



DEC 18 1997

WARNING LETTERFood and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville MD 20850

VIA FEDERAL EXPRESS

Yehoshua Weinstein
General Manager
Sor-Van Radiation, Ltd.
Kiryat Soreq, P.O.B. 214
Yavne, Israel 81800

Dear Mr. Weinstein:

During an inspection of your firm located in Yavne, Israel, on August 31 through September 3, 1997, our Investigator determined that your firm irradiates medical devices and foods.

The above stated inspection revealed that products irradiated at your facility 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 their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice (CGMP) requirements of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. The 1987 Good Manufacturing Practices (GMP) Regulation was superseded on June 1, 1997, by the Quality System Regulation. Since the records reviewed were dated prior to June 1, 1997, the deficiencies noted during the inspection are cross referenced to the 1978 GMP's. We have received your response dated September 30, 1997, to the FDA 483 issued by the Investigator following the inspection.

1. Failure to validate a process with a high degree of assurance where the results of a process cannot be fully verified by subsequent inspection and test, as required by 21 CFR 820.75(a). This would also be a violation of the 1978 Good Manufacturing Practices Regulation, 21 CFR 820.100(a)(1). For example, there was no "process validation" (dosage mapping) performed between 1994 and May 22, 1997.

Your response is not adequate. You stated that procedures are to be changed to prevent a repetition of this problem in the future. However, no documentation for the new procedures was included in the response.

2. Failure to document the approval of required documents, including the date and signature of the individual(s) approving the document, as required by

21 CFR 820.40(a). This would also be a violation of the 1978 Good Manufacturing Practices Regulations, 21 CFR 820.181. For example:

- a. Specification drawings for the [] system upgrade have no approval signatures by designated representatives of the firm.

Your response is not adequate because it does not include documentation giving evidence of approval signatures for the drawings

- b. Changes made to the software program for the [] have not been formally reviewed and approved by designated representatives of the firm.

Your response is not adequate because it does not include documentation showing formal review and approval of the software program changes.

3. Failure to maintain a device master record which includes production process specifications including the appropriate equipment specifications, production methods, production procedures, and production environment specifications, as required by 21 CFR 820.181(b). This would also be a violation of the 1978 Good Manufacturing Practices Regulation, 21 CFR 820.181(b). For example:

- a. A user manual (or SOP) is not available for the [] computer software that controls the [] system.

Your response is not adequate because it does not provide evidence of a manual or SOP for the []

- b. There are no written, reviewed and approved, specifications for the software program for the [] system.

The response is not adequate because no documentation was provided showing approved specifications for the software program for the [] system.

4. Failure to ensure that all inspection, measuring, and test equipment is suitable for its intended purposes and is capable of producing valid results, including the establishment and maintenance of procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, and these activities are documented, as required by 21 CFR 820.72(a). This would also be a violation of the 1978 Good Manufacturing Practices Regulation, 21 CFR 820.61. For example:

- a. There is no calibration record for the [] used for all dosimeter readings from February 17, 1997, to May 1, 1997.

Your response is not adequate because documentation of the calibration was not included. A letter confirming calibration was included, but the actual documentation of the calibration was not included.

- b. There has been no performance of the monthly Performance Evaluation for the [] of the [] recommended by the manufacturer of the [] on page 8-8 of the operator's manual.

Your response is not adequate because evidence of performance of monthly evaluations was not provided.

- c. The copy of the 1997 [] Protocol is not complete, and the test results do not have signatures for "completed by" and "approved by."

Your response may be adequate if reinspection finds that all required pages of the 1998 protocol and all required signatures are present.

5. Failure to ensure that device history records for each batch, lot, or unit are maintained to demonstrate that the device is manufactured in accordance with the device master record, including the acceptance records which demonstrate the device is manufactured in accordance with the device master record and the device identification and control number used, as required by 21 CFR 820.184. This would also be a violation of the 1978 Good Manufacturing Practices Regulation, 21 CFR 820.184. For example, verification of irradiation was not possible for eight cartons because []

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] were absent and because label numbers on other cartons did not match their certificate numbers. The procedures for [specifies the placement of [on packages or cartons prior to entrance to the irradiation chamber.]]

Your response may be adequate if reinspection finds that this problem has not reoccurred.

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 483 issued at the close-out 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 Food and Drug Administration. 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

We acknowledge that you have submitted a response dated September 30, 1997, concerning our Investigator's observations noted on the form FDA 483. As discussed in our review, your response does not adequately address these violations.

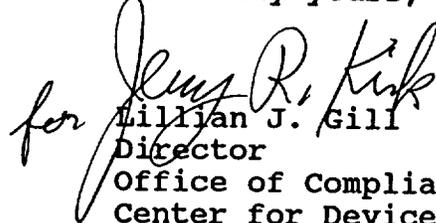
Please notify this office, in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, HFZ-323, 2098 Gaither Road, Rockville, MD 20850, to the attention of Sarah Mowitt.

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If you have any questions, please contact Sarah Mowitt at the above address. If you need assistance, contact Mrs. Mowitt by phone at (301) 594-4595 or by FAX (301) 594-4636.

Sincerely yours,

for  Lillian J. Gill

Director
Office of Compliance
Center for Devices and
Radiological Health