8 de Noviembre de 2016

A quien pueda interesar,

CERTIFICACIÓN

El titular que suscribe certifica que el principio activo Clorhidrato de Dorzolamida utilizado en el producto COSOPT (registro ISP Nro. F-1.875/14) los cuales se exportan a Chile a la empresa Alpes Chemie S.A., utilizan el principio activo de este proveedor, que cuenta con Certificación GMP vigente hasta el 29 de Febrero 2020.
Que la información proporcionada en esta declaración de conformidad es verdadera, exacta y completa a lo mejor de su / sus conocimientos.

DECLARACIÓN DE CONFORMIDAD de Buenas Prácticas de Manufactura (cGMP)

Esta carta es para afirmar que todos los ingredientes farmacéuticos activos suministrados por Merck Sharp and Dohme Corp., Elkton, Virginia USA se fabrican de acuerdo con cGMP [Q7, Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients] y cumple con todas las especificaciones de la USP. Además, la instalación de Merck Sharp and Dohme Corp., se ha registrado en la Administración de Alimentos y Medicamentos (FDA).
Las instalaciones son inspeccionadas de forma rutinariamente para el cumplimiento de cGMP según las directrices de la FDA. A medida que el Food and Drug Administration de Estados Unidos (FDA) no emite licencias ni certificados de cumplimiento de la fabricación, el registro de establecimientos farmacéuticos se puede confirmarse a través del siguiente weblink de la FDA (una captura de pantalla se adjunta en el documento enviado en anexo a la presente declaración): http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

Katia Esteves dos Santos
Farmacéutica
Directora de Asuntos regulatorios y Garantía de la calidad – Latino América
+ (55 11) 988126749/ 51716854
Katia.esteves@mundipharma.com.br
www.mundipharma.com

This Apostille is not valid for use anywhere within the United States of America, its territories or possessions.

This Apostille only certifies the authenticity of the signature and the capacity of the person who has signed the public document, and, where appropriate, the identity of the seal or stamp which the public document bears.

This Apostille does not certify the content of the document for which it was issued.

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 KAMAL S. AHMAD
3. acting in the capacity of NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA
4. bears the seal/stamp of KAMAL S. AHMAD, NOTARY PUBLIC IN AND FOR THE DISTRICT OF COLUMBIA

CERTIFIED

5. at Washington, D.C.
6. the 13, day of SEPTEMBER 2016
7. by *Secretary of the District of Columbia*
8. No. 418668
9. Seal/Stamp
10. Signature: LAUREN C. VAUGHAN

MSD
Merck Sharp & Dohme Corp.
2778 South East Side Highway
Elkton, VA 22827
US
T 540-298-1211
F 540-298-5650
merck.com

MSD

September 6, 2016

True and Accurate Copy Declaration

To Whom It May Concern

I, Christopher J. Milano, declare that this is a true and accurate copy of the Merck Elkton Site Declaration and FDA web site screen shot of Merck Elkton, VA sites' current FDA registration number. This document will be used in Chile.

Christopher J Milano
Executive Director, Quality Assurance

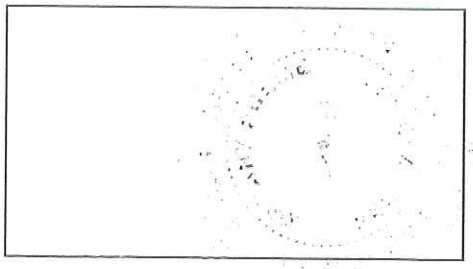
07.09.2016
Date

Commonwealth of Virginia
SS: County of Rockingham

On this day, the 7th day of September 2016 before me a notary public, the undersigned officer, personally appeared Christopher J. Milano 07.09.2016, known to me (or satisfactorily proven) to be the person whose name is subscribed to the within instrument, and acknowledge that he executed the same for the purposes therein contained.

In witness hereof, I hereunto set my hand and official seal.

Gina B. Neese #7131432
Notary Public Signature
my commission expires Feb 29 2020



I Certify That This Is An
Original Document
Betty

District of Columbia: SS
Subscribed and sworn to before me,
this 13 day of Sept ,2016

Kamal S. Ahmad, Notary Public, D.C.
My Commission expires December 14, 2019

MERCK
Manufacturing Division

02-Aug-2016

To Whom It May Concern,

The following information is being provided in support of the registration of the following license holder for the implementation of electronic supervision for Merck, Sharp & Dohme products.

Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., a United States corporation with manufacturing facilities located in **Merck Sharp & Dohme Corp., UDA; 2778 South East Side Highway, Elkton, Virginia, VA 22827, USA**, manufactures a range of products for various countries in the world.

GMP Certificate

The FDA does not issue formal GMP certificates to sites as is the practice with other countries. However, I can certify that the facility, API components, sterile products, and the vaccine products manufactured at this facility undergo routine inspections by worldwide regulatory authorities including US FDA, and are approved for distribution worldwide. Further, I can certify that the Active Pharmaceutical Ingredients, Vaccine & Sterile Manufacturing Operations at the Elkton location remain in GMP good standing with the US FDA and were most recently inspected by the US FDA CDER as part of a General GMP Inspection in August-September 2015, and by the US FDA CBER as part of a General GMP Inspection 03-10-Jun-2014.

Manufacturing License

From 01-Jun-2009 onwards, the US FDA no longer issues a hardcopy of drug establishment registrations but requires companies to submit information electronically.

The current registration status can be found at the FDA website at:
http://www.accessdata.fda.gov/scripts/cder/drls/default.cfm

This is to certify that the attached document is a true and accurate copy of the current search results from the above mentioned website, as proof of the current registration status of Merck Sharp & Dohme Corp., **Merck Sharp and Dohme Corp., USA; 2778 South East Side Highway, Elkton, Virgina, VA 22827, USA** with the US FDA.

Regards,

C.J. Milano

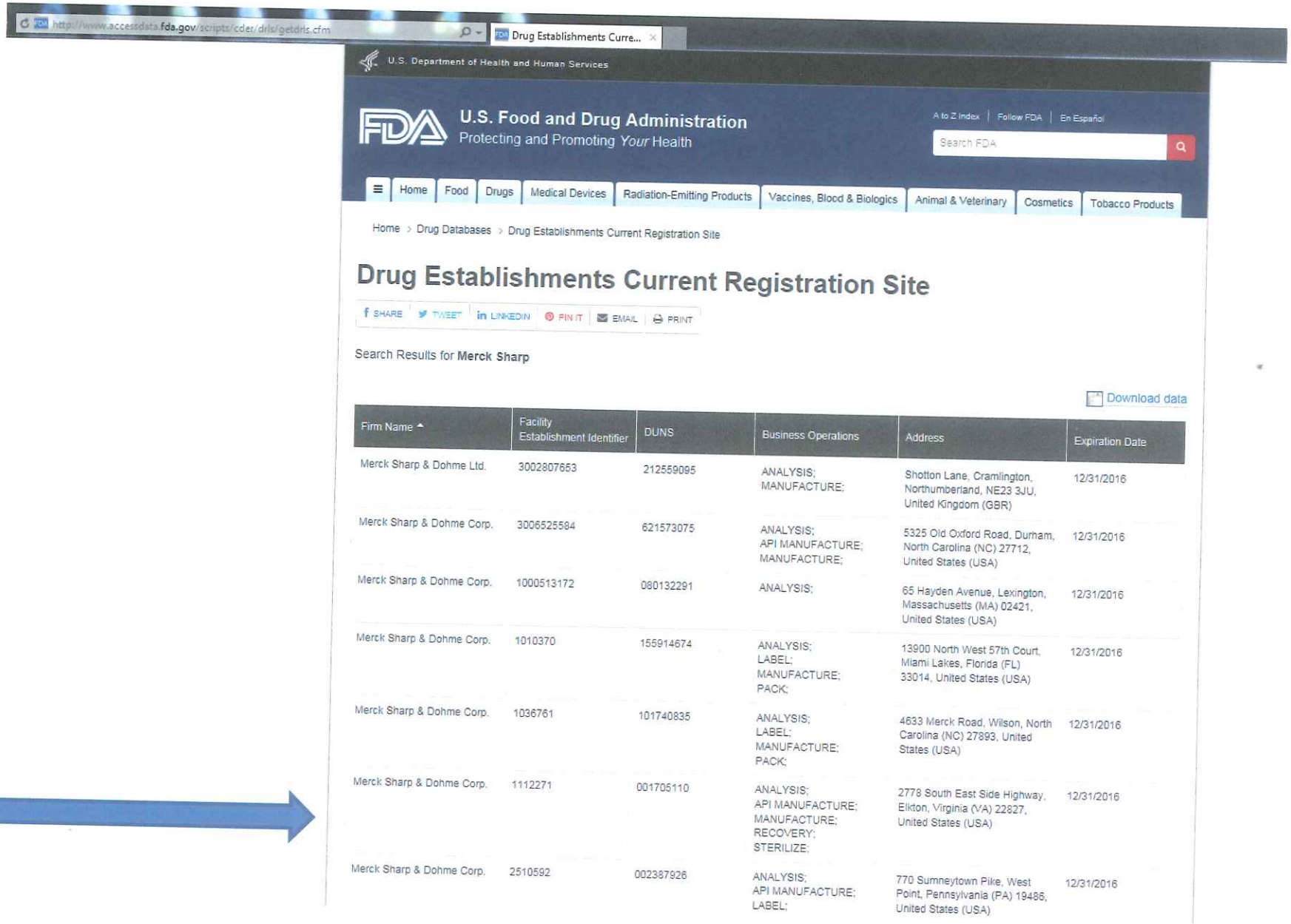
Christopher J. Milano, PhD
Executive Director of Quality, Elkton, VA

