



DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration  
New Orleans District Office  
6600 Plaza Drive, Suite 400  
New Orleans, LA 70127

June 15, 2001

**Via Federal Express**

Mr. Walter C. Edge, Jr.  
President  
Edge Biologicals, Inc.  
598 North Second Street  
Memphis, TN 38105

**Warning Letter No. 01-NSV-33**

Dear Mr. Edge:

During an inspection of your firm on May 16-18, 2001, our investigator determined that your facility manufactures in-vitro diagnostic media that 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 Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820.

The inspection revealed deviations from 21 CFR Part 820 including inadequate Quality Control procedures, failure to adequately investigate customer complaints, Standard Operating Procedures for media preparation were not always dated and signed, and expired media was not separated from finished product awaiting shipment in the walk-in cooler and acceptable media in the production area.

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 the Form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's Quality System. You are responsible for investigating and determining the causes of the violations identified by the FDA.

We acknowledge that you have submitted to this office a response dated May 23, 2001 concerning our investigator's observations noted on the Form FDA 483. We have reviewed your response and have concluded that it is inadequate; specifically, we request a response to the following:

1. When will your Quality Control Procedures be established and implemented? The Form FDA 483 identified 12 critical procedures that must be in place for your firm to be in compliance. Please provide this office a copy of the completed procedures.

2. Please indicate what action was taken to investigate and correct your customer complaints. Our inspection identified at least 14 instances of product defects and contamination that have no documentation that an investigation was done to identify and correct the underlying cause(s).
3. Observation No. III on the FDA 483 was not specifically addressed in your response.
4. Please indicate how you plan to control expired media in the future. There is lack of assurance that expired media stored with acceptable media in the production and shipping areas will be withheld from commercial distribution.

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 request for Certificates to Foreign Governments will be approved until the violations related to the subject device 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.

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 prevent the recurrence of similar violations.

If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,



Carl E. Draper  
Director, New Orleans District

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Enclosure:

21 CFR 820