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(Convention de La Haye du 5 octobre 1961)

1. District of Columbia, United States of America
2. This public document has been signed by SAMI A. SWADEK
3. acting in the capacity of NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA
SAMI A. SWADEK, NOTARY PUBLIC IN AND FOR THE
4. bears the seal/stamp of DISTRICT OF COLUMBIA

CERTIFIED

5. at Washington, D.C.
10 JANUARY 2019
6. the _____ day of _____
7. by Secretary of the District of Columbia
8. No. 534841
9. S _____
10. Signature:



Kimberly A. Bassett
Kimberly A. Bassett
Secretary of the District of Columbia

Steven E Grieve
Director
Technical Development and Regulatory Affairs

7 January 2019

To Whom It May Concern:

Declaration

I, Steven E Grieve, Director, Technical Development and Regulatory Affairs, Pfizer CentreOne, hereby certify that the attached is an authorized copy of the Affidavit of Good Manufacturing Practices issued by Michael Davidson, Vice President, Quality Systems & Compliance, *being duly sworn, certifies that* Pharmacia and Upjohn Company LLC, a subsidiary of Pfizer Inc., located at 7000 Portage Road, Kalamazoo, Michigan 49001, United States.

I also certify that Pharmacia & Upjohn Company is a wholly owned subsidiary of Pfizer, Inc. and that Pfizer CentreOne is the division of Pfizer Global Manufacturing held responsible for the marketing of active pharmaceutical ingredients and intermediates to third party manufacturers.


Steven E Grieve
Director,
Technical Development & Regulatory Affairs

Subscribed and sworn before me, a Notary Public, in the State of Michigan, United States of America, this 7 day of January in the year 2019.

HALEIGH L SAGER
Notary Public, State of Michigan
County of Calhoun
My Commission Expires 03-05-2024
Acting in the County of Kalamazoo

Haleigh L. Sager



Pfizer Inc

100 Route 206 North - Mailstop 331

Peapack, NJ 07977

Tel 908-901-7243

Fax 908-901-6556

Email: michael.g.davidson@pfizer.com

Michael G. Davidson

Vice President

Pfizer Global Supply

Quality Systems & Compliance

*Affidavit
of
Good Manufacturing Practices*

State of New Jersey

County of Somerset

Michael G. Davidson, Vice President, Quality Systems & Compliance, Pfizer Inc, being duly sworn, certifies that Pharmacia and Upjohn Company LLC, a subsidiary of Pfizer Inc., located at 7000 Portage Road, Kalamazoo, Michigan (MI) 49001, United States (USA), is registered with the Food and Drug Administration (FDA). A copy of the current FDA Drug Establishment Registration with registration number 1810189 is attached for your reference. Further, this manufacturing site is registered with the FDA in accordance with US Federal Regulation 21 CFR Subpart C and Subpart D.

The regulation can be accessed at:

www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm

The manufacturing facility is subject to periodic inspections by FDA. The latest inspection, completed September 2018 showed that the plant, at that time, was in substantial compliance with the current Good Manufacturing Practices (GMP) regulations set out by Title 21 CFR §210-211, as required by the Federal Food, Drug and Cosmetic Act and as recommended by the World Health Organization.

Michael G. Davidson

December 19, 2018

Date

STATE OF NEW JERSEY)
COUNTY OF SOMERSET)

On this 19th day of December 2018 before me came Michael G. Davidson, known to me personally and known to me to be the individual described herein, and who executed the foregoing instrument and acknowledged that he executed same.

Mary Ann Miskulik
Notary Public of New Jersey

I.D. #2253059

My Commission Expires 08/31/2020

Drug Establishments Current Registration Site

 [SHARE \(HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](https://www.facebook.com/sharer/sharer.php?u=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)

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 [EMAIL \(MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM\)](mailto:?subject=DRUG%20ESTABLISHMENTS%20CURRENT%20REGISTRATION%20SITE&body=https://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm)

New Search (default.cfm)

Search Results for **Pharmacia and Upjohn Company LLC**

CSVExcel

Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Pharmacia and Upjohn Company LLC	1810189	618054084	ANALYSIS; API MANUFACTURE; LABEL; MANUFACTURE; PACK; REPACK;	7000 Portage Road, Kalamazoo, Michigan (MI) 49001, United States (USA)	12/31/2019

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