APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: *United States of America*

This public document

2. has been signed by Andrei Perlloni

3. acting in the capacity of Branch Chief, Drug Import Export Compliance Branch

4. bears the seal/stamp of U.S. Department of Health and Human Services

Certified

5. at Washington, D.C.

6. the fifteenth of November, 2018

7. by *Assistant Authentication Officer, United States Department of State*

8. No. 19007020-12

9. Seal/Stamp:

10. Signature:

Zelda Daley

United States Food and Drug Administration

Center for Drug Evaluation and Research

10903 New Hampshire Ave, Silver Spring, MD 20993, United States of America

CDERExportCertificateProgram@fda.hhs.gov - Telephone (301) 796-4950

Certificate of a Pharmaceutical Product - Approved Drug Product

Certificate Number: **FFJE-Q8SH** Certificate Issue Date: **October 30, 2018** Certificate Expiration Date: **October 29, 2020**

Importing Country: **CHILE** Exporting Country: **UNITED STATES of AMERICA**

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **SOLU-MEDROL®, Injection, powder for solution**
1.1	Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **methylprednisolone sodium succinate 500 MG**
1.2	Is this product licensed to be placed on the market for use in the exporting country? **Yes**
1.3	Is this product actually on the market in the exporting country? **Yes**
2.A.1	Product license number & date of issue: **011856 12/18/1970**
2.A.2	Product license holder name & address: **Pharmacia and Upjohn Company, 235 East 42nd Street, New York, NY 10017 United States of America**
2.A.3	Status of Product license holder: **Neither**
2.A.3.1	Manufacturer name & address: **Pharmacia and Upjohn Company LLC, 7000 Portage Road, Kalamazoo, MI 49001 United States of America**
2.A.4	Is a summary basis for approval appended? **Yes**
2.A.5	Is the attached product information, complete and consonant with the license? **Yes**
2.A.6	Applicant name & address for certificate (if different from the license holder): **Pfizer Inc, 235 E 42nd St, New York, NY 10017 United States of America**
2.B.4	Remarks: **Manufacturing and Packaging Facility: Pharmacia and Upjohn Company LLC, 7000 Portage Road, Kalamazoo, MI 49001 USA**
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? **Yes**
3.1	Periodicity of routine inspections (years): **Pursuant to section 510(h)(3) of the Federal Food, Drug & Cosmetic Act, Inspections will occur in accordance with a risk-based schedule**
3.2	Has the manufacture of this type of dosage form been inspected? **Yes**
3.3	Do the facilities and operations conform to GMPs as recommended by the WHO? (GMPs including 21 Code of Federal Regulations parts 210, 211, or ICH Q7A): **Yes, at time of inspection, site complies with FDA cGMP**
3.4	Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product undertaken by another party? **Yes**

Andrei Perlloni

Andrei Perlloni, Branch Chief
Drug Import Export Compliance Branch
Division of Imports, Exports & Recalls
Office of Drug Security, Integrity & Response

ms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int

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