DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 4 2014

Marcus M. Reidenberg, M.D., F.A.C.P.
Weill Cornell Medical College
1300 York Avenue, Box 70
New York, NY 10065

Re: Docket No. FDA-2013-P-1001

Dear Dr. Reidenberg:

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 August 16, 2013. Your petition requests that FDA require the addition of a warning to the labeling of all nonprescription drug products containing an ingredient with anticholinergic or histamine H1 inverse agonist effects.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by FDA 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,

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