DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 14 2014

Mr. Ralph G. Neas
President and CEO
Generic Pharmaceutical Association
777 6th Street, N.W., Suite 510
Washington, D.C. 20001

Re: Docket No. FDA-2013-P-1153

Dear Mr. Neas:

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 September 17, 2013. Your petition requests that the Agency implement its nonproprietary naming policy equally to all biological products and that all biological products approved under section 351(k) of the Public Health Service Act share the same international nonproprietary name as the reference product.

FDA has been unable to reach a decision on your petition because it raises complex 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,

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