



March 20, 1997

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

WARNING LETTER
CHI-21-97

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Lakshman M. Agadi, President
Medgyn Products
328 North Eisenhower Lane
Lombard, IL 60148

Dear Mr. Agadi:

During an inspection of your firm from January 14 to March 4, 1997, Investigators Colleen Aspinwall and Yvonne Lozano determined that your firm manufactures endosamplers and other assorted obstetric/gynecological devices. Your products are 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 the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to ensure environmental control (in the clean room areas) for manufacture of sterile devices. Environmental monitoring of your clean room identified surface samples with excessive counts. There was no follow-up to this finding.
2. Failure to validate or adequately validate critical processes for the manufacture of medical devices, for example:
 - a) The injection molding process for rigid curettes has not been validated.
 - b) The validation of the 100% ethylene oxide sterilization cycle for the diagnostic sets did not determine the bioburden based on three lots. Also, there was no verification of product/package functionality following sterilization.

- c) The validation of the gamma irradiation sterilization process did not include documented evidence that the 16mm Rigid Curette is the most difficult to sterilize. Also during quarterly dose audits, some of the dose audit records are missing and some of the specified or delivered doses differed from the original dose.
 - d) The validation of the packaging and heat sealing process did not control the time and pressure of the process. Also, the validation did not determine the reproducibility of the process.
3. Failure to perform maintenance of the [REDACTED] heat sealer as recommended by the manufacturer.
 4. Failure to train personnel (involved with product returns and customer service) on complaint handling procedures.

We acknowledge the receipt of your response to our FDA 483, dated March 11, 1997. We have reviewed your response and find that it does not adequately address our concerns. This response lacks the specificity and detail to ensure that appropriate corrections have or will be made. We will provide an additional response within the next two weeks detailing our concerns with your response.

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.

In order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that it has conducted an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device GMP regulations (21 CFR Part 820). You should also submit a copy of the consultant's report, and certification by your firm's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certifications of audit and corrections and subsequent certifications of updated audits and corrections (if required) should be submitted to this office by the following dates:

- o Initial certifications by consultant and firm - 5/27/97
- o Subsequent certifications - 5/27/98

Until these violations are corrected, and FDA has documentation to establish that such corrections have been made, Federal Agencies will be 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 premarket approval (PMAs) or export approval requests will be approved and no premarket notifications (Section 510(k)s) will be found to be substantially equivalent for products manufactured at the facility in which the above GMP violations were found until the violations 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.

You do not need to respond to this letter. We will ask you to respond following your receipt of our additional correspondence.

Sincerely,



Raymond V. Mlecko
District Director

Attachment