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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Mid-Atlantic Region

Telephone (201) 331-2909

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

May 23, 1997

WARNING LETTER

Mr. Peter Heinz
ISP Technologies, Inc.
1316 Alps Road
Wayne, New Jersey 07470

File No: 97-NWJ-36

Dear Mr. Heinz:

During an inspection of your firm located at 1316 Alps Road, Wayne, New Jersey, on April 15 - 28, 1997, our Investigators determined that your firm manufactures RAD-SURE radiation indicator labels. This radiation indicator is a device as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act).

The above-stated inspection revealed that this device is considered adulterated within the meaning of Section 501(h) of the Act, in that manufacturing and related quality assurance activities are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal regulations (CFR), Part 820, as follows:

1) Your firm's complaint handling system and failure investigation documentation is deficient, for example:

- Reports concerning product performance, such as premature darkening of indicators labeled to darken at 15 Gy and 25 Gy respectively, are considered unjustified and therefore not evaluated as product complaints.
- There is no further investigation of confirmed complaints which involve failure of the product to meet performance specifications, as labeled.

2) There is no formal system to evaluate, approve and implement changes to the original formulation and product labeling, for example:

- Changes were implemented as corrective actions resulting from a recent recall of indicator labels for premature darkening. This recall was attributed to contamination of the imaging material. Changes implemented included a modification of the original formulation to prevent potential contamination and the addition of refrigerated storage conditions to the

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REVIEWED BY Heinz NOT 5/27/97
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product label, to improve product stability. These modifications have not been validated to demonstrate that the product will continue to meet all performance specifications.

○ There is no change control document to demonstrate that modifications made to the original Device Master Record have been formally reviewed and approved.

3) Manufacturing processes, critical to product performance, have not been formally validated to demonstrate assurance that the device conforms to its original design or approved changes.

4) There are no formal validation or stability studies to support the two year expiration date, as assigned.

5) There is no documentation to demonstrate that your firm conducts periodic audits of quality assurance activities, including audits of your contract manufacturers. Additionally, your firm lacks a written agreement with contract manufacturers that would describe the Quality Assurance responsibilities for each firm.

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 FDA483 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 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 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 devices have been corrected.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory

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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 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 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 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 the New Jersey District Office, Food & Drug Administration, 10 Waterview Blvd., 3rd Floor, Parsippany, New Jersey 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,

Edward H. Wilkens

EDWARD WILKENS
Acting District Director
New Jersey District

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED

MBM:np