MERCK
Merck Sharp & Dohme Corp.
a subsidiary of Merck & Co., Inc.
2778 South East Side Highway
Elkton, VA. USA 22827

C.J. Milano
Christopher J. Milano, PhD.

03 Aug 2016
Date

http://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm



http://www.accessdata.fda.gov/scripts/cder/drls/getdrls.cfm

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Firm Name	Facility Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
Merck Sharp & Dohme Ltd.	3002807653	212559095	ANALYSIS; MANUFACTURE;	Shotton Lane, Cramlington, Northumberland, NE23 3JU, United Kingdom (GBR)	12/31/2016
Merck Sharp & Dohme Corp.	3006525584	621573075	ANALYSIS; API MANUFACTURE; MANUFACTURE;	5325 Old Oxford Road, Durham, North Carolina (NC) 27712, United States (USA)	12/31/2016
Merck Sharp & Dohme Corp.	1000513172	080132291	ANALYSIS;	65 Hayden Avenue, Lexington, Massachusetts (MA) 02421, United States (USA)	12/31/2016
Merck Sharp & Dohme Corp.	1010370	155914674	ANALYSIS; LABEL; MANUFACTURE; PACK;	13900 North West 57th Court, Miami Lakes, Florida (FL) 33014, United States (USA)	12/31/2016
Merck Sharp & Dohme Corp.	1036761	101740835	ANALYSIS; LABEL; MANUFACTURE; PACK;	4633 Merck Road, Wilson, North Carolina (NC) 27893, United States (USA)	12/31/2016
Merck Sharp & Dohme Corp.	1112271	001705110	ANALYSIS; API MANUFACTURE; MANUFACTURE; RECOVERY; STERILIZE;	2778 South East Side Highway, Elkton, Virginia (VA) 22827, United States (USA)	12/31/2016
Merck Sharp & Dohme Corp.	2510592	002387926	ANALYSIS; API MANUFACTURE; LABEL;	770 Sumneytown Pike, West Point, Pennsylvania (PA) 19486, United States (USA)	12/31/2016

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MERCK

MEMO

DATE: September 1, 2016

TO: Distribution

FROM: Chris Milano

SUBJECT: **ABSENCE FROM OFFICE**

I will be on vacation on Friday, September 2nd. Ms. Rhonda Carpenter will hold my GOA and will act on my behalf, including signing authority as outlined in the Corporate Grant of Authority.

Rhonda can be reached at extension 8-4080 (outside of Elkton 540-298-4080).

The following week (beginning Monday September 5th), I will be supporting the Oss Biotech site in the Netherlands. I will have access to my e-mail and phone during this time period, but due to the time difference, responses may be delayed.

Between September 5th and 9th, for all Elkton Quality related matters, Ms. Lauren Long will hold my GOA and will act on my behalf, including signing authority as outlined in the Corporate Grant of Authority.

Lori can be reached at extension 8-4139 (outside of Elkton 540-298-4139).

All mail should be directed to my office as usual.

C. J. Milano

Christopher J. Milano, PhD
Executive Director of Quality
Merck Elkton VA