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DEC 18 2001

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850WARNING LETTER

Ref:OC:I1-1908

Via FEDERAL EXPRESS

Mr. Arne Roestel
President
Multidata Systems International Corporation
9801 Manchester Drive
St. Louis, MO 63119

Dear Mr. Roestel:

This letter is written to advise you of items of non-compliance with electronic product radiation control requirements and premarket notification requirements encountered during an inspection of your firm conducted from May 31, 2001, through September 21, 2001, by FDA investigators, Dennis Butcher, Georgia Layloff, and Philip Boston.

Electronic Product Radiation Control

The following failure to comply with the regulations regarding performance standards for electronic products was observed:

1. 21 CFR 1010.2, Certification, requires that all manufacturers of electronic products certify their products as compliant with applicable standards. During the September 21, 2001, inspection, no evidence was provided that the Multidata model 8532 Block Cutter was certified in accordance with the Federal laser performance standard. Specifically, the investigator observed:
 - a) Aperture labels were absent from the product as required by 21 CFR 1040.10(g)(5).
 - b) Warning logotype for a Class II laser product was absent from the product, as required by 21 CFR 1040.10(g)(2).
 - c) Product literature lacked required warnings, reproductions of labels and logotypes, and laser output specifications, as required by 21 CFR 1040.10(h).

Because the Multidata model 8532 Block Cutter contains an alignment laser, it is a laser product and is subject to the Federal laser performance standard. The block cutter must be certified as compliant with the standard. This certification must be based on a test or testing program to assure the product complies with the Federal laser performance standard. Certification is evidenced by affixing a label to the product, stating it conforms to the Federal laser performance standard.

Section 538(a) of the Federal Food, Drug, and Cosmetic Act (the Act), Chapter V, Subchapter C (formerly the Radiation Control for Health and Safety Act of 1968) prohibits any manufacturer from certifying or

introducing into commerce laser products which do not comply with the standard. This section also prohibits any manufacturer from failure to establish and maintain required records or to submit required reports. Failure to respond to this letter may be considered to be a violation of paragraph 538(a)(4) of the Act. The Food and Drug Administration (FDA) is prepared to invoke regulatory actions if you fail to comply with these requirements. These actions may include an injunction and/or imposition of civil penalties as provided for in Section 539. Persons failing to correct violations and/or continued violations of the Act are subject to civil penalties of up to \$1,000 per violation and up to a maximum penalty of \$300,000 without further notification by the FDA. In cases where a foreign manufacturer fails to respond, penalties may be imposed upon importers.

You must respond in writing within fifteen (15) working days of receipt of this letter to one of the options listed below. In your response you must also provide the number of the referenced products which have been produced and the number of such products that have left the place of manufacture. In addition, if the product distribution was confined to specific geographical areas of the United States, please specify those areas.

1. Refutation - You may submit your views and evidence to establish that the alleged failure to comply does not exist.
2. Exemption Request - You may request an exemption from user and dealer/distributor notification and from obligation to correct the violative products. Your request must include the grounds upon which such exemption is requested (see 21 CFR 1003.30 and 1003.31).
3. Purchaser Notification and Corrective Action - If you neither refute the noncompliance nor request an exemption, then you must: (a) notify purchasers and dealers/distributors of the violative products as specified in 21 CFR 1003.10(b), and (b) submit a written corrective action plan (CAP) to fulfill your obligation under 21 CFR 1004.1 to repair, replace, or refund the cost of the violative products.
 - a. Notification Letter - Requirements for preparation of notification letters are prescribed in 21 CFR 1003.21 and 1003.22. A copy of the notification letter(s) sent to purchasers and dealers must also be sent to the FDA. It is recommended that you submit a draft of this letter to us for review.
 - b. Corrective Action Plan - Instructions for preparation of a CAP may be found in 21 CFR 1004.2, 1004.3, or 1004.4.

If you request additional time to prepare your refutation, notification, CAP, or evidence to support a requested exemption, you must provide the reasons for any delays and a reasonable target date for the full submission of your response. Be aware that if an

acceptable CAP cannot be prepared promptly, you may be required to proceed with interim notification to affected persons as required by 21 CFR 1003.11(c) and 1003.21. Therefore, you are encouraged to immediately begin your preparation of accurate user location lists.

The following failure to comply with the regulations regarding reports and record keeping was observed:

1. 21 CFR 1002, Reports and Records, requires that all manufacturers of electronic products submit reports describing the product and how it complies with applicable standards. During the September 21, 2001 inspection, no evidence was provided that Multidata submitted a radiation safety product report to FDA for the model 8532 Block Cutter.

Because the Multidata model 8532 block cutter is an electronic product (laser product) Multidata is required to submit reports describing the product and how it complies with the Federal laser performance standard.

When you have completed any production changes necessary to assure compliance of future units and you have submitted the required reports and report supplements, you may resume introduction of these products into commerce.

Premarket notification

The September 21, 2001 inspection and a review of Multidata's web site indicate you are distributing radiation therapy equipment prior to receiving pre-market clearance. These accessories to radiation therapy equipment include Multidata's:

- Model 8532 Multicut Block Cutter System
- Model 8533 Compensator Milling System
- Multidose Electrometer with Adapter Cable, Solid State (diode) Detectors (6 to 8 MeV), Depth Dose and Energy Phantom (Model 9310)
- Model 9390 Therapy Beam Monitor
- Model 9723 In-Air Scanning Frame
- Model 9763-XL Extra-Large, Model 9750 Universal, Model 9740 Portable Waterphantoms

Radiation therapy equipment and accessories are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

Under Section 510(k) of the Act, you are required to notify the Food and Drug Administration (FDA) at least ninety (90) days prior to the introduction of a device into commercial distribution in the United States. This requirement is accomplished by submission of a Premarket Notification (510(k)). The information necessary to comply with the 510(k) requirement is found in Title 21 of the Code of Federal Regulations (CFR) Part 807, Subpart E, Premarket Notification Procedures. We are requesting a response within fifteen (15) working

days describing the action you have taken to achieve compliance with the premarket notification requirements of the Act.

Failure to comply with these requirements causes your products to be misbranded under Section 502(o) of the Act, and adulterated under Section 501(f)(1)(B) of the Act. You may not legally distribute a product that requires the submission of a 510(k) until your firm receives notice from FDA clearing the device for commercial distribution.

Your response(s) should be sent to: Director, Division of Enforcement III (HFZ-340), Office of Compliance, Center for Devices and Radiological Health, 2098 Gaither Road, Rockville, Maryland 20850. You are also requested to send a **copy** of your response to: Director, Compliance Branch, Kansas District Office, Food and Drug Administration, 11630 West 80th St., Lenexa, KS 66214-3338. If you have further questions on these requirements, please contact LT Sean M. Boyd of the Electronic Products Branch at (301) 594-4654 x128.

Sincerely yours,

Christy Foreman for

Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health