



U.S. FOOD AND DRUG ADMINISTRATION

NEW YORK DISTRICT
850 THIRD AVENUE, BROOKLYN, NEW YORK 11232

8/21/97
NEI-358
F18

Telephone: [718] 340-7000 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL **RETURN RECEIPT REQUESTED**

Mr. Tony Anthony
President
DOFI Communications, Inc.
1441 Lakeland Avenue
Bohemia, New York 11716

August 11, 1997

Ref.: 70-NYK-97

Dear Mr. Anthony:

During an inspection of your firm located in Bohemia, NY, conducted between the dates of July 8 and 28, 1997, our investigators determined that your firm manufactures the DOFI Raster Screen, an optical screen for endoscopic procedures. These screens are 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 current good manufacturing practice, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish quality system procedures including procedures for quality audits.
2. Failure to establish procedures for;
 - a. receiving, reviewing, and evaluating complaints,
 - b. finished device acceptance to ensure that each production run, lot or batch of finished devices meets acceptance criteria,
 - c. control of products that do not conform to specified requirements,
 - d. implementing corrective and preventive action, including investigation of the cause of nonconforming product,
 - e. control of documents, including approval and changes,
 - f. changes to specifications, production and processes,
3. Failure to document acceptance activities, including inspections, tests, or other verification activities for incoming products, in-process products, and finished devices.
4. Failure to maintain a device master record, device history records, and a quality system record.

5. Failure to establish procedures for and document of the removal of manufacturing materials, abrasives.
6. Failure to validate manufacturing processes to ensure that predetermined specifications are consistently met.

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 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 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 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 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 15 working days, state the reason for the delay and the time within which corrections will be completed.

Your response should be sent to Laurence D. Daurio, Compliance Officer, Food and Drug Administration, 850 Third Avenue, Brooklyn, New York 11232.

Sincerely,



Brenda J. Holman
District Director