DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 12, 2013

FILE COPY

Teva Pharmaceuticals
Vice President, Global Specialty Medicines
J. Michael Nichols, Ph.D.
11100 Nall Avenue
Overland Park, KS 66211

Dear Dr. Nichols:

Your petition to the Food and Drug Administration requesting the that Agency Refrain from approving any Abbreviated New Drug Application referencing Copaxone (Glatiramer Acetate Injection) until certain conditions are met was received by this office on 12/5/2013. It was assigned docket number FDA-2013-P-1641/CP1, and it was filed on 12/12/2013. 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,

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