



**PURGED** RAK

January 13, 1997

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

cc: HFI-35/FOI Staff  
DWA

**WARNING LETTER**

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

Refer to MIN 97 - 27

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

Dear Mr. Coborn:

During an FDA inspection of your firm located in St. Cloud, MN, on November 20, 1996, our investigator determined your firm manufactures **in vitro diagnostic media kit devices**. This product is a medical device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above stated inspection revealed the following violations:

- ▶ Section 501(f)(1)(B) of the Act in that your GC Plus kit is a **Class III device** under Section 513(f) and does not have an approved application for pre-market approval in effect pursuant to Section 515(a) or an approved application for an investigational device exemption under Section 520(g).
- ▶ Section 502(o) of the Act in that a notice or other information regarding the device was not provided to the FDA as required by Section 510(k).

This letter is not intended to be an all-inclusive list of the deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

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Robert C. Coborn  
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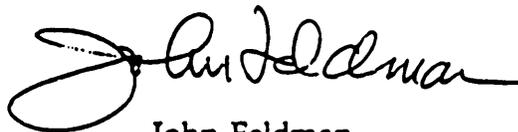
Until it has been determined that corrections are adequate, Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates for Products for Export will be approved.

You should take prompt action to correct these deviations by submitting a Pre-market Notification for your GC Plus Kit as required by Section 510(k) of the Act. 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.

Please notify this office within 15 working days of receipt of this letter of the anticipated date that your firm will be ready for re-inspection.

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

Sincerely yours,



John Feldman  
Director  
Minneapolis District

TPN/ccl