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Apostille

(Convention de La Haye du 5 octobre 1961)

1. District of Columbia, United States of America
2. This public document has been signed by SAMI A. SWADEK
NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA
3. acting in the capacity of SAMI A. SWADEK, NOTARY PUBLIC IN AND FOR THE
DISTRICT OF COLUMBIA
4. bears the seal/stamp of _____
5. at Washington, D.C. 7, FEBRUARY 2017
6. the _____ day of _____
7. by Secretary of the District of Columbia
8. No. 433016
9. Seal/Stamp



10. Signature:

LAUREN C. VAUGHAN



Worldwide Safety & Regulatory
Pfizer Inc
235 East 42nd Street
New York, NY 10017
Tel 212 733-7277 Fax 212 857 3516

Worldwide Research & Development

Jason Kim
Manager Product License Support

ATTESTATION

For use in Chile

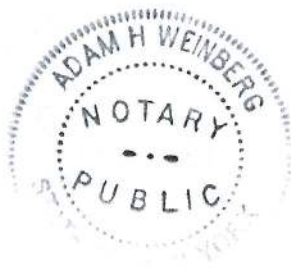
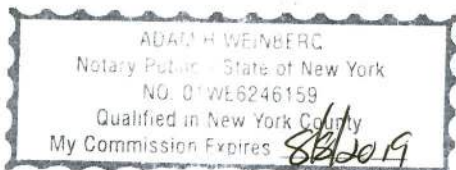
To Whom It May Concern:

I, Jason Kim, Manager, Product License Support, Pfizer Inc, a corporation organized and existing under the laws of the state of Delaware and having a principal place of business at 235 East 42nd Street, New York, New York 10017 USA, hereby declare that attached hereto is a true and accurate copy of the cGMP Certification for Hospira, Inc., located at Highway 301 North, Rocky Mount, North Carolina 27801, United States of America. The Drug Firm Annual Registration Status can be referenced at <http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm> by entering the Drug Firm name via the Drug Registration Query link.



Jason Kim
Manager, Product License Support
Pfizer Inc

State of New York
County of New York
Subscribed and sworn to before me this 1 day of FEBRUARY, 2017




BLAIR 819136
CONSULAR SERVICES LTD

Pfizer Internal Reference: 23454-37888

Chile 145072



Hospira, Inc.

CGMP CERTIFICATION – ROCKY MOUNT, NC

1. The buildings and equipment in which the drug is manufactured, held, controlled, packaged, and labeled are of suitable design, size, construction, and location to facilitate maintenance and operation for their intended purposes in an orderly and clean manner.
2. The key personnel involved in the manufacture and control of this drug have backgrounds of education and experience appropriate for assuming responsibility to ensure that the drug has the safety, identity, strength, quality, and purity we purport it to possess.
3. The raw materials used in the preparation and processing of this drug conform to appropriate standards of identity, strength, quality, and purity.
4. Adequate batch and control records are kept for each batch of drug produced.
5. The production and control procedures include reasonable precautions to ensure that the drug produced has the identity, strength, quality, and purity we purport it to possess.
6. Suitable specifications, test methods, cleaning procedures, and when indicated, sterilization procedures are used to ensure that containers, closures, and other component parts of packages are suitable for their intended use.
7. Packaging and labeling operations are adequately controlled to prevent mix-ups between drugs; to ensure that correct labeling is employed for the drug; and to identify finished products with lot or control numbers which permit determination of the history of the manufacture and control of the batch of drug.
8. Laboratory controls include adequate specifications and test procedures to ensure that raw materials, drug preparations in the course of processing, and finished products conform to appropriate standards of identity, strength, quality, and purity.
9. Complete records are maintained as to the distribution of each batch of drug in a manner which will facilitate its recall if necessary.
10. Adequate provision is made for testing the stability of raw materials, drug preparations in the course of processing when needed, and finished drugs.

Hospira, Inc. hereby certifies that the methods used in, and the facilities and controls used for the manufacture, processing, packing, and holding of the drug are in conformity with current good manufacturing practice in accordance with parts 210 and 211 (21 CFR) of the regulations.

Daniel Brennan for Shane Ernst
Shane Ernst
Vice President Quality
Hospira, Inc.,
Rocky Mount, NC

29 Feb 2016
Date