

HFI-35



DEPARTMENT OF HEALTH & HUMAN SERVICES

g1842d Food and Drug Administration

Dallas District Office
4040 North Central Expressway
Suite 300
Dallas, Texas 75204

October 9, 2001

Ref: 2002-DAL-WL-01

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Bert Davis, President and Chairman
Chase Medical, Inc. (Corporate Offices)
1876 Firman Drive
Richardson, Texas 75081

Dear Mr. Davis:

During an inspection of your firm's manufacturing facility located at 1704 Enterprise Street, Athens, Texas 75751, on August 6 through 10, 2001, our investigator determined that your firm manufactures various cardiovascular products, including Aortic Arch Cannula, Access Cannula, Cardioplegia Cannula, and Suction/Venting devices. These products are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Your 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 their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulations, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. Significant GMP deviations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for acceptance activities [21 CFR 820.80]. For example, your firm:
 - a) does not conduct in-process or finished device testing to ensure bond strength specifications are met for Aortic Arch Cannula products [FDA-483 Item 1].

- (b) failed to remove obsolete components from inventory, following a design change, to prevent distribution and a subsequent recall of five non-conforming lots of Dual Stage Venous Return Cannulas (Product Code DNF-3651S) [FDA-483 Item 3].
2. Failure to establish and maintain procedures to ensure that the device design is correctly translated into production specifications [21 CFR 820.30(h)] and failure to segregate non-conforming products or components [21 CFR 820.90]. For example, a design change of the Dual Stage Venous Return Cannula was initiated on [REDACTED], to use a new [REDACTED] (part # [REDACTED]) for production but your firm failed to dispose of the obsolete [REDACTED] (part # [REDACTED]) to prevent its continued use [FDA-483 item 3].

We have received your response letter with attachments, dated September 28, 2001, responding to our list of inspectional observations (FDA-483 - copy enclosed) issued to Mr. Dave Herson, Vice President Regulatory Affairs, at the completion of the inspection. You state to have completed corrective actions and attached revised procedures for FDA-483 Items 1, 2, and 8. Your response is incomplete because you:

- (a) have not identified specific changes in the attached procedures, explained how changes would correct the observations, and provided employee training records to ensure that your employees have been trained and are familiar with the revised procedures; and
- (b) have not explained if the previous and revised [REDACTED] test could cause any adverse effect to the bond integrity after testing; and
- (c) have not explained how design changes and assembly processes are controlled, verified, or validated to prevent bonded part separation and leakage in light of three recalls you have initiated since 1998.

For the remaining observations, our investigator reported corrections were taken but not verified. Corrective actions taken to address these observations will be verified during the next scheduled compliance follow-up inspection.

Your devices are also misbranded within the meaning of Section 502(t)(2) of the Act in that information was not submitted to FDA within the 30-day time period as required by the Medical Device Reporting Regulation, 21 CFR 803.50. Our investigator documented that on 11/8/00 your firm received a complaint of two separate incidents of tip separation in two cannulas during surgery (complaint #00-054) and subsequently initiated a recall of this product on or about 12/9/00. Our review of the MDR database revealed that FDA did not receive the reports of these two adverse events until 8/14/2001, after completion of our inspection.

Your devices are further misbranded under Section 502(t)(2) of the Act in that a report of correction or removal was not submitted to FDA as required by Section 519(f)(1) of the Act. The Correction and Removal Regulation (21 CFR 806), promulgated under Section 519(f)(1), requires manufacturers and importers to promptly report to FDA, within 10 working days, any correction or removal of a device to reduce a risk to health.

Our inspection revealed that on or about December 9, 2000, your firm notified customers of the removal of 280 Dual Stage Venous Return Cannulas with Bullet Tip (Product Code DNF-3651S) because of complaints of tip separation during use. Your subsequent investigation revealed that obsolete material was not removed from inventory following a design change and that components with incorrect bond geometry were subsequently used to manufacture 280 units of this product code. Your firm's action to retrieve the product meets the definition of a "removal" as defined in 21 CFR 806.2(i) and 21 CFR 806.10(a)(1), which requires manufacturers and importers to promptly report to FDA any correction or removal of a device if the correction or removal was initiated to reduce a risk to health. You did not report the product removal until 9/4/2001, after the inspection.

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 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.

Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, federal agencies will be advised of the issuance of this Warning Letter so that they may take this information into account when considering the award of contracts.

Page 4 – Mr. Bert Davis, President and Chairman
October 9, 2001

You should take prompt action to correct these violations. 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 penalties.

Please provide this office in writing within 15 working days of receipt of this letter a report of the specific steps you have taken or will take to identify and correct 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 frame within which the corrections will be completed. Your reply should be directed to Thao Ta, Compliance Officer, at the above letterhead address.

Sincerely,



Michael A. Chappell
Dallas District Director

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Enclosure