



May 26, 1999

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

WARNING LETTER
CHI-18-99

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Edward Goldberg, President
Uresil L.P.
5418 W. Touhy Ave.
Skokie, IL 60077

Dear Dr. Goldberg:

During an inspection of your establishment located in Skokie, IL, from March 1, 1999, to March 9, 1999, our investigator, Chad E. Schmeier, determined that your establishment manufactures drainage catheters, balloon occlusion catheters, drainage bags and laparoscopic instruments. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The 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 the Quality System Regulation for medical devices, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish adequate complaint handling procedures. For example, your complaint handling procedures did not identify customer dissatisfactions recorded on Returned Goods Authorization (RGA) Forms as complaints. RGA numbers 561, 565, 568, 589, 623, and 624 contained descriptions such as, "Damage Goods," "Unsealed pouched", "sticking catheter", and "pouched open when arrived." These RGA's were not documented or handled as complaints.
2. Failure to establish adequate procedures for implementing corrective and preventive action. For example, your Preventive and Corrective Action Procedure #J4.0 did not address verifying or validating corrective and preventive actions prior to implementation of such action. Also, there were no established procedures for routinely analyzing Discrepant Material Reports and Return Goods Authorization Forms for possible trends and the need for corrective action.

3. Failure to establish adequate procedures to control product that does not conform to specifications. For example, your Material Review Board Procedure #F-6.2, used to record and track nonconforming product prior to distribution, does not require an evaluation of the nonconformance to determine if an investigation is necessary. Material Report Form numbers 98-185, 98-088, 98-087 and 98-052 describe detection of nonconforming product and do not contain documentation of an investigation or an evaluation of the need for an investigation.

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 Form 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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.

We acknowledge the receipt of your response, dated April 2, 1999, concerning Investigator Schmeier's observations noted on the form FDA 483. It appears that your response is adequate. However, we require verification that your corrective actions are adequate by FDA inspection or by a third party auditor's written verification.

Until we verify your corrections are adequate by FDA inspection or receive verification that your corrective actions are adequate from a third party auditor, 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 Class III devices to which the Quality System/GMP deficiencies are reasonably related will be cleared or approved until the violations have been corrected and verified. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

You should take prompt action to prevent a repeat of these deviations. Failure to prevent 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.

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Please notify this office in writing whether you will contract a third party audit or whether you would prefer FDA to perform a reinspection. Your response should be sent to Michael Lang, Acting Compliance Officer, at the above address.

Sincerely,

/s/

Raymond V. Mlecko
District Director