



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

July 19, 2001

WARNING LETTER  
CHI-39-01

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Mr. Edwin J. McDonough  
Chief Executive Officer  
Progeny, Inc.  
1407 Barclay Boulevard  
Buffalo Grove, IL 60089

Dear Mr. McDonough:

During the inspection of your facility located in Buffalo Grove, IL, from March 6 to March 12, 2001, Investigator Jesse A. Vazquez determined that your firm manufactures collimators for x-ray systems. Collimators are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The Corrections and Removals regulation requires manufacturers, importers, and distributors to report promptly to FDA corrections or removals of devices undertaken to reduce a risk to health within 10 working days. The inspection revealed that your firm's collimators are misbranded within the meaning of 502(t)(2) of the Act in that your firm failed to submit a Report of Correction or Removal to the FDA as required by Title 21, Code of Federal Regulations (21 CFR), Part 806, Medical Device Corrections and Removals, promulgated under Section 519(f) of the Act.

During the inspection, Investigator Vazquez determined that a complaint you received on October 30, 2000, initiated the recall on January 24, 2001, of [REDACTED] series collimators manufactured from September 24, 1999, to October 24, 1999. Your firm determined that the cause of the complaint was, in certain lots of collimators produced during that time period, the wrong screw size was used to attach the collimator housing to the mounting flange. Your firm determined that, if not repaired, eventually the housing could separate from the mounting plate, allowing the collimator to fall. The recall involved mailing a service bulletin to your customers to inform them of the recall, inspecting returned collimators to determine if the wrong screw size was used, and replacing with the proper screw size if needed. These actions meet the definition of a correction as defined in 21 CFR 806.10(a)(1), which requires manufacturers, importers, and distributors to submit a written report to FDA of any correction or removal of a device if the correction or removal was initiated to reduce a risk to health.

We acknowledge receipt of your Report of Correction for the above-mentioned recall, dated March 13, 2001, addressed to Ms. Kathleen E. Haas, Recall & Customer Complaint Coordinator.

The inspection also 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 (QSR) for medical devices, as specified in 21 CFR Part 820, as follows:

1. Failure to establish and maintain procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. For example, your firm had no procedures for training production line employees and the application engineer (for complaint handling responsibilities). Also, your firm had no documentation that the line employees and the applications engineer received adequate training to perform their assigned duties.
2. Failure to establish and maintain procedures to ensure that all complaints are received, reviewed, and evaluated in a uniform and timely manner. For example, serial numbers and product model, needed for proper identification of Progeny collimators, was omitted from various Progeny Tech Support Log records.

We acknowledge receipt of your response, dated March 22, 2001, to our FDA-483, dated March 12, 2001. We have reviewed your response and determined that it does not include 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.

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 Form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment's quality system. You are responsible for investigating and determining the causes of the violations identified by the FDA. You also must promptly initiate permanent corrective and preventive action on your Quality System.

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. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject devices have been corrected.

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.

Please notify this office in writing within 30 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 30 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, at the above address.

Sincerely,

\s\  
Raymond V. Mlecko  
District Director

cc: Mr. Mark S. Greenwood, President  
Progeny, Inc.  
1407 Barclay Boulevard  
Buffalo Grove, IL 60089