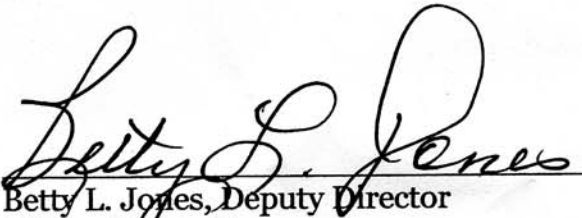




DECLARATION of Betty L. Jones

I, Betty L. Jones, declare the following:

- 1) I am Deputy Director, Office of Compliance, Center for Drug Evaluation and Research, the United States Food and Drug Administration.
- 2) In this capacity, I issue Certificates of Pharmaceutical Products to foreign governments for export purpose concerning the manufacture, preparation, and marketing of drugs in the United States and the GMP status of the plant which produces them.
- 3) The manufacturing facility, Gemini Pharmaceuticals, Inc., located at 87 Modular Avenue, Commack, New York 11725, is subject to periodic inspections by the FDA. The latest inspection showed that the plant, at this time, is in substantial compliance with current Good Manufacturing Practices (cGMPs) as required by the Federal Food, Drug, and Cosmetic Act and as recommended by the World Health Organization.
- 4) The Registration number for the above facility is: 2432926.
- 5) Pursuant to 28 U.S.C. § 1746, I declare under a penalty of perjury that the foregoing is true and correct.


Betty L. Jones, Deputy Director
Office of Compliance
Center for Drug Evaluation and Research

State of Maryland) ss

Subscribed and sworn to before me this 27th day of October 2004.


Notary Public

Roxana L. Newquist
NOTARY PUBLIC
Howard County, Maryland
My Commission Expires 01/01/2008