



DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

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November 7, 1997

WARNING LETTER NO. 98-NOL-03

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Frank B. Gelder, President
Gelco Diagnostics, Inc.
220 Carroll Street, Suite C-1
Shreveport, Louisiana 71105

Dear Dr. Gelder:

During an inspection of your establishment, located in Shreveport, Louisiana, on September 29 - October 2, 1997, our investigators determined that your establishment manufactures in-vitro diagnostic products and reagents for laboratory research uses. In-vitro diagnostic products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed 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 ensure that finished devices meet all specifications prior to distribution. For example, there is no documentation the ouchterloney double diffusion testing procedures were performed on (1) all in-vitro diagnostic samples in the stability program during May and November, 1995, June and December, 1996, and May 16, 1997, or (2) finished product samples of X human IgM, lot # 290; X human IgG, lot # 301; and X human Kappa, lot # 294;
2. Failure to establish and document an adequate quality assurance program. For example, growth promotion tests were not performed on the media used during microbial tests; the bioburden of the unfiltered product was not determined; the daily temperature checks were not documented for the two finished product freezers since January, 1997, or for the three component freezers on January 1, 2, 3, March 31, May 31, July 18, 21, 22 or 23, 1997; environmental conditions were not evaluated to determine airborne contaminants present during manufacturing, testing, and packaging operations; maintenance of shipping container temperatures at -20 to 4°C was not determined; and cleaning procedures prior to manufacturing and packaging operations are not documented;

3. Failure to maintain complete device history records for the following: manufacture of 33/2ml units of X human IgM, lot # 290, released 10/16/96; preparation and type of media used during microbial tests; preparation of the ouchterloney plates used during the double diffusion tests; manufacture and packaging of X human IgM, lot # 290, X human kappa lot # 294, X human immunoglobulin, lot # 299, and X human IgG, lot # 301, in that representative labels are not contained in the device history record;
4. Failure to maintain an adequate device master record. For example, each step of the packaging operations is not documented as specified in the Standard Operating Procedure, "PROCEDURE FOR RECORDING DISBURSEMENTS FROM BULK TO FINISHED INVENTORY, PIPETTING AND PACKAGING PRODUCT".

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 premarket 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.

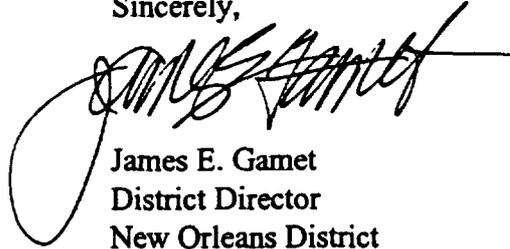
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within 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.

November 7, 1997

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896.

Sincerely,

A handwritten signature in black ink, appearing to read 'James E. Gamet', with a large, sweeping flourish extending to the left.

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483

/tjt