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Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

PURGED B4

May 12, 1998

cc: RFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 24

William T. Monahan
Chief Executive Officer
Imation, Inc.
One Imation Place
Oakdale, Minnesota 55128

Dear Mr. Monahan:

We are writing to you because on April 21-27, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the Laser Imaging Systems that are manufactured at your 3400 Granada Avenue, Building 505, Oakdale, MN, location for use with X-ray, MRI, and CT for diagnostic purposes.

Under United States Federal law (the Federal Food, Drug, and Cosmetic Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. These laser imaging systems are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The law requires that manufacturers of medical devices adhere to Quality System Regulations for Medical Devices as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820 in the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of medical devices.

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Our inspection found your products are in violation of the law because of:

- Failure to establish and maintain procedures that designate an individual(s) to review for adequacy and approve prior to release, all ECO documents [form FDA-483, Inspectional Observations, item #1c; 21 CFR 820.40(a)];
- Failure to establish and maintain procedures for the review and approval, effective date, and identification of the documents affected by document changes [FDA-483, item #1(b and d), #2; 21 CFR 820.40(b)]
- Failure to establish and maintain procedures for changes to specifications, methods, processes, or procedures and verify such changes or, where appropriate, validate according to §820.75 before implementation [FDA-483, item #1a, #3; 21 CFR 820.70(b)];
- Failure to verify or validate corrective and preventive actions to ensure that such actions are effective (FDA-483 item #4 re: the Complaint Handling Procedure) and do not adversely affect the finished device [21 CFR 820.100 (a)(4)]
- Failure to document the investigation into complaints [21 CFR 820.198 (e)] in that the completed forms do not give details on the complaint evaluation, including identification of the device, the dates and results of the investigation, and any corrective action taken (FDA-483 item #5); and
- Failure to establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process capability and product characteristics [21 CFR 820.250] in that manufacturing processes such as electronic enclosure and final inspection were validated using only one run (FDA-483 item #6).

In legal terms, the products are adulterated under section 501(h) of the Act.

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You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

The specific violations noted in this letter and in the FDA-483 issued 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 have received your written response to the FDA-483 which is dated May 4, 1998. Although some of the responses adequately address the concerns referenced in the FDA-483, we have the following comments:

FDA-483 item #1: The ECO procedure still lacks a reference to a procedure or method for performing validations, provisions for documenting the date on which the ECO becomes effective, and a requirement/method for identifying other documents that will be affected by the new procedure. No Engineering Responsibility Matrix (as referenced in the ECO procedure) was included for our review.

FDA-483 item #2: See the comments to FDA 483 item #1 above.

FDA-483 item #3: This response is adequate.

FDA-483 items #4 and #5: The Complaint Handling Procedure does not address corrective and preventive actions and failure investigations.

FDA-483 item #6: Please be reminded that the regulations require that you establish and maintain procedures for identifying valid statistical techniques required for establishing, controlling, and verifying the acceptability of process

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capability and product characteristics. The number of validation runs required to establish the foregoing is not set at three. It is the responsibility of your firm to establish an appropriate test plan based on a valid statistical technique.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As CEO, the most responsible individual at Imation, Inc., it is ultimately your responsibility to ensure that devices manufactured at your facility in Oakdale, MN, are in compliance with each requirement of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard E. Manresa at the address shown on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of Quality System Requirements for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at I-(800)638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Manresa at (612)334-4100 ext. 156.

Sincerely,



James A. Rhato
Director
Minneapolis District

HEM/ccl
Enclosures: FDA-483, 4/27/98