DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED

July 16, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 43

Curtis H. Miller
President
Micromedics, Inc.
1285 Corporate Center Drive, #150
Eagan, Minnesota 55121

Dear Mr. Miller:

We are writing to you because an investigator from the Food and Drug Administration (FDA) recently collected information that revealed a serious regulatory problem involving the ventilation tubes, surgical sealant applicators, surgical blades, nasal splints, septal buttons and applicator tips that are manufactured at your facility in Eagan, MN.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. They are medical devices as defined by Section 201(h) of the Act.

The law requires that manufacturers of medical devices adhere to Quality System Regulations for Medical Devices (QSRs) as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), in the methods used in, facilities or controls used for manufacturing, packing, storage or installation of medical devices. Our inspection found your products violate the law because of:

1. Failure to establish and maintain procedures for changes to a specification, method, process or procedure, and verify, or where appropriate validate, such changes according to Section 820.75 [FDA-483 item 1, 21 CFR 820.70(b)] in that placement and use of the [redacted] used in validation and for release of product during routine sterilization have not been correlated with the biological indicators (BIs) used to represent the most difficult to sterilize locations.

2. Failure to validate the [redacted] sterilization operations to a high degree of assurance and according to established procedures [FDA-483 item 2, 21 CFR 820.75] in that the validation and cycle development do not include the following:

   * Correlation and supporting data for the simulated product used for each product covered by the sterilization validation;

   * A demonstration that the simulated product represents the same or a more difficult challenge to the sterilization process cycle that is being validated;

   * The effects on the [redacted] sterilization cycle of differences between the simulated product-packaging configuration and actual product-packaging configuration for the products being validated;

   * Test results of the bioburden samples which reflect the entire bioburden of the product; samples that were sent for bioburden testing do not include the paper wrap used as an inner barrier for sterility (FDA-483 item 3).

3. Failure to establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling and verifying the acceptability of process capability and product characteristics [21 CFR 820.250] in that the sample sizes used for receiving inspection, package integrity tests, and bioburden testing are not based on a statistical rationale

and the procedures for determining sample sizes do not require a statistical rationale (FDA-483 item 5).

4. Failure to establish and maintain schedules for the adjustment, cleaning and other maintenance of equipment [21 CFR 820.70(g)(1)] in that required preventive maintenance for the [redacted] part no. 70003 (JB3), was not completed as required by the preventive maintenance procedure (FDA-483 item 6).

5. Failure to develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications [21 CFR 820.70(a)] in that biocompatibility tests have not been performed on any of the products which use silicone, including the Shikani Stents, since the source of silicone was changed from [redacted] to [redacted] (FDA-483 item 7).

6. Failure to maintain a Device History Record (DHR) including acceptance records which demonstrate that the device is manufactured in accordance with the Device Master Record [21 CFR 820.184(d)] in that Advance Deviation Authorization (ADA #18) for the addition of the post-sterilization on the packaging for the FibriJet products was not recorded on several affected DHRs, leaving in doubt whether the process included use of the procedure for the manufacture of these products (FDA-483 item 8).

In legal terms, the products are adulterated under Section 501(h) of the Act.

Additionally, you are required to file pre-market notifications for the septal buttons under Section 510(k) of the Act. You are also required to notify the FDA at least 90 days prior to the introduction of a device into commercial distribution in the United States. An order allowing you to begin distributing your devices must be in your receipt before commencing any distribution. The information necessary to comply with the 510(k) requirement may be found in 21 CFR 807, Subpart E, Pre-market Notification Procedures. Promotion and distribution of these devices without the submission of 510(k)'s may result in the devices being misbranded under Section 502(o) of the Act and adulterated under Section 501 of the Act. FDA believes your septal buttons are adulterated under Section

501(f)(1)(B) of the Act because they are considered to be Class III devices under Section 513(f) which is not exempt under Section 520(g) and is required to have in effect an approved application for pre-market approval, and no such approval is in effect for it.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include but are not limited to seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

We have received your written responses dated May 18 and June 19, 1998, responding to the FDA-483 that was issued to your firm on May 15, 1998. Your responses are noted and are being made part of the official file. In general, the actions that you are taking are appropriate for addressing the concerns denoted in the FDA-483. However, in reference to FDA-483 item 2, we note that your firm continues to manufacture, sterilize and sell product prior to re-validation. A risk assessment should be prepared regarding this decision. Your responses to the specific items will be evaluated during our next scheduled inspection.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As president, the most responsible individual at Micromedics, Inc., it is ultimately your responsibility to ensure that devices manufactured at your facility in Eagan, MN, are in compliance with each requirement of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter

how you plan to prevent them from happening again. If you need more time, let us know why and when you expect to complete your corrections. Please direct your response to Compliance Officer Howard E. Manresa at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of Quality System Requirements for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of 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.

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter, please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,

James A. Rahto
Director
Minneapolis District

HEM/ccl

Enclosure: FDA-483, 5/15/98