



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

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4/25/97  
CJH

Dallas District  
3310 Live Oak Street  
Dallas, Texas 75204-6191

April 21, 1997

Ref: 97-DAL-WL-21

**WARNING LETTER**

**VIA FACSIMILE AND  
FEDERAL EXPRESS**

Mr. Jimmy J. Girouard, Owner  
Colon Therapeutics  
6249 25th Street  
Groves, Texas 77619

Dear Mr. Girouard:

We are writing to you because on January 7, 8 and 13, 1997, an investigator from the Food and Drug Administration (FDA) conducted an inspection of your firm that revealed a serious regulatory problem involving the product known as the Jimmy John, colon hydrotherapy unit and related devices, which are made and marketed by your firm.

The rectal nozzle, used with the Jimmy John Hydrotherapy Unit, is misbranded within the meaning of Section 502(o) of the Federal Food, Drug and Cosmetic Act (the Act), in that premarket notice or other information respecting the device was not provided to the Food and Drug Administration as required by Section 510(k), as described under 21 Code of Federal Regulations part 807.81(a)(3)(I). The device has significant modifications in the material and manufacturing process that could affect the safety and effectiveness of the device, in that the nozzle material has changed from Tenite propionate formula 350 to PVC without proper bioavailability testing. Furthermore, the method of sterilization has changed from ETO to gamma without any validation of the sterility assurance levels.

The rectal nozzle is also adulterated within the meaning of Section 501(f)(1)(B) of the Act, in that it is a class III device under Section 513(f) of the Act and does not have an approved application for premarket approval (PMA), and it is not exempt from such requirements under an investigational device exemption (IDE) Section 520(g).

Additionally, our investigator documented serious deviations from the Good Manufacturing Practice (GMP) for Medical Device Regulations (Title 21, Code of Federal Regulations

(CFR), Part 820). The deficiencies cause your Colonic System and related devices to be 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 21 CFR, Part 820. The inspectional observations, FDA-483, were discussed with you at the completion of the inspection. GMP deficiencies noted during the inspection include:

Failure to establish, implement and control written manufacturing specifications and processing procedures to assure that the device conforms to its original design or any changes in that design, as required by 21 CFR 820.100. For example, changes in the sterilization, packaging and material used in the rectal nozzle have not been validated. The sealing process for the rectal nozzle and the water purification system for the colonic system also have not been validated.

Failure to maintain complete device master records to include device specifications, production process specifications, quality assurance procedures and specifications, and packaging and labeling specifications as required by 21 CFR 820.181.

Failure to maintain adequate manufacturing and quality control records, including in-process and final test results, temperature and leak test results and seal inspection results.

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 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.

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 pending applications for premarket approval (PMA's) or export approval requests will be approved for products manufactured at your Groves, Texas facility until the violations have been corrected.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil penalties.

Mr. Jimmy J. Girouard  
April 21, 1997

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It is necessary for you to take action on this matter now. Please let this office know in writing in fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your corrections. Please direct your response to Gwendolyn S. Gilbreath, Compliance Officer, at the above letterhead address.

Sincerely

A handwritten signature in black ink, appearing to read "Joseph R. Baca". The signature is written in a cursive style with a large initial "J".

Joseph R. Baca  
Dallas District Director

JRB/GSG