



Certified - Return Receipt Requested

December 9, 1997

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

WARNING LETTER

Gary L. Stewart, Owner
The Brown Laboratory
302 Watson
Topeka, KS 66606

Ref.# - 98-KAN-005

Dear Mr. Stewart:

During an inspection of your firm located in Topeka, Kansas, on October 14, 1997, our investigators determined that your firm manufactures in-vitro diagnostic biologicals. In-vitro diagnostic biologicals are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (Act).

The above-stated inspection revealed that your 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 its manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, in all areas of manufacturing. For example, there are no written complaint procedures. Additionally, there are no records for equipment calibration, maintenance, or validation.

Some of your devices are misbranded under Section 502(a) of the Act in that their labeling contains the word "sterile" which represents or suggests that the devices are sterile, which is false or misleading or otherwise contrary to fact because your facility does not contain adequate equipment necessary for sterile processing nor are the containers sterile.

Your devices are misbranded within the meaning of Section 502(f)(1) in that labeling fails to bear adequate directions for use for the purposes for which they are intended because labeling lacks the information required under 21 CFR 809.10, i.e., indications for use, precautions, expiration dates, lot numbers, appropriate statements regarding alteration of the product (turbidity, color change), etc.

DISTRIBUTION:

Orig.: Addressee

bcc: LF; FF(1935028); HFA-224; HFZ-321(Staples); HFI-35/DIB(via FOI); HFC-210; HFC-240(MPOAS); RRW; WMR(chrono) RF

CRP:jl

Page 2
December 9, 1997
The Brown Laboratory

This letter, and the observations listed on the Form FDA 483, 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 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 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 fifteen (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 reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District