



March 27, 1997

WARNING LETTER
CHI-22-97

Chicago District
300 S. Riverside Plaza, Suite 550 South
Chicago, Illinois 60606
Telephone: 312-353-5863

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Joseph DaMico, Chief Operating Officer
Allegiance Healthcare Corp.
1450 Waukegan Road
McGaw Park, IL 60085

Dear Mr. DaMico:

During the inspection of your McGaw Park, IL Custom Sterile facility from November 13, 1996 to February 18, 1997, Investigators Steven B. Barber and Lisa Hornback determined your firm manufactures custom sterile procedure kits. Custom sterile procedure kits are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The devices are adulterated under Section 501(h) in that the methods used in, or the facilities or controls used for manufacturing, packaging, storage, or installation are not in conformance with the Good Manufacturing Practice Regulations (GMP) for Medical Devices specified in Title 21, Code of Federal Regulations (CFR), Part 820:

1. Failure to control device processing to assure that devices conform to their original design, for example:
 - a. Validation of the 4-mil pouch was unsuccessful (reported in January 1996). This pouch continued to be used (until at least November 1996) after determining it could not be validated.
 - b. Pouch 5M3228 could not be validated for Ethylene Oxide (EtO) sterilization. Kits with this pouch were sterilized by EtO for work orders 189474, 201164, 193282, 203375 and 203056.
 - c. The package insert for Lidocaine states do not sterilize with EtO. Lidocaine was incorporated into kits that were EtO sterilized.
 - d. There is no documentation to ensure that drug components of medical device kits are free from EtO.

2. Failure to validate the packaging for all medical device products, for example:
 - a. Failure to validate 3-mil kit packaging.
 - b. Failure to validate tyvek pouches.
3. Failure to withhold from distribution medical device kits which were identified to have quality concerns. For example, work orders 202850, 202748, 208673, and 202448 were identified in a routing department logbook to be on hold for seal concerns. There was no documentation that these concerns were corrected before distribution.

We acknowledge Ms. Vojna McCarthy's response, dated February 25, 1997, concerning our investigator's observations noted on the Form FDA 483 (enclosed). We also recognize your representative's commitments made at a meeting at our district office on March 6, 1997. We have reviewed Ms. McCarthy's written response and found it to be generally acceptable. However, we do have the following concerns:

FDA 483 Observation #1 and others

Please explain why the findings of the validation were not recognized and followed. Also explain how future validation findings will be appropriately implemented.

FDA 483 Observation #2

Please ensure that all appropriate processes requiring validation have been validated or have been scheduled to be validated.

FDA 483 Observation #19

Please evaluate the effect of the EtO sterilization on the Lidocaine drug. Why did [REDACTED] label the product not to be sterilized by EtO?

FDA 483 Observation #22

Please provide time frames for completion of these studies.

Also, in the meeting of March 6, 1997, Allegiance representatives stated that FDA 483 issues had been recognized by Allegiance's own internal audits. Please describe why your own audit findings were not corrected and how future findings will be corrected.

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 enclosed 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.

Also, we are concerned by the number of kits that are manufactured under your single 510(k). We request that you prepare a comparison of the old (seven kits of your 510(k)) and new kits in a chart format grouped by kit family and subgroups of those requiring new 510(k)s and those not requiring further action. Each device group should include a brief description of how the group differs from other groups and from the predicate device. The rationale for the subgroup categorization should also be provided. Kits which are entirely new can be described in brief paragraphs. Please provide this review to Mr. David Berkowitz, Reviewer, Plastic and Reconstructive Surgery Branch, Office of Device Evaluation, Center for Devices and Radiological Health, Food and Drug Administration, 1390 Piccard Drive, Rockville, Md 20850.

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 verified to be corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been verified to be corrected.

You should take prompt action to ensure continued compliance with the Act and promulgated regulations. Failure to remain in compliance 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.

Please notify this office in writing within 15 working days of receipt of this letter, with the additional responses (regarding the GMP concerns) requested as a result of our review of your letter. If your response cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

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Your response should be sent to Stephen D. Eich, Compliance Officer.

Sincerely,

/s/

Raymond V. Mlecko
District Director