AFFIDAVIT

State of Maryland, Montgomery County

I, Marlene S. Bobka, under oath, hereby depose and state as follows:

1. I am the president of F.O.I., Inc. d/b/a FOI Services, Inc. ("FOI Services").

2. FOI Services is a privately-held corporation organized and operating under the laws of the State of Maryland, with its principal place of business at 704 Quince Orchard Road, Suite 275, Gaithersburg, Maryland 20878-1770, U.S.A.

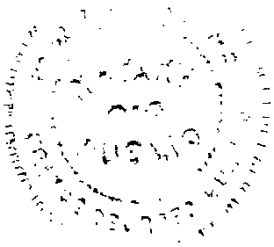
3. FOI Services specializes in United States Food & Drug Administration ("FDA") information and maintains a private library of over 150,000 FDA documents obtained under the Freedom of Information Act ("FOIA") in all categories of products regulated by FDA, including drugs, biologics, veterinary products, foods and medical devices. These documents are sold individually; the copies we maintain and sell are faithful reproductions of the original documents supplied to us by FDA and, except for cover sheets, are not altered in any way. Many U.S. courts have accepted our documents as true copies of official FDA documents.

4. The document attached as Exhibit A, FOI Services' Document Number 143374 A, titled "[N20622] Copaxone (Teva Pharm): Approval Letter, Review & Evaluation of Clinical Data, Statistical Review, Pharmacology & Toxicology, Chemistry, FONSI, Environmental Assesment, Microbiology" was publicly available, incorporated into the FOI Services publicly available files, and was provided to a third party at least as early as April 8, 2005.

5. FOI Services provided the document attached as Exhibit A to Mylan Pharmaceuticals Inc. on July 17, 2007.

6. The record attached as Exhibit A was kept in the course of our regularly conducted business activity. Making the record was a regular practice of my job duties and our business activities.

7. I hereby declare that all statements made herein of my own knowledge are true and correct. I further declare that all of my statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code.



Marlene S. Bobka

December 9, 2014
Date

SUBSCRIBED AND SWORN before me on December 9, 2014.

Notary Public

My commission expires: 7/21/2017

EXHIBIT A

20622

Copaxone

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-622

DEC 20 1996

Teva Pharmaceuticals USA
Attention: Deborah Jaskot
1510 Delp Drive
Kulpsville, PA 19443

Dear Ms. Jaskot:

Please refer to your June 15, 1995 new drug application and your resubmission dated October 11, 1995 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Copaxone (glatiramer acetate) injection.

We also refer to an Agency Approvable letter dated October 4, 1996, and we acknowledge receipt of your response amendments dated:

October 2, 1996	October 21, 1996	October 31, 1996	November 6, 1996
November 11, 1996	November 27, 1996		

This new drug application provides for the indication of reduction of relapses in patients with relapsing-remitting multiple sclerosis.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the attached version of labeling. Accordingly, the application is approved effective on the date of this letter.

Accompanying this letter (ATTACHMENT) is the labeling that should be used for marketing this drug product. These revisions are terms of the NDA approval. Marketing the product before making the agreed upon revisions in the product's labeling may render the product misbranded and an unapproved new drug.

We have the following additional comments:

Chemistry:

We remind you of the following specifications agreed upon in a December 3, 1996 telecon between Dr. Paul Leber, Dr. Russell Katz, Dr. Stanley Blum, Dr. Martha Heimann, and Ms. Teresa Wheelous of the Division and Dr. Carol Ben-Maimon and Debbie Jaskot of your firm:

RRT at peak maximum:

RRT at -2SD:

RRT at -1SD:

RRT at +1SD:

The approximate molecular weight range of is acceptable for use in the drug product labeling.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Phase 4 Commitments

We remind you of the Phase 4 commitments specified in the October 4, 1996 approvable letter. Protocols, data, and final reports should be submitted to your IND for this product and a copy of the cover letter sent to this NDA. Should an IND not be required to meet your Phase 4 commitments, please submit protocol, data, and final reports to this NDA as correspondences. For administrative purposes, all submissions, including labeling supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

Please submit sixteen copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy weight paper or similar material. For administrative purposes this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-622. Approval of this submission by FDA is not required before the labeling is used.

Additionally, please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print.

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