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 Imports and Exports Compliance Branch

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

Certified

5. at Washington, D.C.

6. the ninth of May, 2019

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

8. No. 19035055-14

9. Seal/Stamp:

10. Signature:

Chana M Turner

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 - Active Pharmaceutical Ingredient (API)

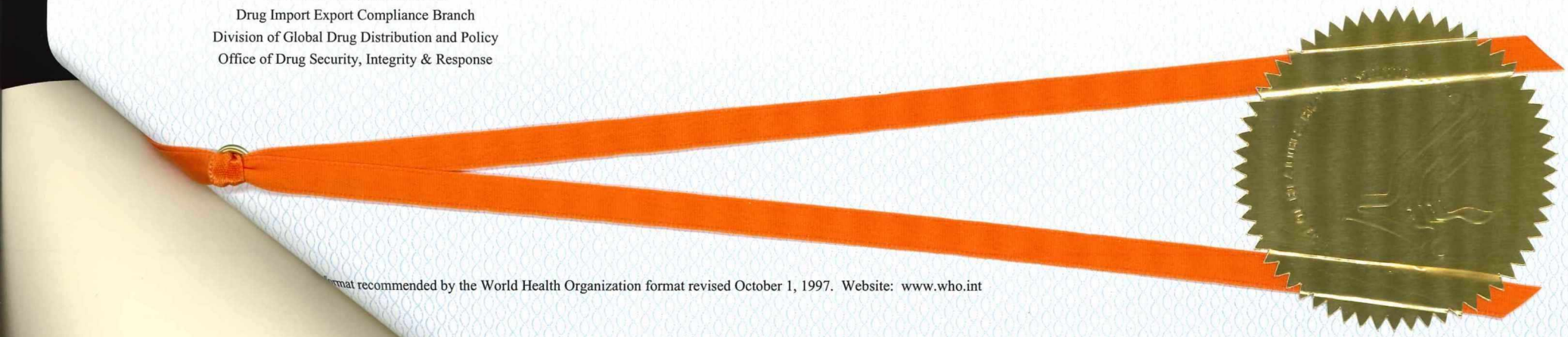
Certificate Number: **U9FV-SMXZ** Certificate Issue Date: **April 25, 2019** Certificate Expiration Date: **April 24, 2021**

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

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **TRAVOPROST**
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? **No**
1.3	Is this product actually on the market in the exporting country? **Yes**
2.B.1	Applicant for certificate name & address: **Cedarburg Pharmaceuticals, Inc (Division of AMRI), 870 Badger Cir, Grafton, WI 53024 United States of America**
2.B.2	Status of Applicant: **Manufacturer**
2.B.2.1	Manufacturer name & address: **Cedarburg Pharmaceuticals, Inc (Division of AMRI), 870 Badger Cir, Grafton, WI 53024 United States of America**
2.B.3	Why is marketing authorization lacking? **Not Required**
2.B.4	Remarks:**The firm proposes to export the active pharmaceutical ingredients (API) listed above, which when properly labeled with statement "Caution: For further manufacturing, processing or repacking", may be freely marketed in the United States of America at this time.**
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 Global Drug Distribution and Policy
Office of Drug Security, Integrity & Response



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

U9FV-SMXZ

Cedarburg Pharmaceuticals, Inc.
870 Badger Circle, Grafton, WI 53024

Product Name: Travoprost
Product Code: API-S-026 **CAS No.:** 157283-68-6
NDC No.: 64181-0028**
Batch No.: XX/XXX **DOM:** DD MM YY
Retest: MM YYYY

XXX g	XXX g	XXX g
Gross Wt.	Tare Wt.	Net Wt.

Store in sealed glass container under nitrogen in a freezer (-25 to -15°C) and protected from light.

Known Hazards: Handle with safety glasses and gloves. Avoid contact and inhalation. Use only with adequate ventilation. Reproductive hazard. Consult MSDS for more information.
Caution: For manufacturing, processing or repacking. Rx only.