



Chicago District
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Chicago, Illinois 60606
Telephone: 312-353-5863

May 8, 2000

WARNING LETTER
CHI-17-00

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Laksham M. Agadi, President
MedGyn Products, Inc.
328 N. Eisenhower Lane
Lombard, IL 60148

Dear Mr. Agadi:

During an inspection of your establishment from February 3 to February 17, 2000, our investigator, Tamara Brey, determined that your establishment manufactures obstetrical and gynecological devices such as endometrial curettes, uterine curettes, hygroscopic cervical dilators, vaginal speculums, and colposcopes. These products are devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

This 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 adequately validate manufacturing processes. For example:
 - 1a) Your firm's process validation for Disposable Rigid Curettes contained the following deficiencies:
 - The validation did not provide evidence that installation and operation qualification activities were performed.
 - The validation did not provide evidence that the process consistently produces a product that meets its predetermined specifications during multiple, successive process runs.
 - The validation did not document rigid curette size or the number of curettes to be tested.

- The validation did not document the individuals performing the process or the date the validation was performed.
- 1b) Several injection molding process parameters, in the *Rigid Curette – Molding Parameters QAI #1000.7.2.1*, were outside the parameters found as acceptable in the current process validation. Your firm did not perform a revalidation to review and evaluate these process changes.
- 1c) Your firm failed to establish any bioburden specifications for sterilized products.
2. Failure to document the disposition of nonconforming product. For example, your firm did not routinely document the number of nonconforming Rigid Curettes detected by manufacturing personnel during in-process inspection.
 3. Failure to maintain adequate Device History Records. For example, the Rigid Curettes Device History Records did not include production process parameters, such as temperatures and pressures, for the [REDACTED] injection molding process.
 4. Failure to establish and adequate procedures to control product that does not conform to specified requirements. For example, your firm had no written procedures to specify the frequency of quality control tests or quantity of products to be sampled during the manufacture of Disposable Rigid Curettes.
 5. Failure to maintain procedures to ensure manufacturing equipment is routinely inspected, checked, and maintained. For example, your firm had no documentation showing that the maintenance activities for the [REDACTED] Injection Molding Machine were conducted in November 1999, December 1999, and January 2000, as specified in the procedure entitled, "Maintenance of Injection Molding Machine QAI # 3200.1, Rev. 1."
 6. Failure to provide adequate resources including the assignment of trained personnel for management, performance of work, and assessment activities to meet the requirements of the Quality System Regulation. For example, your firm's Management Representative lacked training to effectively establish and maintain the requirements of the Quality System Regulation.
 7. Failure to document the dates and results of quality system reviews. For example, your firm lacked documentation of Quality Council meetings for the following months: November 1999, December 1999, and January 2000. Your procedure entitled, "Quality Council Meeting and Annual Management Review QAI # 300.1, Rev. 3," requires a monthly Quality Council meeting between the Quality Assurance Representative and the Quality Council to discuss Quality System issues and ensure corrective actions were taken to rectify problems.

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.

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 requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected and verified.

We request that you 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.

In order to facilitate FDA in making the determination that corrections to the deviations from the Quality System Regulation have been made and thereby, enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts for medical devices, and to resume Certificates to Foreign Governments for medical devices manufactured at your facility located in Lombard, IL, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant that he/she has conducted an audit of your establishment's manufacturing and quality assurance systems relative to the requirements of the device Quality System Regulation (21 CFR Part 820). You should also submit a copy of the consultant's report, and certification by your establishment's CEO (if other than yourself) that he or she has reviewed the consultant's report and that your establishment, located in Lombard, IL, has initiated and 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 should be submitted to this office on the following dates:

- Initial certifications by consultant and establishment: November 1, 2000 (or sooner)
- Subsequent certifications of updated audits and corrections: November 1, 2001
November 1, 2002

We did not receive your consultant's audit report and your CEO's certification, due on May 27, 1998, as requested in the previous Warning Letter, dated March 20, 1997. Please submit all future consultant audit reports and CEO certifications by the due dates listed above.

We acknowledge that your firm responded by letter, dated March 1, 2000, to our investigator's FDA-483. We do not consider your firm's response adequate because of the following:

- Observation 1. Your response does not correct the process validation deficiencies our investigator detected during the inspection and it fails to explain how similar deficiencies will be prevented from recurring.
- Observation 2. Your response does not correct the observation that your firm was operating the injection molding process outside the parameters determined in the process validation to consistently produce product within specifications. Your response is also confusing because our investigator determined your Rigid Curette injection molding process validation to be dated April 1, 1997. However, your response states that the process parameters were established in 1996 and then revised in 1998. Also, your promise to "further evaluate the entire process to ensure the validated parameters are; true, will not compromise device integrity, and are reflected in appropriate SOP's and QAI's," is vague. Please be more specific and explain, in detail, how your firm will "evaluate the entire process."
- Observation 3. Your response does not contain any evidence that the individuals who performed your "internal/external audits" followed your standard operating procedure (SOP) entitled, "QAI # 1000.24, Annual Review of ETO Process Rev. 1." This SOP requires an internal review of the firm's manufacturing equipment, manufacturing process, product and packaging to seek out any changes that may require a ½ cycle validation. Your response does not show how the "internal/external audits" performed in 1999 met the requirements of your SOP QAI # 1000.24. Furthermore, your response does not address how your firm plans to prevent this deviation from recurring.
- Observation 6. Your response does not assure that the actual process parameters (settings and measurements), used to manufacture a product lot, will be recorded in the Device History Record.
- Observation 7. This observation addressed the periodical in-process quality control inspections performed on product as it comes off the injection-molding machine. Your response failed to address the deficiency in the observation; that is, lack of written instructions for the frequency of quality control tests and the number of samples per test.

Observation 11. Your response does not explain why Quality Council meetings were not conducted during the months of November 1999, December 1999, and January 2000, as required by your SOP entitled, "Quality Council Meeting and Management Review, QAI # 300.1, Rev. 3." Furthermore, your response fails to address how your firm plans to prevent this deviation from recurring.

Please notify this office in writing within 15 working days of 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 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 sent to Michael Lang, Compliance Officer.

Sincerely yours,

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Raymond V. Mlecko
District Director
Chicago District