DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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September 18, 2013

J. Michael Nicholas, Ph.D.
Vice President, Global Specialty Medicines
Teva Pharmaceutical Industries Ltd.
Teva Neuroscience, Inc.
901 E. 104th Street, Suite 900
Kansas City, MO 64131

Dear Dr. Nicholas:

Your petition to the Food and Drug Administration requesting the Agency to refrain from approving any abbreviated new drug application ("ANDA") that references Copaxone® (glatiramer acetate injection) unless and until the conditions specified in this Petition are satisfied, was received by this office on 09/12/2013. It was assigned docket number FDA-2013-P-1128/CP1, and it was filed on 09/12/2013. 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

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