



DEPARTMENT OF HEALTH & HUMAN SERVICES

Redacted  
A  
d1613b

11/1/35

Public Health Service  
Cincinnati District

Food & Drug Administration  
1141 Central Parkway  
Cincinnati, OH 45202-1097

**CERTIFIED MAIL  
RETURN RECEIPT REQUESTED**

December 26, 1996

**WARNING LETTER  
CIN-WL-97-129**

Gary Fenton, President  
Marlen Manufacturing and Development Co.  
5150 Richmond Road  
Bedford Heights, Ohio 44146

Dear Mr. Fenton:

During an inspection of your firm located at the above address on November 13-14, 1996 our Investigator determined that your firm manufactures colostomy rods and ileostomy/colostomy/urostomy bags and accessories. These items are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act). The Inspection revealed that your 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, 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, as follows:

Failure to ensure that devices meet finished device specifications before distribution. The "Inspection Procedure" states that "final inspection is done during the packaging phase of production." There are no records of any quality assurance inspections at this stage.

Failure to establish and implement an adequate complaint handling program. Complaints are given a code as to the type of problem and action taken, but the codes do not provide details as to the corrective action taken. Thirteen of the nineteen complaints logged into the complaint system since 2/9/96 did not have any documented further investigations.

Failure to establish and implement adequate record keeping procedures. Device Master Records are not signed and dated for the various medical devices manufactured.

Failure to establish and implement an adequate failure investigation program. Of eight complaints received that met the definition of a failure per your firm's "Failure Investigation Procedure", only one had a failure investigation report done.

Failure to establish adequate sampling procedures for in-process and finished devices. There are no written procedures specifying what to inspect/test for or how many units to inspect/test. Sampling procedures are not based on any statistical sampling plan.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure 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 FDA inspection of your facility 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.

Page 2  
December 26, 1996

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, to resume marketing clearance, and export clearance for products manufactured at Marlen Manufacturing & Development Co.'s facility, we are requesting that you submit to this office on the schedule below, certification by an outside expert consultant. The consultant shall conduct an audit of your firm's manufacturing and quality assurance systems relative to the requirements of the device GMP regulation (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: June 30, 1997 and June 30, 1998.

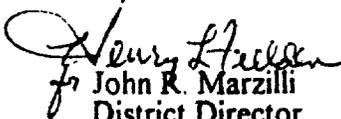
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject device 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. Possible actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing within fifteen (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 prevent the recurrence of similar violations. If corrective action cannot be completed within fifteen (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 Evelyn D. Forney, Compliance Officer, Food and Drug Administration, 1141 Central Parkway, Cincinnati, Ohio 45202.

Sincerely,

  
John R. Marzilli  
District Director  
Cincinnati District

Enclosure