



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration  
10903 New Hampshire Avenue  
Building #51  
Silver Spring, MD 20993

**MAY 15 2014**

Nancy Sander  
President & Founder, Allergy & Asthma Network Mothers of Asthmatics  
8201 Greensboro Drive  
Ste. 300  
McLean, VA 22102

Re: Docket No. FDA-2013-P-0711

Dear Ms. Sander:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on June 13, 2013, and submitted on behalf of Allergy & Asthma Network Mothers of Asthmatics, et. al. Your petition requests that the Agency promulgate regulations, pursuant to section 505 (21 U.S.C. § 355), of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to exempt from compliance, modify or waive the requirements for compliance under sections 503(b), 505(d)(1) and (d)(4) for OTC monographs, and specifically exempt asthma and anaphylaxis medications from OTC non-prescription drug status.

FDA has been unable to reach a decision on your petition because it raises significant issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

A handwritten signature in black ink, appearing to read "Jane A. Axelrad", is written over the typed name. The signature is fluid and cursive.

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research