

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 mailing address at 23219 Stringtown Road, Suite 240, Clarksburg, MD Maryland 20871, 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 is FOI Services’ Document 5223777G, which contains the Clinical Pharmacology & Biopharmaceutics Review portion of the drug approval package for NDA 21450, Zomig Nasal Spray. This document is a selected portion of Document 5211576A, which contains the complete approval package for NDA 21450, Zomig Nasal Spray. Document 5211576A was available to the public no later than April 22, 2005 via www.foiservices.com, as this is the date of FOI Services’s first record of this document being ordered through our website.
5. Document 5211576A was, as of April 22, 2005, searchable and locatable via an electronic keyword search on www.foiservices.com, where such keywords included the drug brand name (Zomig®) and active ingredient generic name (zolmitriptan). The document attached as Exhibit A includes a true and correct copy of the materials FOI Services received from FDA in response to FOI Services’ request.
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 have prepared this affidavit as part of my duties at FOI Services. I have not been retained as an outside consultant by any party in this action. FOI Services has been compensated for this affidavit at its usual rate of \$300 per affidavit, and no part of that compensation is dependent on the outcome of this action.
8. 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

7 Dec 2018

Date

SUBSCRIBED AND SWORN before me on



Notary Public

My commission expires: _____

JAMME RAY II
NOTARY PUBLIC
MONTGOMERY COUNTY
MARYLAND
MY COMMISSION EXPIRES APRIL 21, 2021



EXHIBIT A

foi



* 5 2 2 3 7 7 7 *



* G *

5223777 G

**Zomig Nasal Spray (AstraZeneca) 09/30/2003 Approval [Migraine]:
Clinical Pharmacology & Biopharmaceutics**

This document was provided by: FOI Services, Inc
704 Quince Orchard Road • Suite 275
Gaithersburg MD 20878-1751 USA
Phone: 301-975-9400
Fax: 301-975-0702
Email: infofoi@foiservices.com

Do you need additional U.S. Government information?

Since 1975, FOI Services, Inc has specialized in acquiring government files using the Freedom of Information Act. We have millions of pages of unpublished documentation already on file and available for immediate delivery.

**Many of the documents you need are available for immediate downloading at:
www.foiservices.com**

Unless specified otherwise, all of FOI Services' documents have been released by the U.S. Government under the provisions of the Freedom of Information Act and are therefore available to the general public. FOI Services, Inc. does not guarantee the accuracy of any of the information in these documents; the documents will be faithful copies of the information supplied to FOI Services, Inc.

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
21-450

**CLINICAL PHARMACOLOGY AND
BIOPHARMACEUTICS REVIEW(S)**

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.