



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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10/8/97
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Food and Drug Administration
One Montvale Avenue
Stoneham, MA 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

NWE-16-97W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 25, 1997

Mr. John Sullivan
President and CEO
Behring Diagnostics, Inc.
3403 Yerba Buena Road
San Jose, CA 95135-1500

Dear Mr. Sullivan:

During an inspection of your firm located in Westwood, MA from August 26, 1997 through September 4, 1997, our Investigator determined that your firm manufactures and distributes under your own label certain in-vitro diagnostic products, including the AFT System 1 Antibody Kit, which was the subject of this inspection. These products are medical 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 Systems Regulations (Q.S. Regulations) for Medical Devices, as specified in Title 21 Code of Federal Regulations, (21 CFR) Part 820. You are responsible for compliance with all aspects of the Q.S.

Regulations in which you are engaged. Regarding the AFT System 1 Antibody Kit, our Investigator has determined that you [REDACTED] This inspection has revealed that your operations are in violation of the Q.S. Regulations, 21 CFR Part 820, as follows:

- ▶ Failure to establish and maintain procedures to ensure that all purchased or otherwise received product conforms to specifications. For example, there are no written procedures, specifications, or a written contract with your contract manufacturer which includes, for example, product specifications, labeling specifications, or delineation of various responsibilities.
- ▶ Failure to establish and maintain adequate procedures to control labeling activities. For example, your inspection master record contains incorrect extended storage specifications. The printer's proof for your package insert contains an extended storage specification of processed slides at -20°C , whereas your approved inspection master record contains an extended storage specification of processed slides at -2°C . The labeling of all received product was compared to an incorrect inspection master record resulting in the release of product with an incorrect extended storage specification.

The pre-market notification (510(k)) you had identified for this product was cleared on [REDACTED]. For your information, you are responsible for notifying the FDA before making a change or modification that could significantly affect the safety or effectiveness of the device (e.g. a significant change or modification in the design, material, chemical composition, energy source or manufacturing process) or a major change or modification in the intended use of the device.

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 close-out of the inspection may be symptomatic of serious underlying problems in your firm's quality assurance systems. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action.

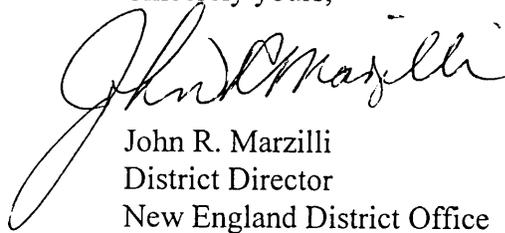
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct the deviations discussed in this letter. Failure to promptly correct these deviations may result in regulatory action 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 within fifteen (15) 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.

Your response should be sent to David K. Elder, Compliance Officer, United States Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180. If you have any questions concerning this matter, please contact Mr. Elder at 781-279-1675, Extension 125.

Sincerely yours,



John R. Marzilli
District Director
New England District Office

cc: Mr. Werner Hampl
Site Leader
Behring Diagnostics, Inc.
151 University Ave.
Westwood, MA 02090