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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 & 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 November 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.

DocuSigned by:

Siobhan Carmody

December 14, 2020

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Siobhan Carmody

Drug Establishments Current Registration Site

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Search Results for **pharmacia & upjohn**

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Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Pharmacia & Upjohn Company LLC	1810189	618054084	ANALYSIS; API MANUFACTURE; LABEL; MANUFACTURE; PACK;	7000 Portage Road, Kalamazoo, Michigan (MI) 49001, United States (USA)	12/31/2021

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