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CFN: 1125076

Food and Drug Administration
Baltimore District Office
900 Madison Avenue
Baltimore, MD 21201-2199
Telephone: (410) 962-3461
FAX: (410) 962-2219

February 18, 2000

CORRECTED WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Ludovico Giavotto, President
Amuchina International, Inc.
8-8 Metropolitan Court
Gaithersburg, Maryland 20878

Dear Mr. Giavotto:

On August 4-18, 1999, Food and Drug Administration (FDA) Investigator Steven J. Thurber conducted an inspection at your Gaithersburg, Maryland facility that documented Medical Device Reporting (MDR) and Quality System Regulation (QSR) GMP violations involving products imported and distributed by your firm, specifically Amukin-D.

Amukin-D is considered a device as that term is defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Amukin-D is misbranded within the meaning of Section 502(t)(2), in that adverse event files were not established and maintained, and information required to be submitted to the FDA per 21 Code of Federal Regulations (CFR), Part 804, MDR, was not submitted, as follows:

- Failure to submit a report, as required by 21 CFR 804.25(a)(2), containing the information required by 21 CFR 804.28, after receiving information that reasonably suggests that one of your marketed devices may have caused or contributed to a death or serious injury. For example:
 - Twelve incidents at [REDACTED] on or about March 17, 1998 through April 5, 1998, involving at least eight patients who experienced facial swelling, queasiness, and hypotension after receiving dialysis with equipment reprocessed with Amukin-D. Four of the patients were administered fluids, oxygen and/or medication to relieve the symptoms. This event should have been reported as a serious injury.
 - Incidents at the [REDACTED], on or about January 28, 1998 and February 28, 1998, involving three patients whose post-dialysis blood tests revealed gram-negative bacteria after receiving dialysis with equipment reprocessed with Amukin-D. This event should have been reported as a serious injury.

- Failure to establish and maintain a device complaint file, including records of all events that were considered for possible MDR reporting, as required by 21 CFR 804.35. There are no records that the following complaints were considered for MDR reporting, based on the information available:
 - An incident at [REDACTED] on May 17, 1999, in which a patient experienced shortness of breath and stomach cramps during dialysis performed using equipment disinfected with Amukin-D.
 - Incidents at [REDACTED] on or about March 17, 1998 through April 5, 1998, involving at least eight patients who experienced a drop in blood pressure and swelling of the lips and eyes during dialysis with equipment disinfected with Amukin-D.
 - Incidents at the [REDACTED] on January 28, 1998 and February 28, 1998, involving three patients whose post-dialysis blood tests revealed gram-negative bacteria after receiving dialysis with equipment reprocessed with Amukin-D.

A written MDR report for each of the above listed incidents is to be submitted within 15 working days of receipt of this letter. The MDR reports should reference this Warning Letter and be directed to:

Victoria A. Schmid
Food and Drug Administration
Reporting Systems Monitoring Branch (HFZ-533)
Office of Surveillance and Biometrics
Center for Devices and Radiological Health
1350 Piccard Drive
Rockville, Maryland 20850

In addition, your device is adulterated under Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation, do not conform to Current Good Manufacturing Practice regulations (CGMP) as described in 21 CFR 820, QSR. Specifically, you failed to adequately investigate and evaluate complaints for possible mandatory reporting to the FDA under the MDR regulation.

These are serious violations of the law that may result in FDA taking regulatory action without further notice. Federal agencies are advised of the issuance of all Warning Letters concerning devices so that they may take this information into account when considering the award of contracts or when issuing certificates of export.

You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and prevent recurrence, including the timeframe within which the corrections will be completed. Corrective action plans should also indicate the person responsible for effecting the correction, and include any supporting documentation indicating that correction has been achieved. If corrective action cannot be completed within 15 working days, please state the reason for the delay and the time within which the corrections will be completed.

We acknowledge receipt of your response to the FDA Form 483 dated September 14, 1999. We also acknowledge your supplemental responses to the FDA-483 and to the original Warning Letter dated December 2, 1999, including your correspondence dated November 23, 1999, December 3, 1999, December 22, 1999, and January 13, 2000. The current Warning Letter reflects changes made as a result of a review of these responses by Baltimore District and the Center for Devices and Radiological Health.

You should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter addresses issues relating to mandatory reporting of adverse events and certain requirements under the QSR, and does not necessarily address other obligations you have under the law. You may obtain general information regarding FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1- (800) 638-2041 or through the Internet at <http://www.fda.gov>.

Your reply should be sent to the Food and Drug Administration, 101 W. Broad Street, Suite 400, Falls Church, Virginia 22046-4200, to the attention of Gerald Miller, Compliance Officer. Mr. Miller can be reached at (703) 235-8440, extension 504, if you have questions about the content of this letter.

Sincerely,



Carl E. Draper
Acting Director, Baltimore District

cc: Amuchina S.p.A.
Genova, Italy