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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
555 Winderley Pl., Ste. 200
Maitland, Fl 32751

WARNING LETTER

FLA-04-37

June 28, 2004

Andrew C. Swanson, President
Clinical Diagnostic Solutions
1660 NW 65th Avenue, Ste. 2
Plantation, Florida 33313-4580

Dear Mr. Swanson:

On April 21-23, 2004, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your establishment, which manufactures CDS-LTX Control and Primer, CDS 3-PD Hematology Controls, and various hematology and other reagents. These products are medical devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h).

The inspection revealed that these products 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, their manufacture, packing, storage, or installation are not in conformity with the current Good Manufacturing Practice (cGMP) requirements set forth in FDA's Quality System (QS) Regulation, codified in Title 21, Code of Federal Regulation (CFR), Part 820.

The inspector noted the following QS Regulation violations, which are also listed in the FDA Form 483 provided to your facility at the end of the inspection:

1. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. Internal quality audit procedures failed to address, for example, Corrective and Preventive Action (CAPA), Medical Device Reporting (MDR), Design Control, Stability, and Purchasing Controls. Audits

conducted did not cover all quality systems. Three documented audits conducted on February 21, 2001, July 10, 2001, and June 13, 2003 were limited to auditing design control, production and process control, manufacturing facility, warehouse, handling, storage, distribution and storage (FDA 483; Item #5 & 9).

2. Failure to establish and maintain procedures for implementing corrective and preventive action, including requirements for identifying the action(s) needed to correct and prevent recurrence of non-conforming product and other quality problems, as required by 21 CFR 820.100(a)(3). Four complaints were received that referenced high Coefficient of Variation (C/V) results for volume and conductivity for its latex control (lot #2040). Investigation did not definitively determine the root cause. No preventive action was taken except to discontinue using CDS Latex Control (lot #2040) and replace it with CDS Latex Control (lot #2109) (FDA 483; Item #4).
3. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a). There is no written procedure to handle out-of-specification results during testing, and to handle finished product/components if the temperature deviates from the specified range of 2 -8°C (FDA 483; Item #7).
4. Failure to establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants, as required by 21 CFR 820.50(a). Verification of Certificates of Analysis (C of A) for the assay of blood control IVD products have not been conducted by in-house testing, independent testing, physical audits, or written audit of suppliers including C of As from the supplier of bulk latex particles (FDA 483; Item #1).
5. Failure to establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed, as required by 21 CFR 820.160(a). Validation of method to keep blood controls within specified storage temperature range during transport was inadequate because it failed to address a worst case challenge (FDA 483; Item #3).
6. Failure to establish and maintain schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that the manufacturing specifications are met, as required by 21 CFR 820.70(g)(1). There are no established schedules to check or replace HEPA filters in the Laminar Flow Hood used to manufacture blood controls (FDA 483; Item #10).

7. Failure to conduct periodic inspections in accordance with established procedures to ensure adherence to applicable equipment maintenance schedules, as required by 21 CFR 820.70(g)(2). Minimum/maximum readings from temperature monitoring devices used in finished product and component storage coolers were not documented and there is no schedule to monitor these devices (FDA 483; Item #8).
8. Failure to ensure that all inspection, measuring, and test equipment, including mechanical, automated, or electronic inspection and test equipment, is suitable for its intended purposes and is capable of producing valid results, as required by 21 CFR 820.72(a). Temperature monitoring devices in coolers used to store finished devices and components were not calibrated (FDA 483; Item #2).
9. Failure to establish and maintain a Design History File (DHF) for each type of device, as required by 21 CFR 820.30(j). No risk analysis was documented for latex and blood control products (FDA 483; Item #6).

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. 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.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in FDA regulatory action without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties. Additionally, no premarket submissions for Class III devices to which QS Regulation deficiencies are reasonably related will be cleared until the violations have been corrected. Additionally, pending export approval requests may not be approved until the above violations are corrected.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the steps you have taken to correct the noted violations, including (1) the time frames within which the corrections will be completed, (2) any documentation indicating the corrections have been achieved, and (3) 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.

Your response should be sent to Timothy J. Couzins, Compliance Officer, Food and Drug Administration, 555 Winderley Place, Suite 200, Maitland, Florida 32751, (407) 475-4728.

Sincerely,


for
Emma Singleton
Director, Florida District