



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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of
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PURGED

Food and Drug Administration
Minnesota District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

January 6, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 97 - 21

Darlow T. Madge
Owner
Allied Medical Associates
2338 Commerce Boulevard
Mound, Minnesota 55364

Dear Mr. Madge:

During an inspection of your firm located in Mound, MN, on December 12, 1996, our investigator determined that your firm is an own-label distributor of a sterile disposable plastic drape. Sterile disposable plastic drapes are medical devices as defined by 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 manufacturing, packing, storage, or installation are not in conformance with Current Good Manufacturing Practice (CGMP) regulations for Medical Devices as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to maintain a device master record including specifications for the device, production process, quality assurance procedures, and packaging and labeling (21 CFR Part 820.181).

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2. Failure to have a sterilization validation record. Your contract sterilizer, , had no records demonstrating that sterility validation was ever performed for your product [21 CFR Part 820.100 (a)(1)]. Further, your product is misbranded within the meaning of Section 502(a) of the Act in that it is not exempt under 21 CFR Part 801.150(e) because it does not meet the requirements that specify the contents of a written agreement between your firm and the contract sterilizer that must be in effect for this exemption to apply. An exemption would allow you to manufacture and/or assemble, package and fully label a device as sterile at one establishment and then ship the device to a contract sterilizer for sterilization.
3. Failure to have a complaint handling system for: written and oral complaints relative to the identity, quality, durability, reliability, safety, effectiveness, or performance of a device; review, evaluation, and investigation into the possible failure of a device to meet its performance specifications; and the recording of investigations (21 CFR Part 820.198).
4. Failure to maintain a device history to demonstrate that the devices are manufactured in accordance with the device master record (21 CFR Part 820.184).

Subsequent to the previous inspection of your operation on December 15, 1994, you were issued an FDA-483 citing the lack of a device master record and the lack of validation for your sterilization process. The current inspection found that you have not taken action to correct these deficiencies.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As owner, the most responsible individual at Allied Medical Associates, it is ultimately your responsibility to ensure that devices manufactured for your facility in Mound, MN, are in compliance with 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

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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.

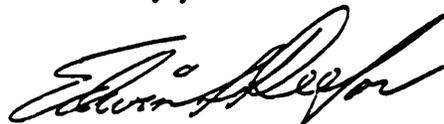
Federal Agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no pending applications for pre-market approval (PMAs) or export approval requests will be approved and no pre-market notifications [Section 510(k)] will be found to be substantially equivalent for products manufactured for your facility until the violations have been corrected.

You should take prompt action to correct these violations. Failure to correct these violations 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.

We request that you notify this office in writing within 15 working days of your receipt of this letter of the specific 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 system problems necessary to ensure that similar violations will not recur. If the corrections cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be directed to Compliance Officer Howard E. Manresa at the address indicated on the letterhead. Mr. Manresa may be reached at (612)334-4100 ext. 156.

Sincerely yours,



John Feldman
Director
Minneapolis District

HEM/ccl

Enclosures: FDA-483