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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

BUFFALO DISTRICT  
Food and Drug Administration  
599 Delaware Avenue  
Buffalo, NY 14202

12 September 1997

WARNING LETTER BUF 97-25

Vijay Kumar, Ph.D., President & CEO  
Immco Diagnostics, Inc.  
60 Pineview Drive  
Buffalo, New York 14228

Dear Dr. Kumar:

An inspection of your facility at 60 Pineview Drive, Buffalo, NY was conducted by Food and Drug Administration (FDA) Investigator Joseph A. Famiglietti from 27 June through 17 July 1997. The inspection revealed AFT System I test kits manufactured at your facility are adulterated within the meaning of Section 501(h) of the Federal Food, Drug and Cosmetic Act (the Act).

These kits are medical devices, and are adulterated because the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation were not in conformance with the Current Good Manufacturing Practice (CGMP) Regulations for Medical Devices which were in effect when they were manufactured [Title 21 Code of Federal Regulations (21 CFR) Part 820]. In addition, they would not be in conformance with the current Quality System Regulation (QSR), which became effective 6/1/97 [21 CFR 820].

CGMP deviations noted include the following:

- failure to adequately investigate complaint 96-0003 which reported unexpected thickening of the mounting medium supplied as a kit component [21 CFR 820.162]. This would be a deviation from current regulation 21 CFR 820.198(c);
- failure to take adequate corrective actions in response to two complaints of unexpected thickening of the mounting medium component, 96-0003 and 97-003 [21 CFR 820.20(a)(3)]. This would be a deviation from current regulation 21 CFR 820.100;
- failure to document a complaint received orally from a customer [21 CFR 820.198(a)]. This would be a deviation from current regulation 21 CFR 820.198;



- failure to have stability data to support the 15-month expiration periods assigned to both the reformulated mounting medium, and to the reformulated conjugate; for the previous formulation of mounting medium, the stability studies were not based on meaningful, scientifically sound test procedures, and were not performed in accordance with a written approved testing program [21 CFR 820.100(a)(1) and 809.10(a)(6)]. This would still be a deviation from 21 CFR 809.10(a)(6);
- there was no validation study performed for a formulation change to internal solution no. 3, a component of the conjugate supplied with the kits [21 CFR 820.100(a)(2)]. This would be a deviation from current regulation 21 CFR 820.75(c);
- there is no documented approval by the formally designated individual for a formulation change made to internal solution no. 3 [21 CFR 820.100(a)(2)]. This would be a deviation from current regulation 21 CFR 820.70(b);
- written manufacturing specifications and processing procedures were not implemented and controlled in the manufacture of a lot of AFT Conjugate. There was no record to document the FITC Solution was used within the time period mandated by written procedures [21 CFR 820.100(a)]. This would be a deviation from current regulation 21 CFR 820.70(a);
- lack of adequate controls to assure labeling integrity; errors were observed in the inserts included in kits which were released and shipped to customers [21 CFR 820.120(a)]. This would be a deviation from current regulation 21 CFR 820.120(b);
- written procedures were not always followed for the use and maintenance of the deionized water system [21 CFR 820.100(a)]. This would be a deviation from current regulation 21 CFR 820.70.

I received your letter of 31 July 1997 responding to deficiencies pointed out at the conclusion of our inspection. It has been made a part of the official file maintained for your firm and will be considered with other records there. Your letter adequately addresses some of the deficiencies noted during the inspection. However, your response it not adequate for the following:

- We do not agree with your assessment that the mounting medium is a non-essential component, as stated in your response to observation one. If the mounting medium does not perform as expected, and the user does not have replacement medium available, the test results cannot be determined.
- We do not agree with your response to observation two. Based on the nature of the complaints, your investigation should have extended to product under the control of the contractor/distributor.

- Your response to observation seven does not indicate whether a designated individual has approved the formulation change.
- Regarding your response to observation ten, there is no documentation to support your conclusion, and you do not indicate how you determined the FITC Solution was used within the time period specified in the written procedure.
- Your response to observation eleven does not address what, if any, corrective actions have been taken for product previously distributed with the inaccurate inserts.

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 violation and deficiencies noted in this letter and in the FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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.

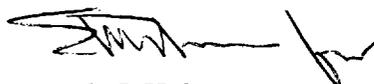
Information regarding instances where the AFT System 1 kits deviate from the 510(k) submission, have been referred to our Center for Devices and Radiological Health, for further review. Additional information may be forthcoming based on the results of their review of these materials.

Federal agencies are advised of the issuance of all Warning Letters about devices so they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests 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 this violation, and all other violations existing at your firm. Failure to achieve prompt corrective action may result in regulatory action - without further notice. This action may include, but is not limited to, seizure, injunction and/or civil penalties.

Please notify this office, in writing, within 15 days, of the specific steps you have taken, or intend to take, to correct this violation. Your response may be directed to James M. Kewley, Compliance Officer/Team Leader, at the above address.

Sincerely,



Brenda J. Holman  
District Director