U.S. Department of Health & Human Services

U.S. Food and Drug Administration

Inspections, Compliance, Enforcement, and Criminal Investigations

Verichem Laboratories, Inc. 12/16/10

Department of Health and Human Services

Public Health Service
Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 596-7700
FAX: (781) 596-7896

WARNING LETTER
NWE-06-11W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

December 16, 2010

Anthony J. Di Monte, President
Verichem Laboratories Inc.
90 Narragansett Avenue
Providence, RI 02907

Dear Mr. Di Monte:

During an inspection of your firm located at 90 Narragansett Avenue, Providence, RI on September 14, 2010 through October 29, 2010, an investigator from the United States Food and Drug Administration (FDA) determined that your firm is a manufacturer and contract manufacturer of clinical chemistry reference materials for in-vitro diagnostic (IVD) use. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are medical devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or function of the body.

The inspection revealed that your products Verichem Ethanol Standard Kit 9670 , Verichem Enzyme ER Verifier Kit 9410 and Multi-Enzyme Verifier Kit 9440 are adulterated within the meaning of section 501(h) of the Act, 21 U.S.C. § 351(h), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations (CFR), Part 820.
The violations include, but are not limited to, the following:

1. Failure to validate the design under defined operating conditions and by using initial production units, lots, batches, or their equivalents, as required by 21 CFR 820.30(g).

   a) Your firm failed to follow your design validation for the Verichem Ethanol Standard Kit 9670 in that you have not conducted or documented the **(b)(4)** stability study on any of the **(b)(4)** original validation lots produced.

   b) Your firm failed to perform design validation for the data analysis software used in the Cal Ver EP Evaluator to determine out of specification stability results for Verichem products.

2. Failure to establish and maintain procedures to control product that does not perform to specified requirement as required by 21 CFR 820.90(a)

   Your firm failed to maintain a procedure to thoroughly evaluate, investigate and document nonconformities in your processes, products and testing results.

We have received your response to the FDA 483 dated November 10, 2010 which did contain proposed corrective actions to your quality system, and find it to be inadequate. We acknowledge your plan to perform a thorough review of your manufacturing operations including validation/verification of Verichem processes and products but find that your

corrective action completion date is not timely. Your response indicates that review of deficient processes and procedures including implementation of your identified corrective actions will not be completed until April 1, 2011. In response to this letter please state the reasons for the delay and the date by which you have completed the corrections. Please also indicate if your firm intends to continue manufacturing operations without adequate processes and procedures in place to address the violations identified in the Warning Letter. If your firm has decided to continue manufacturing operations please provide your justification for doing so, clearly explain any interim controls implemented by your firm, and supply supporting documentation.

You should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations 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 money penalties. Also, 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, premarket approval applications for Class III devices to which the Quality System regulation deviations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Include documentation of the corrective actions you have taken. I your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to: Anthony P. Costello, Compliance Officer, USFDA 1 Montvale Avenue, Stoneham, MA 02180 or if you have any questions concerning the content of this letter please contact Mr. Costello at 781 596-7716.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your facility. It is your responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, Form FDA 483 (FDA 483), issued at the closeout of th inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You should investigate and determine the causes of the violations, and take prompt actions to correct the violations and to bring your products into compliance.

Sincerely yours,

/s/

Mutahar S. Shamsi
District Director
New England District

Links on this page: