UNITED STATES FOOD AND DRUG ADMINISTRATION

Certificate No.
(Conforms to WHO format)

Exporting Country: USA
Importing Country:

CERTIFICATE OF A PHARMACEUTICAL PRODUCT

Proprietary Name (if applicable) and dosage form:

Active Ingredient(s) and amount(s) per unit dose: SEE ATTACHED APPROVED LABELING

1. Is this product licensed to be placed on the market for use in the exporting country? If yes, complete box A; if no, complete B

A	B
Product license holder:	Application for Certificate:
Status of License Holder: APPROVED	Status of Applicant:
Number of product license and date of issuance:	Why is authorization lacking? not required not requested consideration refused
Is an approved technical summary appended? NO	
Is the attached product information complete and consistent with the license? YES	
Applicant for certificate if different from the license holder:	

2. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced: Yes
Periodicity of routine inspection (years): Every 2 years per U.S.A. regulations
Has the manufacture of this type of dosage form been inspected: Yes
Do the facilities and operations conform to GMP as recommended by the World Health Organization: Yes, at time of inspection

3. Does the information submitted by the applicant satisfy the authority on all aspects of the manufacturer of the product undertaken by another party?

Address of certifying authority: U.S. Food and Drug Administration

7520 Standish Place
Rockville, MD 20855, USA
Telephone: (301) 594-0063

Deputy Director, Division of
Drug Labeling Compliance
Center for Drug Evaluation and Research

State of Maryland
County of Montgomery

Subscribed and swore before me
This _____ Day of _____, 1994.

THIS CERTIFICATE EXPIRES TWELVE MONTHS FROM THE DATE NOTARIZED

_____
Notary Public