



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

m4203m
Food and Drug Administration
New Orleans District Office
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

September 15, 2000

CERTIFIED MAIL—RETURN RECEIPT REQUESTED

Mr. Craig B. Watson
Chief Executive Officer
Delta Medical Center
3000 Getwell Road
Memphis, TN 38118

Quayle
9/15/00
JGA

Warning Letter No. 00-NSV-28

Dear Mr. Watson:

During an inspection of your facility located in Memphis, Tennessee, on August 22-23, 2000, our investigator determined that you failed to submit a Medication and Device Experience Report, FDA Form 3500A, to the Food and Drug Administration (FDA) and/or manufacturer of the device. These reports are required when a device has or may have caused serious injury to patients of your facility. These devices are misbranded under Section 502(t)(2) of the Federal Food, Drug, and Cosmetic Act (the Act) in that your facility failed to submit the information to the FDA and/or the manufacturer of the device as required by the Medical Device Reporting (MDR) Regulations, as specified in 21 CFR Part 803. Specifically, you failed to submit an MDR report to FDA and/or manufacturer of the device after receiving information which reasonably suggests that certain devices had malfunctioned and may have caused or contributed to a serious injury, as required by 21 CFR part 803.30. For example:

1. A cardiac pacemaker manufactured by [REDACTED] which was implanted on September 4, 1999, was replaced on November 4, 1999 due to a malfunction of the pacemaker.
2. A patient was injured on July 15, 2000 as a result of a broken belt on a [REDACTED] manufactured by [REDACTED]
3. Three reports of electric shock from a defibrillator manufactured by [REDACTED]

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, injunction and/or civil penalties.

Written MDR reports for the above incidents must be submitted within fifteen (15) working days of receipt of this letter. You must also submit written reports for any other MDR reportable incidents that occurred at your facility during the two-year period prior to the date of this letter that you have not already reported. If submission of these reports cannot be accomplished within fifteen (15) working days, you are requested to provide the FDA with a tabulation of the reports involved and an estimate of when your facility will be able to complete the submission.

We would also like to point out that 21 CFR Part 803.17 requires that your facility develop, maintain, and implement written MDR procedures.

Your reply should be addressed to the attention of Joseph E. Hayes, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, Tennessee 37217.

Sincerely,



Carl E. Draper
Director, New Orleans District

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Enclosures:

21 CFR Part 803 – Medical Device Reporting
Form FDA 3500A
Medical Device Reporting for User Facilities Instruction Booklet