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7/22/98*

Food and Drug Administration
St. Louis Branch
12 Sunnen Drive, Suite 122
St. Louis, Missouri 63143-3800

voice: (314) 645-1167
fax: (314) 645-2969

July 16, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Arne R. Roestel
President
Multidata Systems International Corp.
9801 Manchester Road
St. Louis, Missouri 63119

STL-98-3

Dear Mr. Roestel:

During an inspection of your establishment located at 9801 Manchester Road, St. Louis, Missouri, on June 23 through July 2, 1998, our investigator determined that your firm manufactures a Decision Support System (DSS) for Radiation Support device. The DSS system 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 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 the Good Manufacturing Practice (GMP) for Medical Devices regulation as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure of management with executive responsibility to appoint a member of management to establish authority over and responsibility for (a) ensuring that quality system requirements are effectively established and effectively maintained, and (b) reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3)(i) &(ii).

2. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA) for the Decision Support System as required by 21 CFR 820.100.
3. Failure to define, document, and implement procedures for quality audits as required by 21 CFR 820.22.
4. Failure to establish and maintain procedures for the identification, documentation, validation, or where appropriate, verification, review and approval of design changes before their implementation, as required by 21 CFR 820.30(i). For example:
 - a. The Multidata Standard Operating Procedure Re: Software Change Order (SCO), updated September 30, 1997, is incomplete in that it implies various levels of effort in review, control testing and validation of a software modification which are linked to the severity classification of the software change, and does not identify or describe the activities, tasks, etc., or their associated documentation and completion criteria, which are to be conducted at each level of effort,
 - b. There is no plan which describes or references the activities, tasks, procedures and responsibilities associated with the implementation of the "Make MLC conventions configurable" enhancement for the DSS per SCO # 19069807, dated on or after June 1, 1998,
 - c. There is no identification or listing of the required design inputs and their sources, procedures to be followed, or indication of approval to proceed with this design change to the DSS,
 - d. There is no documentation that a formal design review has been conducted, or is planned, for the "Handling MLC Conventions in DSS" enhancement to the DSS software (SCO # 19069807, dated on or after June 1, 1998),
 - e. There are no written procedures addressing the validation tasks to be performed for new or changed software,

- f. There is no risk analysis associated with SCO # 19069807 ("Make MLC conventions configurable"), or documentation of a planned risk analysis, or justification that a risk analysis is not necessary,
 - g. There is no design transfer procedure for the DSS software device, and
 - h. There are no written procedures which define the format and systematic design reviews which are to be conducted for software changes.
5. Failure to establish and maintain procedures for verifying the device design, failure to ensure that design verification confirms that the design output meets the design input requirements, as required by 21 CFR 820.30(f). For example:
- a. There are no written procedures addressing the verification tasks to be performed for new or changed software (i.e. complexity analyses, code inspections, unit coverage analyses),
 - b. There is no written test plan covering the testing of the changes in DSS software per SCO # 19069807, dated on or after June 1, 1998. There is a Product Test Report dated June 23, 1998, but it does not include or reference documentation of the specific test inputs and the actual test results, and
 - c. There is no documentation of regression analysis or regression testing, or plans for such analyses and tests, associated with the DSS design change implemented with SCO # 19069807, dated on or after June 1, 1998. The Multidata Standard Operating Procedure, dated May 10, 1996, Re: Guidelines for Engineering & Testing of Software Change indicates regression analysis and regression testing are to be performed as part of the Software Change Test Methodology.
6. Failure to establish and maintain procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements, failure to ensure that design output procedures contain or make reference to acceptance criteria; failure to ensure that those design outputs that are

essential for the proper functioning of the device are identified, failure to ensure that design output is documented, reviewed, and approved before release, as required by 21 CFR 820.30(d). For example:

- a. The design output as stated in the Multidata Internal Memo dated June 15, 1998, titled Handling MLC Conventions in DSS is incomplete, in that:
 1. The referenced "IEC Convention" is not identified by IEC Standard Number, or the specific items which comprise the conventions,
 2. The MLCs which are to be converted to IEC, how they are to be converted, and where/when they are to be converted, is not addressed in the Implementation section,
 3. The terms "PDX output" and "preteritary[sic]format" are not defined and do not appear in the Table of Contents of the DSS User's Guide, and there is no index in the DSS User's Guide,
 4. The impact/implementation of the statement "Multidata DSS doesn't support MLC with leafs [REDACTED] To accomodate the situation that requires MLC [REDACTED] the MLC" is not linked with a particular model or machine,
 5. For [REDACTED] MLC earlier than [REDACTED] the attributes of [REDACTED] which [REDACTED] are not defined,
 6. For [REDACTED] MLC, the attributes of [REDACTED] the [REDACTED] are not defined, and

7. The modifications to be made to the [REDACTED] and [REDACTED] are not specified.
 - b. The Multidata Standard Operating Procedure, dated May 10, 1996, Re: Guidelines for Engineering & Testing of Software Change does not identify design outputs to be created or revised for a software change, or their acceptance criteria, and
 - c. There is no documentation of the review and approval of the Multidata Internal Memo dated June 15, 1998, titled Handling MLC Conventions in DSS, which contains the specified design changes to implement SCO # 19069807, dated on or after June 1, 1998.
7. Failure to establish and maintain procedures that ensure the existence of a mechanism for addressing incomplete, ambiguous, or conflicting requirements; failure to ensure that design input requirements are documented, reviewed, and approved by a designated individual(s), as required by 21 CFR 820.30(c). For example:
 - a. There is no documentation that the design inputs to SCO# 19069807, dated on or after June 1, 1998, ("Make MLC conventions configurable") have been reviewed and approved, and
 - b. The Multidata Standard Operation Procedure, dated May 10, 1996, Re: Guidelines for Engineering & Testing of Software Change lacks a mechanism for addressing incomplete, ambiguous or conflicting requirements.
8. Failure to maintain a device master record (DMR) to contain information as required by 21 CFR 820.181 that is prepared and approved in accordance with 21 CFR 820.40.
9. Failure to validate the [REDACTED] as required by 21 CFR 820.70(i).

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 applicable regulations. The specific violations noted in

this letter and in the FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your establishment'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.

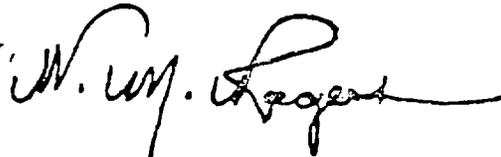
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for Class III devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates to Foreign Governments will be approved until the violations related to the subject device 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 within 15 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 the corrections will be completed.

Your response should be sent to Spencer L. Sorenson, Compliance Officer, Food and Drug Administration, St. Louis Branch, 12 Sunnen Drive, Suite 122, St. Louis, Missouri 63143-3800.

Sincerely,



W. Michael Rogers
District Director
Kansas City District