



HFI-35 M354N

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION

4298 Elysian Fields Avenue
New Orleans, LA 70122-3896
Telephone (504) 589-7166
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June 23, 1998

WARNING LETTER NO. 98-NOL-26

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Bobbie F. Butler, President and CEO
Associated Hospital Services, Inc.
7639 Townsend Place
New Orleans, Louisiana 70126

Dear Mr. Butler:

During an inspection of Associated Hospital Services, Inc., 7639 Townsend Place, New Orleans, Louisiana, on April 30-May 7, 1998, our investigator determined that your establishment manufactures packages each containing surgeon's gowns and/or operating room towels labeled as sterile. Sterile surgeons' gowns and/or operating room towels are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed 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 manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Device Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to provide documentation to demonstrate that environmental controls, cleaning procedures, and the manufacturing processes have been validated to assure the finished products are sterile; and
2. Failure to provide documentation to demonstrate that the installation and operation of the heat sealer has been qualified and validated.

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 closeout 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. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

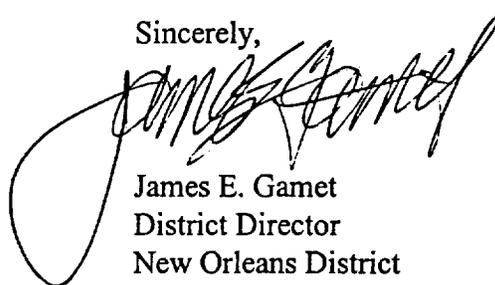
You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Also, please be aware that FDA has received letters from your firm dated May 15, 1998 and June 3, 1998, which were written in response to the Report of Observations (FDA-483) issued at the conclusion of the referenced inspection. The contents of these letters are currently under review.

Please notify this office in writing, within 15 working days of receipt of this letter, of any additional steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to 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 within which the corrections will be completed.

Your response should be directed to Nicole F. Hardin, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896.

Sincerely,

A handwritten signature in black ink, appearing to read "James E. Gamet", written over a large, stylized loop.

James E. Gamet
District Director
New Orleans District

Enclosure: FDA-483

/tjt