



**PURGED**

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

December 13, 1996

cc: HFI-35/FOI Staf.  
DWA

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Refer to MIN 97-18

Robert C. Coborn  
President  
Microbiologics, Inc.  
217 Osseo Avenue North  
St. Cloud, Minnesota 56303

Dear Mr. Coborn:

During an inspection of your firm located in St. Cloud, MN, on November 19-20, 1996, our investigator determined that your firm manufactures in vitro diagnostic kits. These in vitro diagnostic kits are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act in that the methods used in or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. The manufacturing processes for  
and . have not been properly  
validated.

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2. The quality assurance system has not provided solutions to quality problems such as pH variation, viable particle contamination, pouring and mixing, and other processing problems.
3. The pouring and packaging rooms, flooring, table legs and filter locations are not suitable for manufacturing medias that consistently meet specifications.
4. The device history record for lot 24268 (fabrication date 9/18/96), does not indicate the status for ten of the 40 units sampled for sterility verification.
5. The employees involved in pouring media have not signed the pouring media training procedures, Section 4: Fabrication Procedures and instructions.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the closeout 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.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pre-market submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration 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, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to Compliance Officer Thomas P. Nelson at the address indicated on the letterhead.

Sincerely yours,

A handwritten signature in black ink, appearing to read "John Feldman". The signature is fluid and cursive, with a large initial "J" and a long, sweeping underline.

John Feldman  
Director  
Minneapolis District

TPN/ccl