



mail

July 9, 1998

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

WARNING LETTER
CHI-30-98

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Daniel L. Peters, President
Amersham Holdings
101 Carnegie Center
Princeton, New Jersey 08540-9998

Dear Mr. Peters:

During an inspection of the 3350 N. Ridge Ave, Arlington Heights, Illinois facility of Medi-Physics from April 2 to 24, 1998, Investigator Mary Kay Concannon determined that Medi-Physics is a manufacturer of iodine implantable seeds. Iodine implantable seeds are medical 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 Quality System Regulation (QSR) as specified in Title 21, Code of Federal Regulations, Part 820, as follows:

1. Failure to ensure quality audits are performed to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system. The quality audit procedure does not contain complete audit instructions and the specific criteria to be covered.
2. Failure to maintain complete device history records. Over [REDACTED] "seed event" reports have been made since February 1998. These reports (documenting various process discrepancies) were not included in the device history record and were not provided to the quality assurance staff.
3. Failure to ensure that critical device manufacturing processes are validated. The [REDACTED] processes have not been validated since April 1993. There is no schedule for revalidating these processes.

page 2

This letter is not intended as 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 (enclosed) issued to Mr. Thomas Springer 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.

We acknowledge receipt of Ms. Susan K. Olinger's response to our Form FDA 483, dated May 28, 1998. We find the response adequately addresses our concerns. However, we require verification of correction either by FDA inspection or by a third party auditor's written verification.

Until 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.

You should take prompt action to prevent a repeat of these deviations. Failure to prevent these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office in writing whether you will contract a third party audit or whether you would prefer FDA to perform a reinspection.

Your response should be sent to Stephen D. Eich, Compliance Officer, Food and Drug Administration, 300 South Riverside Plaza, Suite 550 South, Chicago, Illinois 60606.

Sincerely,

\s\
Raymond V. Mlecko
District Director

Enclosure

cc: Mr. Thomas J. Springer
Vice President of Operations
Medi-Physics Inc.
3350 North Ridge Ave
Arlington Heights, IL 60004