



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

June 13, 2013

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

Dear Ms. Sander:

Your petition to the Food and Drug Administration on behalf of American Academy of Allergy, Asthma and Immunology, the American Association for Respiratory Care, the American College of Allergy, Asthma & Immunology, the American Latex Allergy Association, the American Thoracic Society, and the American Chronic Obstructive Pulmonary Disease Foundation requesting action to promulgate regulations, pursuant to section 505 (21 U.S.C. 355), of the Federal Food, Drug and Cosmetic Act ("FDCA") 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 exempts asthma and anaphylaxis medications from OTC non-prescription drug status, was received by this office on 06/13/2013. It was assigned docket number FDA-2013-P-0711/CP1, and it was filed on 06/13/2013. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

A handwritten signature in cursive script, reading "Gloria Ortega", is positioned above the typed name.

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)