



DEPARTMENT OF HEALTH & HUMAN SERVICES

742679
Food and Drug Administration

Dallas District
4040 North Central Expressway
Dallas, Texas 75204-3145

August 27, 2003

2003-DAL-WL-18

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Ms. Joyce E. Crumpler
Chief Executive Officer
Bowie Memorial Hospital
705 East Greenwood Avenue
Bowie, Texas 76230

Dear Ms. Crumpler:

On April 30 through May 1, 2003, FDA investigators conducted an inspection of your establishment located at the above-referenced address in Bowie, Texas. The investigators determined that your establishment was reprocessing various types of used surgical instruments, such as scissors, forceps, and hemostats, that were initially labeled for single use by their respective original equipment manufacturers (OEMs). These surgical instruments are medical devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

On August 14, 2000, FDA issued a guidance document entitled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," outlining the Agency's position regarding the reprocessing of single-use devices (SUDs). A copy of this document can be found on the Agency's web site at <http://www.fda.gov/cdrh/reuse>. As explained in this guidance, facilities that reprocess SUDs – including hospitals - are now subject to the same regulatory requirements applicable to OEMs.

As of August 14, 2001, hospital reprocessing facilities should have been in compliance with the regulatory requirements applicable to device manufacturers. These requirements include, for example, the Current Good Manufacturing Practice (CGMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (21 CFR) Part 820. Hospital reprocessors must also register their establishments and list the SUDs they reprocess with FDA, as set forth in Section 510 of the Act and 21 CFR Part 807. These facilities also should have developed, maintained, and implemented written Medical

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Device Reporting (MDR) procedures, as described in section 519 of the Act and 21 CFR Part 803. Our inspection documented that you have not satisfied these requirements.

The inspection revealed that your reprocessed 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 CGMP requirements of the Quality System Regulation in 21 CFR Part 820. At the close of the inspection, you were issued a Form FDA 483 which delineated a number of significant deviations including, but not limited to, the following:

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully implemented and maintained at all levels of the organization [21 CFR 820.20]. For example:
 - a) Your facility has not established or implemented a quality policy for the reprocessing of SUDs [21 CFR 820.20(a)] [FDA 483 Item 4];
 - b) Your facility has not established and maintained procedures for management review of the quality system and quality audits [21 CFR 820.20(c) and 820.22, respectively] [FDA 483 Items 3 and 5]; and
 - c) Your facility has not established and maintained quality system procedures and instructions, including procedures for corrective and preventive actions, complaint handling, acceptance or rejection of contaminated devices, and maintenance of device history records [21 CFR 820.20(e)] [FDA 483 Item 5]. [See also 21 CFR 820.100, 820.198, 820.80, and 820.184.]
2. Failure to establish and maintain procedures for acceptance of incoming product [21 CFR 820.80(b)]. Our inspection documented that your facility had not established procedures to inspect or test incoming contaminated SUDs or to document their acceptance or rejection for reprocessing.
3. Failure to establish and maintain procedures to document instructions, standard operating procedures (SOPs), and methods that define and control the manner of production [21 CFR 820.70(a)(1)]. Our inspection documented that:

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- a) Your facility had not established or provided any specific or uniform procedure to each of your departments to ensure that used SUDs are dismantled, cleaned, disinfected, and reassembled in a uniform and consistent method;
 - b) Your facility had not established a limit on the number of times an SUD can be reprocessed or procedures to determine when an SUD can no longer be reprocessed; and
 - c) Your facility had not established procedures or defined whether there are different cleaning processes for different devices.
4. Failure to validate significant reprocessing processes (cleaning, disinfecting, packaging, and steam sterilization) with a high degree of assurance [21 CFR 820.75] [FDA 483 Item 6]. Our inspection documented that your facility could not locate any recognized sterilization standards during the inspection.
 5. Failure to maintain device master records for each type of reprocessed SUD to include or refer to the location of device specifications, production process specifications, quality assurance procedures and specifications, and packaging and labeling specifications [21 CFR 820.181] [FDA 483 Item 8].

Your reprocessed devices are also misbranded under section 502(o) of the Act in that the devices were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the Act, and were not included in a list required by section 510(j) of the Act. You did not register your establishment with FDA or submit a listing of the devices that you reprocess.

Additionally, your reprocessed devices are misbranded under section 502(t)(2) of the Act in that your facility failed to furnish material or information required by or under section 519 of the Act, as specified in 21 CFR Part 803 (MDR regulation). For example, you did not establish or maintain any records or procedures for the reporting of adverse events or device malfunctions relating to SUDs that you reprocess.

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 related 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 facility's reprocessing and quality assurance systems. You are responsible for investigating and determining the causes of these violations. If

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you determine that these violations reflect systemic deficiencies, you must promptly initiate comprehensive corrective actions.

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, no premarket submissions for class III devices to which the Quality System Regulation 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 devices have been corrected.

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 may include, but are not limited to, seizure, injunction, and/or an action to impose civil penalties.

Please provide this office, within 15 working days of receipt of this letter, a written 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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