

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.

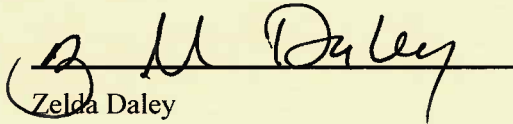
6. the fifteenth of November, 2018

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

8. No. 19067020-12

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 Issue Date: October 30, 2018

Certificate Number: FFE-Q8SH

Importing Country: CHILE

Certificate Expiration Date: October 29, 2020
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 Periloni

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



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