

Global Regulatory Affairs Pfizer Inc 235 East 42nd Street New York, NY 10017 Tel 212 733 5848 Fax 212 857 3516

Global Product Development

Brandon C. Hall
Product License Support Manager

ATTESTATION

For use in Chile

To Whom It May Concern:

I, Brandon C. Hall, Manager, Product License Support, Pfizer Inc, a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 235 East 42nd Street, New York, New York 10017 USA, hereby declare that attached hereto is a true and accurate copy of the CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER for Pharmacia and Upjohn Company LLC, located at 7000 Portage Road, Kalamazoo, Michigan (MI) 49001, United States (USA).

ADAM H WEINBERG

Notary Public - State of New York

NO 01WE6246159

Qualified in New York County

My Commission Expires

Brandon C. Hall

Product License Support Manager

Pfizer Inc

State of New York County of New York

Subscribed and sworn to before me this

day of

2020

Pfizer Internal Reference: 46502-85299



Pfizer Inc

500 Arcola Road Collegeville, PA 19426 Tel 484-865-3683 Fax 484-865-4301

Email: siobhan.carmody@pfizer.com

Siobhan Carmody

Vice President
Pfizer Global Supply
Quality Systems and Compliance

Affidavit of Good Manufacturing Practices

State of Pennsylvania
County of Montgomery

Siobhan Carmody, Vice President, Quality Systems and 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 US FDA Drug Establishments Current Registration Site can be accessed at: https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site

The manufacturing facility is subject to periodic inspections by FDA. The latest inspection, completed December 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.

Siobhan Carmody

On this Is day of Invert 2020 before me came Siobhan Carmody, known to me personally and known to me to be the individual described herein, and who executed the foregoing instrument and acknowledged that she executed same.

Rosemarie Connor

inno

Notary Public

Commonwealth of Pennsylvania - Notary Seal Rosemarie Connor, Notary Public Montgomery County My commission expires April 24, 2023 Commission number 1351494

Member, Pennsylvania Association of Notaries

Drug Establishments Current Registration Site

SHARE (HTTPS://WWW.FACEBOOK.COM/S	HARER/SHARER.PHP?U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CD	٦=
R/DRLS/GETDRLS.CFM)		

<u>TWEET (HTTPS://TWITTER.COM/INTENT/TWEET/?TEXT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&URL= HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)</u>

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MEMAIL (MAILTO:?SUBJECT=DRUG ESTABLISHMENTS CURRENT REGISTRATION SITE&BODY=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/DRLS/GETDRLS.CFM)

New Search (default.cfm)

Search Results for Pharmacia and Upjohn

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;	7000 Portage Road, Kalamazoo, Michigan (MI) 49001, United States (USA)	12/31/2020

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