DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

December 31, 2012

J. Michael Nicholas, Ph.D.
Sr. Director
Teva Pharmaceutical Industries Ltd.
901 E. 104th Street, Suite 900
Kansas City, MO 64131

Dear Dr. Nicholas:

Your petition to the Food and Drug Administration requesting to refrain from approving any new drug for the treatment of multiple sclerosis, unless and until it has been reviewed by the appropriate advisory committee, was received by this office on 12/31/2012. It was assigned docket number FDA-2013-P-0025/CP1, and it was filed on 12/31/2012. 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,

Gloria Ortega
Administrative Proceedings Officer
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)