United States Food and Drug Administration

Center for Drug Evaluation and Research

10903 New Hampshire Ave, Silver Spring, MD 20993, United States of America

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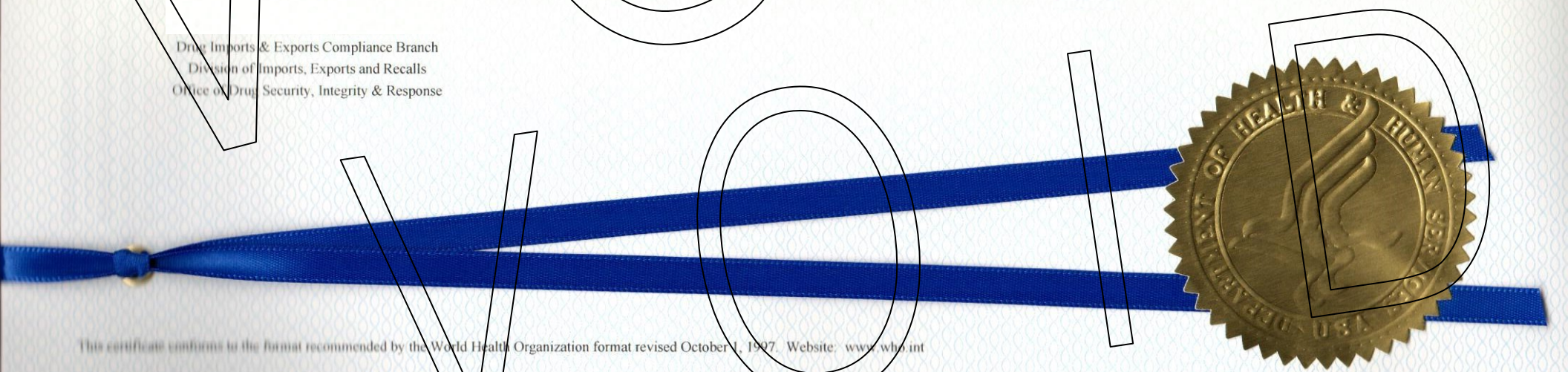
Certificate of a Pharmaceutical Product - Unapproved Drug Product

Certificate Number: Certificate Issue Date: Certificate Expiration Date:

Importing Country: Exporting Country:

1.	Drug Trade Name, International or National non-proprietary name (as applicable) & dosage form:
1.1	Active Ingredient(s) and amounts(s) per unit dose (complete quantitative composition is preferred):
1.2	Is this product licensed to be placed on the market for use in the exporting country?
1.3	Is this product actually on the market in the exporting country?
2.B.1	Applicant for certificate name & address:
2.B.2	Status of Applicant:
2.B.2.1	Manufacturer name & address:
2.B.3	Why is marketing authorization lacking?
2.B.4	Remarks:
3.	Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
3.1	Periodicity of routine inspections (years):
3.2	Has the manufacture of this type of dosage form been inspected?
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):
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?

Drug Imports & Exports Compliance Branch
Division of Imports, Exports and 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