



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

5270

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

March 12, 2001

Mr. Robert J. Nolly, Administrator
University of Tennessee Bowld Hospital
951 Court Avenue
Memphis, TN 38103

Handwritten signature
3/12/01
JEN

Dear Mr. Nolly:

Warning Letter No. 01-NSV-17

During an inspection of your facility located in Memphis, Tennessee, on February 21-23, 2001, 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 at 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. On February 9, 1999 a cauterizing device burned the dermis skin layer on the right thigh of a patient during a vaginal hysterectomy.
2. On November 16, 2000 a gel pad fell off the paddle of a defibrillator, between shocks, with the patient receiving a burn the size and shape of the paddle on the right side of the chest.

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.

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Written MDR reports for the above incidents should be submitted within fifteen (15) working days of receipt of this letter. If submission of these reports cannot be accomplished within fifteen (15) working days, please provide FDA with the time within which the submission will be completed.

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,

A handwritten signature in black ink, appearing to read 'Carl E. Draper', with a stylized flourish at the end.

Carl E. Draper
Director
New Orleans District

JEH/kl

Enclosures:

21 CFR Part 803-Medical Device Reporting
Form FDA 3500A
Medical Device Reporting for User Facility Instruction Booklet