare professionals – all with a special interest in the research and treatment of patients with allergic and immunological diseases.

Maintain Access to Allergy Shots

The AAAAI asks that you **ensure patients have continued access to allergen immunotherapy (AIT), also known as "allergy shots"**. Allergy/immunology (A/I) physicians prepare allergen extracts based on individual patient's allergies, and have developed specific expertise in how to prepare these allergen extracts for their patients that is not shared by other pharmaceutical compounders. In fact, A/I physicians have been providing AIT for over 100 years, improving the quality of life for millions and saving the lives of those with potentially deadly anaphylactic reactions to certain allergens, such as stinging insects. A/I physicians have been providing this treatment to millions of patients under safety standards established by the United States Pharmacopeia (USP) in 2007, and there are no data to show that this practice has resulted in any serious infections. In addition, a 2013 report by the Agency for Healthcare Research and Quality[1] concluded that AIT is both safe

(more)

[1] http://www.ncbi.nlm.nih.gov/books/NBK133240/

and effective. AIT has long been known to prevent the development of new allergies and asthma; it also reduces overall healthcare costs.[2]

In August 2016, the FDA issued draft guidance -- *"Insanitary Conditions at Compounding Facilities"* -- that sets forth new standards (e.g., requiring physicians that compound drugs in their offices to have engineering control devices capable of maintaining an ISO Class 5 environment or be deemed "insanitary") without scientific evidence to suggest this level of precaution is warranted. Moreover, the process under which these new standards are being established circumvent ongoing deliberations to update USP General Chapter <797>, which FDA currently recognizes as required under statute. As the Agency works to craft final guidance, we urge you to take into account the use of "allergy shots" and ensure continued patient access.

For additional information or if you have any questions, please contact Sheila C. Heitzig, JD, MNM CAE, AAAAI's Director of Practice & Policy at 414-272-6071 or sheitzig@aaaai.org.

Sincerely,

David B. Peden, MD MS FAAAAI
President

[2] https://www.ncbi.nlm.nih.gov/pubmed/25887973