

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

Marlene S. Bobka

7 Dec 2018

Date

SUBSCRIBED AND SWORN before me on

Jamme Ray II

Notary Public

My commission expires: _____

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



EXHIBIT A

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

This document was provided by: FOI Services, Inc
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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)**

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