Form 1

State of New York
County of New York } *ss:*

No. 85057

I, Milton Adair Tingling, Clerk of the County of New York, and Clerk of the Supreme Court in and for said county, the same being a court of record having a seal, **DO HEREBY CERTIFY THAT**

RONALD J. WIENER

whose name is subscribed to the annexed original instrument has been commissioned and qualified as a NOTARY PUBLIC.....
and has filed his/her original signature in this office and that he/she was at the time of taking such proof or acknowledgment or oath duly authorized by the laws of the State of New York to take the same: that he/she is well acquainted with the handwriting of such public officer or has compared the signature on the certificate of proof or acknowledgment or oath with the original signature filed in his/her office by such public officer and he/she believes that the signature on the original instrument is genuine.

IN WITNESS WHEREOF, I have hereunto set my hand and my official seal this
11th day of March, 2015

Milton Adair Tingling

County Clerk, New York County

Nº 002102 *Art. 4/10 Derechos US$ 12.-*

El infrascrito, Cónsul de Chile en Nueva York, certifica la autenticidad de la firma de: ***Milton Adair Tingling,*** *Secretario del Condado y la Corte Suprema de New York, Estado New York, Estados Unidos de de América*

New York, MAR 16 2015

ANA LOBO DONAIRE
Ministro de Fe Pública

CONSULADO GENERAL DE CHILE
NUEVA YORK

GENERAL DE CHILE

4 LEGALIZADA EN EL MINISTERIO
DE RELACIONES EXTERIORES DE CHILE
FIRMA DEL Sr. (a)

23 MAR 2015

Miguel REYES VARGAS
Oficial de Legalizaciones

United States Food and Drug Administration

Center for Drug Evaluation and Research (CDER)
10903 New Hampshire Avenue, Silver Spring, MD 20993, USA
Email: CDERExportCertificateProgram@fda.hhs.gov Telephone: (301) 796-4950

Certificate of a Pharmaceutical Product

Certificate Issue Date: **3/3/2015**
Certificate No: **02-0046-2015-20-CL**

Certificate Expiration Date: **3/3/2017**
Exporting Country: **United States of America**
Importing Country: **Chile**

1. International or National Nonproprietary Name (if applicable) and dosage form: **Celebrex® (celecoxib) Capsules, 200 mg**
1.1 Active Ingredient(s) and amount(s) per unit dose (complete quantitative composition is preferred): **See Attachments**
1.2 Is this product **licensed** to be placed on the market for use in the exporting country? **YES - See Block A**
1.3 Is this product actually on the market in the exporting country? **Yes**

A	B
2A.1 Number of product-license and date of issue: **20-998 12/31/1998**	2B.1 Applicant for certificate (name and address)
2A.2 Product-license holder: **Pfizer Inc.**	2B.2 Status of Applicant:
2A.3 Status of product-license holder: **Neither**	2B.3 Why is authorization lacking? **not required** **not applicable** **under consideration** **refused**
2A.4 Is an approved summary basis appended? **No**	2A.3.1 or 2B.2.1 Manufacturer name and address: **PFIZER PHARMACEUTICALS LLC, Vega Baja, PR 00694**
2A.5 Is the attached product information complete and consonant with the licensed text?	2B.4 Remarks: **Manufactured by: Pfizer Pharmaceuticals, LLC, Km. 1.9 Road 689, Vega Baja, Puerto Rico 00693 USA**
2A.6 Applicant for certificate if different from the license holder (name and address):	

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 inspection (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 GMP as recommended by the WHO? (GMP including 21 CFR Parts 210, 211 or ICH Q7A) **Yes, at time of inspection, site complies with U.S. CGMP**
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**

This certificate conforms to the format recommended by the World Health Organization format revised 10/1/1997.

Huascar Batista

Huascar Batista, Chief
Drug Imports and Exports Compliance Branch
Office of Drug Security, Integrity & Recalls

3-9

CELEBREX® (celecoxib) CAPSULES

Unit Composition of Celebrex 200mg Capsules

Ingredient	Unit Formula for 200mg	Function	Reference to Standards
Celecoxib	200.0 mg	Active Ingredient	Pfizer
Lactose Monohydrate		Diluent	NF
Sodium Lauryl Sulfate		Surfactant	NF
Povidone, K29-32		Binder	USP
Croscarmellose Sodium		Disintegrant	NF
Magnesium Stearate		Lubricant	NF
Purified Water		Granulating Agent	USP
Total Capsule Fill Weight			
Hard Gelatin Capsule White Opaque, Size #2 White/White with Gold Band Capsule			
Hard Gelatin Capsule White Opaque, Size #2 White/White with Blue Band Capsule			