This Apostille is not valid for use anywhere within the United States of America, its territories or possessions.

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.

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Apostille

(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
4. bears the seal/stamp of SAMI A. SWADEK, NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA

CERTIFIED

5. at Washington, D.C.
6. the 13 day of JULY 2017
7. by *Secretary of the District of Columbia*
8. No. 463761
9. Seal/S
10. Signature:

LAUREN C. VAUGHAN

Lauren C. Vaughan
Secretary of the District of Columbia

Worldwide Research & Development

Worldwide Safety & Regulatory
Product License Support
Pfizer Internal Reference: 25672-41479

ATTESTATION

For Use in CHILE

Re: Declaration of Manufacturer for Active Ingredient - Medroxyprogesterone Acetate and Drug Establishment Registration

To Whom It May Concern:

I, Patricia Mehrman, Regulatory Affairs Product License Support Manager at Pfizer Inc, a corporation organized and existing under the laws of the State of Delaware, United States of America, with offices at 500 Arcola Road, Collegeville, Pennsylvania 19426, USA, hereby declare the attached document to be an original signed document from the manufacturer, and a true and accurate copy of Drug Establishment Current Registration status.

Patricia Mehrman

Patricia Mehrman
Product License Support Manager
Pfizer Inc

COMMONWEALTH OF PENNSYLVANIA
NOTARIAL SEAL
HARDIKKUMAR PATEL
Notary Public
BENSALEM TWP, BUCKS COUNTY
My Commission Expires Jun 30, 2020

UNITED STATES OF AMERICA)
COMMONWEALTH OF PENNSYLVANIA)
TOWNSHIP OF BENSALEM, BUCKS COUNTY)

Subscribed and sworn to before me this 26th day of June 2017

Notary

Signature: Hardikkumar Patel

844711

BLAIR CONSULAR SERVICES LTD

Site Regulatory Compliance
Pharmacia and Upjohn Company
(a Division of Pfizer, Inc.)
7000 Portage Road
Kalamazoo, MI 49001

Pfizer Global Supply

June 23, 2017

Declaration of Manufacture

Medroxyprogesterone Acetate API

This is to certify that the Active Pharmaceutical Ingredient and associated intermediates of Medroxyprogesterone Acetate are manufactured by Pharmacia & Upjohn Company (wholly owned subsidiary of Pfizer Inc), located at 7000 Portage Road, Kalamazoo, MI 49001 USA.

Material is manufactured, tested and released in accordance with approved processes, procedures and specifications. Material meets all registered specification requirements prior to release.

Per the Falsified Medicines Directive, sites that are audited by the FDA do not need an EU inspection or an EU GMP certificate. The FDA is required by United States law to conduct routine inspections of the Kalamazoo, Michigan site.

The Pharmacia & Upjohn Company in Kalamazoo site was most recently inspected by the FDA in July 2015 and is in good standing. This can be verified at the FDA Drug Establishment Current Registration Database at the following link:
https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

The FDA does not provide site specific GMP certificates. The website is considered documentation for GMP registration of sites inspected by the FDA.

Nicole L Horvath
Senior Specialist, CMC Compliance
Pfizer Global Supply - Kalamazoo

23 Jun 2017
Date

Drug Establishments Current Registration Site

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; REPACK;	7000 Portage Road, Kalamazoo, Michigan (MI) 49001, United States (USA)	12/31/2017

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Data Current through: Monday, Jun 26, 2017

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