

BE IT KNOWN that I, Sunita Kumeri of, 268 Bath Road, Slough, Berkshire United Kingdom a duly authorised Notary Public

#### **CERTIFY** that

1. The signature set and subscribed to the certificate at the foot of the first page of the copy document annexed hereto is genuine having been subscribed thereto by Zoe Bruce whose identity I the Notary attest and who is duly authorised by Pfizer Limited ("the Company") to represent them in this matter, and Zoe Bruce has thereby certified on behalf of the company that the Affidavit of Good Manufacturing Practice annexed hereto is a certified true copy of the original document.

SIGNED and sealed at 268 Bath Road, Slough, Berkshire aforesaid on 22nd December

2020.

Sunita Kumeri Notary Public England and Wales

Protocol No. 14/20



#### **APOSTILLE** (Convention de La Haye du 5 octobre 1961) Country: United Kingdom of Great Britain and Northern Ireland Pays / Pais: This public document Le présent acte public / El presente documento público Has been signed by Sunita Kumeri a été signé par ha sido firmado por Acting in the capacity of Notary Public agissant en qualité de quien actúa en calidad de Bears the seal / stamp of The Said Notary Public est revêtu du sceau / timbre de y está revestido del sello / timbre de Certified Attesté / Certificado 5. the at London 23 December 2020 le / el día á/en Her Majesty's Principal Secretary of State for by Foreign, Commonwealth and Development Affairs par / por Number APO-2179841 sous no / bajo el numero J. Crook 10. Signature Seal / stamp Sceau / timbre Signature Sello / timbre Firma

This Apostille is not to be used in the UK and only confirms the authenticity of the signature, seal or stamp on the attached UK public document. It does not confirm the authenticity of the underlying document. Apostilles attached to documents that have been photocopied and certified in the UK confirm the signature of the UK official who conducted the certification only. It does not authenticate either the signature on the original document or the contents of the original document in any way.

If this document is to be used in a country not party to the Hague Convention of the 5th of October 1961, it should be presented to the consular section of the mission representing that country



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 & 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: <a href="https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site">https://www.fda.gov/drugs/drug-approvals-and-databases/drug-establishments-current-registration-site</a>

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.

Siebhan Carmedy Dece

December 14, 2020

Siobhan Carmody

2. Zoe Bruce, on behalf of Flizer
certify this document
to be a true copy
of the drightel

# Drug Establishments Current Registration Site

f <u>SHARE (HTTPS://WWW.FACEBOOK.COM/SHARER/SHARER.PHP?</u> U=HTTPS://WWW.ACCESSDATA.FDA.GOV/SCRIPTS/CDER/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>

**±** 

EMAIL (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 & upjohn

<b>CSVExcel</b>	
Filter:	

Firm Name	FDA Establishment Identifier	DUNS	<b>Business Operations</b>	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

Showing 1 to 1 of 1 entries

Previous1Next

Data Current through: Monday, Dec 14, 2020

Return to Drug Firm Annual Registration Status Home Page (default.cfm)