



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

August 28, 2013

**FILE COPY**

Marcus M. Reidenberg, MD  
Weill Cornell Medical College  
1300 York Ave., Box 70  
New York, NY 10065

Dear Dr. Reidenberg:

Your petition to the Food and Drug Administration requesting the Agency to add a warning to the labeling of all nonprescription drugs products containing an ingredient with anticholinergic or histamine H1 inverse agonist effects, was received by this office on 8/16/2013. It was assigned docket number FDA-2013-P-1001/CP1, and it was filed on 8/16/2013. 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 "Karen Kennard", is positioned above the typed name.

Karen Kennard  
Director  
Division of Dockets Management  
FDA/Office of the Executive Secretariat (OES)