

6650 14 JAN -6 A9 45 January 3, 2014

## **BY MAIL**

Dockets Management Branch, HFA-305 Food and Drug Administration Department of Health and Human Services 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Re: Docket No. FDA-2013-P-1128
Withdrawal of Citizen Petition

Dear Sir or Madam:

On behalf of Teva Pharmaceutical Industries Ltd., Teva Neuroscience, Inc. ("Teva") is hereby respectfully withdrawing the Citizen Petition submitted on September 12, 2013 and assigned Docket No. FDA-2013-P-1128. Teva is taking this action because of the submission of a subsequent, comprehensive Citizen Petition on December 5, 2013 (Docket No. FDA-2013-P-1641) that incorporates the new data and arguments addressed in the September 12, 2013 petition.

I certify that, to my best knowledge and belief: (a) I have not intentionally delayed submission of this document or its contents; and (b) the information upon which I have based the action requested herein first became known to me on or about December 24, 2013. If I received or expect to receive payments, including cash and other forms of consideration, to file this information or its contents, I received or expect to receive those payments from the following persons or organization: my employer, Teva. I verify under penalty of perjury that the foregoing is true and correct as of the date of the submission of this petition.

Please do not hesitate to contact me if you have any questions or require additional information regarding this submission.

Respectfully submitted,

J. Michael Nicholas, Ph.D.,

Vice President, Global Specialty Medicines

cc: Janet Woodcock, M.D.

Director, Center for Drug Evaluation and Research

Robert Temple, M.D.

Deputy Center Director for Clinical Science

Acting Deputy Director, Office of Drug Evaluation I

Eric Bastings, M.D. Acting Director, Division of Neurology Products

Kathleen Uhl, M.D., Acting Director Office of Generic Drugs

From: (913) 777-3386 J. Michael Nicholas, Ph.D. Teva Neuroscience Inc. 11100 Nall Avenue

OVERLAND PARK, KS 66211

Origin ID: OJCA





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