

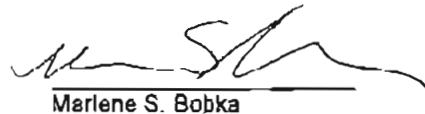
AFFIDAVIT

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, FOI Document Number 146008, titled "Peripheral and Central Nervous System Drug Advisory Committee Meeting 9/19/1996" was in the possession of FOI Services, and therefore publicly available from FDA, and was provided by FOI Services to a third party at least as early as December 14, 2001.
5. The record was kept in the course of our regularly conducted business activity.
6. Making the record was a regular practice of our business activities.

THE FOREGOING IS TRUE


Marlene S. Bobka

Jan 6, 2015
Date

SUBSCRIBED AND SWORN before me this 6 day of [Month], [Year]



Notary Public

My commission expires: 7/21/2017

EXHIBIT A

Agenda

PERIPHERAL AND CENTRAL NERVOUS SYSTEM DRUGS
ADVISORY COMMITTEE
Meeting #44

Food and Drug Administration
Center for Drug Evaluation and Research
Gaithersburg, Maryland

OPEN SESSION

Thursday, September 19, 1996
Gaithersburg Holiday Inn
8:30 a.m. to Conclusion

- I. 8:30 a.m. Call to Order: Welcome and Information
Sid Gilman, M.D.
Chairperson
- Conflict of Interest Statement
Ermona McGoodwin
Executive Secretary
- II. To Follow: Open Session
- NDA 20-622 COPAXONE® (Copolymer-1 for Injection): Safety
and Effectiveness in use for Relapsing-Remitting
Multiple Sclerosis
- IIa. FDA Introductory Remarks: Paul Leber, M.D.
Division Director, DNDP
- Russell Katz, M.D.
Deputy Division Director, DNDP
- IIb. Sponsor Presentations
TEVA Pharmaceuticals, USA
- Introduction: Carole S. Ben-Maimon, M.D.
Senior Vice President
TEVA Pharmaceuticals, USA
- Multiple Sclerosis: Kenneth P. Johnson, M.D.
Professor and Chair
Department of Neurology
University of Maryland
School of Medicine
- Safety and Efficacy: Carole S. Ben-Maimon, M.D.

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PCNS Drugs Advisory Committee Meeting
September 19, 1996

I Ib. Sponsor Presentations: (continued)

Medical Perspective: Jerry Wolinsky, M.D.
Professor of Neurology, Director
Multiple Sclerosis Research Group
University of Texas
Health Sciences Center

I Ic. FDA Response: FDA Staff

III. Committee Discussion

IV. OPEN PUBLIC HEARING

V. Committee Recommendation(s)

VI. Closing Remarks-Information and Followup

NOTE:

There will be a BREAK and/or LUNCH BREAK at the discretion of the Chair.

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FDA

PERIPHERAL AND CENTRAL NERVOUS SYSTEM
DRUGS ADVISORY COMMITTEE

Meeting #44

September 19, 1996

COPAXONE®

TAB A

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