Format for an Export Certificate Application

(APPLICANT'S LETTERHEAD)

Date:

Food and Drug Administration
Center for Drug Evaluation and Research
Export Certificate Program, HFD 323
Montrose Metro II Building
11919 Rockville Pike
Rockville, MD 50852

On behalf of **(firm name)**, I am requesting **(no. of certificates)** Certificate(s) of a Pharmaceutical Product. The required information is provided below:

- **Country of Destination:**
- **U.S. Tradename (brand name) or Generic Name:**
- **Active Ingredient(s):**
- **Registration No., Name, and Address of the Manufacturing Facility, including Zip Code:**

  CFN or FEI Number
  ABC Pharmaceuticals
  0000 Any Street
  Anywhere, USA 12345

- **Certification of Exportation from the U.S. for Foreign Manufacturing Sites:**

  Please include the following statement in the cover letter: ***"We certify that* (Product Name) *is manufactured and/or packaged in* (Name of Foreign Country) *and is exported from the United States."*** Unless a product is sent from the U.S., directly to the requesting country, a Certificate of a Pharmaceutical Product (CPP) will not be issued.

- **Marketing Authority:** (Approved NDA/ANDA, Applicable OTC Monograph, Grandfather Status)
- **Status of Applicant:** (Manufacturer, Packager/Labeler, Neither [Distributor])
- **Applicant's Federal Tax Identification No.:**
- **Status of Product License Holder:** (Manufacturer, Packager/Labeler, Neither [Distributor])
- **Is the product actually on the market in the U.S.?:** (Yes or No)
- **Billing Address and Contact:**
- **Product Identification Statement (for unapproved products):**

  We certify that the product to be exported is in compliance with the applicable provisions of §801 and §802 of the Food, Drug, and Cosmetic Act as amended by the FDA Reform and Enhancement Act of 1996.

- **Certification Statement:**

  The information, contained in this request for a Certificate of a Pharmaceutical Product, is true and accurate based upon the current approved application or other legal basis permitting marketing of the product. We acknowledge that any false or fictitious statements, made in the application that are used by FDA to process the certificate, will be in violation of the United States Code Title 18, Section 1001.

- **Authorization to Release Statement:**

  We authorize the Food and Drug Administration to release this information in the certificate format. I understand that we will be billed a fee for each certificate, not to exceed $175.00.

If you have any questions, or require additional information, regarding this correspondence, please call me at **(phone number)**.