

DEPARTMENT OF HEALTH & HUMAN SERVICES
Administration

Public Health Service
Food and Drug

HFI-35
4/3/97
SFB

Refer to: CFN 1122788

M796N

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

April 4, 1997

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. John M. Brewer, President
Stellar Bio Systems, Inc.
9075 Guilford Rd
Columbia, Maryland 21046

Dear Mr. Brewer:

During a Food and Drug Administration (FDA) inspection of your firm located in Columbia, Maryland on March 13-21, 1997, our Investigator determined that your firm manufactures Indirect Fluorescent Assay (IFA) test kits for Antibodies and animal blood serum, which are 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 Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to prepare, sign and date Device Master Records for Indirect Fluorescent Assay (IFA) test kits for Epstein-Barr Virus Capsid Antigen (EBV-VCA) IgG Antibody, Herpes Simplex Virus (Types 1 and 2) IgG Antibody, Chlamydia trachomatis IgG Antibody and Human Cytomegalovirus Antibody.
2. Failure to implement written manufacturing specifications to assure that the device conforms to its original design. The in-process cell count specifications were not met for Human Cytomegalovirus Antibody in 18 of the 19 lots manufactured since January, 1995 and for Chlamydia trachomatis IgG Antibody in 9 out of 15 lots manufactured during that same time.

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3. Failure to package and ship Cytomegalovirus, Herpes Simplex Virus, Epstein-Barr Virus and Chlamydia trachomatis test kits under refrigerated conditions per product label in order to protect the device from alteration or damage during the customary conditions of shipment.
4. Failure to maintain written records of calibration for the multichannel pipette during the 1995 and 1996 time frame.
5. Failure to conduct a review of production documents such as, Device History records, water monitoring records and calibration records to assure the quality of the product.
6. Failure to control the manufacturing process of the water used in the IFA test kits to ensure that the devices conform to applicable specifications.
7. Failure to follow written SOP procedures for the calibration of multichannel pipettes to ensure that they are suitable for their intended purposes.

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 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

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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 Diane T. O'Brien, Acting Compliance Officer, U.S. Food and Drug Administration, 900 Madison Avenue, Baltimore, Maryland 21201.

Sincerely yours,


Carl E. Draper,
Acting Director, Baltimore District