# *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: **8ZSN-G5VT** Certificate Issue Date: **September 22, 2017** Certificate Expiration Date: **September 21, 2019**

Importing Country: **KOREA, REPUBLIC OF** Exporting Country: **UNITED STATES of AMERICA**

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|---|---|
| 1. | Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form: **ZINC OXIDE** |
| 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: **Zinc Oxide LLC, 600 Printwood Drive, Dickson, TN 37055 United States of America** |
| 2.B.2 | Status of Applicant: **Manufacturer** |
| 2.B.2.1 | Manufacturer name & address: **Zinc Oxide LLC, 600 Printwood Drive, Dickson, TN 37055 United States of America** |
| 2.B.3 | Why is marketing authorization lacking? **Not Applicable** |
| 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 Imports, Exports & Recalls
Office of Drug Security, Integrity & Response

This certificate conforms to the format recommended by the World Health Organization format revised October 1, 1997. Website: www.who.int