



DEPARTMENT OF HEALTH & HUMAN SERVICES

WLF
94746d
Food and Drug Administration

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

June 11, 2003

Ref: 2003-DAL-WL-12

WARNING LETTER

CERTIFIED MAIL
RETURNED RECEIPT REQUESTED

Mr. Robert R. Wright
President
U.O. Equipment Company
5863 West 34th Street
Houston, Texas 77092

Dear Mr. Wright:

Our review of information collected during an inspection of your firm located at the above-referenced address on February 11 through 19, 2003, revealed that your firm manufactures, repackages and/or relabels anesthesiology monitoring and therapeutic devices (e.g., powered emergency ventilator-resuscitators, manual emergency resuscitators, and pressure regulators). These products are devices as defined in 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 their manufacturing, packing, storage, or installation are not in conformance with the Current Good Manufacturing Practice (cGMP) requirements of the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulation (CFR), Part 820. At the close of the inspection, you were issued a Form FDA-483 which delineated a number of significant GMP inspectional observations which include, but are not limited to, the following (note that some of these GMP observations are repeat observations from the previous inspection concluded on September 12, 2000):

1. Failure of management with executive responsibility to ensure that an adequate and effective quality system has been fully

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implemented and maintained at all levels of the organization, as required by 21 CFR § 820.20(a). For example, your firm has not established a quality policy and objectives [FDA-483 Item 1a].

2. Failure to document the appointment of a management representative, as required by 21 CFR § 820.20(b)(3) [FDA-483 Item 1b].
3. Failure to establish procedures for conducting management reviews and quality audits, as required by 21 CFR § 820.20(c) and 21 CFR § 820.22, respectively [FDA 483 Item 1c], a repeat observation from the September 2000 inspection.
4. Failure to conduct any quality audits, as required by 21 CFR § 820.22 [FDA-483 Item 1c].
5. Failure to establish and maintain procedures for implementing corrective and preventive actions to include all the requirements, as required by 21 CFR § 820.100(a)(1) through (a)(7) and (b) [FDA-483 Item 4a and 4b]. In addition, your firm did not maintain complete records of a corrective action involving a product change which did not correct the problem and subsequently was reverted back to the previous design specifications (Diaphragm Type Regulator Models 10800FC and 10800FCA), as required by 21 CFR § 820.100(b) [FDA 483 Item 4c].
6. Failure to establish and maintain acceptance procedures to ensure that devices are not released for distribution until all activities required in the device master record are completed, as required by 21 CFR § 820.80(d) and 21 CFR § 820.80(c) [FDA-483 Items 5 and 8]. For example, your firm does not have written procedures or instructions for performing the final testing of oxygen regulators [21 CFR § 820.80(d)] or in-process acceptance testing of the demand valves [21 CFR § 820.80(c)].
7. Failure to document the acceptance activities, as required by 21 CFR § 820.80(e) [FDA-483 Item 5]. For example, your firm did not document the leak test results and signature of the individual(s) conducting the leak testing of the finished oxygen regulators [21 CFR § 820.80(e)(3) and § 820.80(e)(4)] or acceptance activities relating to in-process and finished device testing of the inhalators and resuscitators [21 CFR § 820.80(e)(1)].

8. Failure to establish and maintain procedures to control product that does not conform to specified requirements, including the identification, documentation, evaluation, segregation, and disposition of nonconforming product, as required by 21 CFR § 820.90(a) [FDA-483 Item 6]. Also, your firm did not maintain records of the evaluation, investigation, and final disposition of the backheads returned to the supplier on [REDACTED] and [REDACTED] for rework, and the defective demand valves returned to the supplier on [REDACTED] [21 CFR § 820.90 (a) and 21 CFR § 820.90(b)].
9. Failure to establish and maintain complaint handling procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR § 820.198(a) [FDA-483 Item 2]. For example, your firm's procedure titled "Complaint File" does not include requirements to ensure that all oral complaints are documented upon receipt [21 CFR § 820.198(a)(2)]; requirements to ensure all complaints and service repairs are evaluated for possible MDR medical device events [21 CFR § 820.198(a)(3)]; or requirements to ensure all valid complaints are investigated [21 CFR § 820.198(b)]. In addition, your firm failed to maintain records of investigation [21 CFR § 820.198(e)]. These are repeat observations from the September 2000 inspection.

Our inspection also documented your firm's failure to develop, maintain, and implement medical device reporting (MDR) procedures, as required by 21 CFR § 803.17. For example, your firm has not established a written procedure to address the timely and effective identification and investigation of events that may be subject to MDR requirements [21 CFR § 803.17(a)(1)] [FDA-483 Item 3] or established a standardized review process to determine when an event meets the MDR criteria and document the decision-making process [21 CFR § 803.17(a)(2)] [FDA 483 Item 3]. These are repeat observations from the September 2000 inspection.

In addition, our inspection documented that you had not listed the anesthesiology monitoring and therapeutic devices (e.g., powered emergency ventilator-resuscitators, manual emergency resuscitators, and pressure regulators) with the Food and Drug Administration (FDA) to ensure compliance with 21 CFR § 807.20(a) and 807.21(a). Also, you did not update your device listing at the time a change occurred in your status of manufacturing the continuous (respirator) ventilator and external cardiac compressor as required by 21 CFR §§ 807.21(b) and 807.30(b)(2). Our inspection documented that you have never manufactured or distributed either of these devices. Failure to list your devices with FDA means your devices are misbranded under Section 502(o) of the Act.

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You can obtain the listing form from our website at <http://www.fda.gov> for the filing of your firm's device listing.

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 the 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.

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 violations may result in regulatory action being initiated by FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Should you need general information concerning FDA's requirements for medical device manufacturers, you may obtain information on the FDA's website at <http://www.fda.gov> or by contacting our Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at (800) 638-2041.

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 Monica J. Wilkins, Compliance Officer, at the above letterhead address.

Sincerely,


Michael A. Chappell
Dallas District Director

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