

Refer to: CFN 1111096

Baltimore District  
900 Madison Avenue  
Baltimore, Maryland 21201  
Telephone: (410) 962-4099

December 16, 1997

**WARNING LETTER**

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

Mr. Vincent A. Forlenza, President  
Becton Dickinson Microbiology Systems  
26 Loveton Circle  
Sparks, Maryland 21152

Dear Mr. Forlenza:

A Food and Drug Administration (FDA) inspection of your firm located in Cockeysville, Maryland on November 3 through December 4, 1997, revealed that your firm manufactures TSA with 5% Sheeps Blood, PEA with 5% Sheeps Blood, and CDC ANA Blood with PEA plated media, which are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The 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 Quality System Regulations (QS) for Medical Device Regulations, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish adequate final acceptance procedures, in that 13 lots of media, which were found to be contaminated with Enterococcus faecium in excess of internal specifications, were released for distribution and shipped after removing only those portions of the lots (i.e., "partialled") which were presumed contaminated.
2. Failure to establish adequate acceptance status for determining whether finished products conform or do not conform to specifications, in that there are no criteria by which a contaminated/nonconforming lot may be rejected. Lots with contamination rates as high as 48% were still released.
3. Failure to take corrective or preventative actions regarding nonconforming products, in that there were no investigations conducted regarding the cause of the contamination of 13 lots with Enterococcus faecium, nor were any actions taken to prevent the contamination of future lots.

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4. Failure to establish, control, and verify the statistical techniques required for determining the acceptability of process capability and product characteristics, or to assure that sampling plans are based on a valid statistical rationale, in that there is no valid statistical rationale for the use of Mil-Standard 105(e) for determining sterility assurance or to assure that the "partialling" methods or double sample analysis sets used are statistically valid.
5. Failure to validate manufacturing processes for the cleaning media sterilizers and clean room gowning. Other than a visual examination, there were no tests for residual manufacturing materials following the cleaning process, nor did the gowning validation account for worst case conditions.
6. Failure to establish and maintain production and process controls, in that there are no tests for residual manufacturing materials.
7. Failure to ensure that employees were adequately trained, in that individuals did not follow proper gowning procedures.

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, 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 are corrected. Also, no requests for Certificates for Products for Export will be approved until the violations related to the subject devices have been corrected.

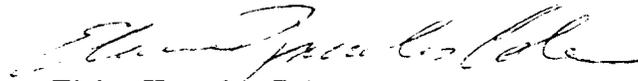
You should take prompt action to correct these deviations. Failure to do so may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

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.

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Your response should be sent to Gerald W. Miller, Compliance Officer, U.S. Food and Drug Administration, 101 West Broad Street (Suite 400), Falls Church, Virginia 22046-4200. Mr. Miller can be reached at 703-235-8440, extension 504.

Sincerely yours,



Elaine Knowles Cole  
Director, Baltimore District

cc: Becton Dickinson  
Attn: Ms. Patricia Shrader, Esq.  
26 Loveton Circle  
Sparks, MD 21152

Becton Dickinson  
Attn: Mr. William Erikson, QS Manager  
250 Schilling Circle  
Cockeysville, MD 21030