DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Ave
Building 51
Silver Spring, MD 20993

JUN 0 9 2014

Dennis Ahern, MS
Senior Director, Regulatory Affairs
Teva Pharmaceuticals USA
41 Moores Road
PO Box 4011
Frazer, PA 19355

Re: NDA 20-2622, Sequence No. 0116
COPAXONE (glatiramer acetate injection)
FDA 2013-P-1641

Dear Mr. Ahern:

This letter responds to your May 23, 2014 letter and submission on behalf of Teva Pharmaceuticals. Your letter was submitted as an amendment and general correspondence concerning NDA 20-622, Sequence No. 0116 for Copaxone (glatiramer acetate injection) and also referenced Teva's sixth citizen petition concerning Copaxone (Docket No. FDA-2013-P-1641, dated December 5, 2013) (the sixth citizen petition).

In its sixth citizen petition, Teva requested that the Food and Drug Administration not approve any abbreviated new drug application (ANDA) that references Copaxone unless and until certain conditions specified in the petition were satisfied. The sixth citizen petition relied on data from gene expression studies that compared Copaxone and several foreign glatiramer acetate products. FDA denied the petition on May 2, 2014.

Teva's May 23, 2014 letter attached a white paper with additional information concerning the same gene expression studies described in the sixth citizen petition. The letter explained:

> In order to address the specific feedback from the Agency, provide the latest findings, and allow FDA to review the methodology and full set of results in-depth, the enclosed document summarizes the available data gathered to date by Teva and analyzed by Immuneering Corporation. This document is being submitted to the NDA file since Docket No. FDA-2013-P-1641 has been closed.

The white paper also referenced Mylan Pharmaceuticals, Inc.'s April 29, 2014 public comments to the sixth citizen petition docket and, in Appendix 3 of the white paper, Teva sought to refute Mylan's comments. At the same time, Teva requested "that all information in this file be treated

as confidential within the meaning of 21 CFR §314.430, and that no information from the file be made public without our prior written consent to an authorized member of your office."

The Federal Food, Drug, and Cosmetic Act (FD&C Act) and FDA regulations establish procedural protections for ANDA applicants in the context of application review, and FDA cannot consider the additional arguments and data provided in Teva's May 23, 2014 white paper in the context of a confidential, ex parte submission. It is thus most appropriate to consider the issues raised in your submission in a public setting. This will allow others the opportunity to comment and participate in the decision-making process, will allow Teva the opportunity to comment publicly on the views and opinions of others, and will facilitate creation of an administrative record on which the Agency may base future decisions.

We also draw your attention to a 2007 amendment to the FD&C Act which addresses communications such as Teva's most recent submission. This provision, as amended by section 1135 of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), states in relevant part:

> The Secretary shall not delay approval of a pending application submitted under subsection (b)(2) [an NDA] or (j) [an ANDA] of this section ... because of any request to take any form of action relating to the application ... unless- (i) the request is in writing and is a petition submitted to the Secretary pursuant to [21 CFR] section 10.30 or 10.35...[1]

Section 505(q) of the FD&C Act provides certain requirements for the filing of such a petition, as well as procedures for the processing of such a petition. For additional information regarding FDA's current interpretation of section 505(q), please refer to FDA's Guidance for Industry entitled "Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act."[2]

We request, therefore, that if you wish the Agency to consider the information and arguments set forth in your May 23, 2014 letter and white paper, that you submit these documents as a citizen petition in accordance with section 505(q) of the FD&C Act.

Sincerely yours,

Nancy K. Hayes
Acting Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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[1] Section 505(q)(l)(A) of the FD&C Act.

[2] June 2011, *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatory information/ Guidances/UCM079353.pdf.