



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

September 19, 2013

FILE COPY

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

Dear Mr. Neas:

Your petition to the Food and Drug Administration requesting the Agency to implement an International Non-proprietary Naming (INN) policy equally to all biologics, was received by this office on 09/17/2013. It was assigned docket number FDA-2013-P-1153/CP1, and it was filed on 09/17/2013. 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 written in black ink.

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