



Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

WARNING LETTER
VIA EXPRESS

MAR 1 2001

Mr. Ron Evans
President
Datrend Systems Inc.
8005 Alexandre Road
Unit 9
Delta, BC V4G 1V6 Canada

Dear Mr. Evans:

During an inspection of your firm located in Delta, Canada, on January 16-18, 2001, our investigator determined that your firm manufactures infusion device analyzers. These products 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 the Quality System Regulation, as specified in Title 21, Code of Federal Regulation (CFR), Part 820, as follows:

1. Failure to adequately establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example:
 - a. [REDACTED] Internal Quality Audit, does not define the frequency of which audits will be performed; and
 - b. there is no documented evidence that quality audits have been performed.

2. Failure by management with executive responsibility to adequately review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of 21 CFR Part 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c). For example, [REDACTED] Management Review, states "Review of the findings of the internal audit program followed by..." However, no internal audits have been performed; therefore, there are no audit reports for management to review.

3. Failure to promptly remove all obsolete documents from all points of use, as required by 21 CFR 820.40(a). For example, [REDACTED], Printed Circuit Board Assembly, is no longer applicable to the method used for PCB assemblies in that [REDACTED] solder is no longer used (see #2.b. of [REDACTED]), [REDACTED] is no longer used for cleaning (see #2.a. of [REDACTED]), and no external assembly or wave soldering is performed (see #4 of [REDACTED]).
4. Failure to adequately establish procedures for implementing corrective and preventive action. For example, while [REDACTED], Investigation of Product Complaints and Failures, references corrective and preventive subject matter, it does not meet all of the requirements of 21 CFR 820.100(a). In addition, the Quality Manual states that [REDACTED] is Corrective and Preventive Action, but the actual [REDACTED] is titled "Investigation of Product Complaints and Failures."
5. Failure to document verification or validation activities for corrective and preventive actions, as required by 21 CFR 820.100(a). For example, there is no verification or validation documentation for the modification identified in [REDACTED] to ensure that the corrective and preventive action is effective and does not adversely affect the finished device.
6. Failure to ensure that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the prevention of such problems, as required by 21 CFR 820.100(a)(6). For example, review of service report no. [REDACTED] showed a known corrective action [REDACTED] dated July 1999 was not immediately implemented to correct a repeated non-conformance complaint of a premature battery depletion problem for a device distributed in August 1999.
7. Failure to ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b). For example, no documented evidence of employee training could be provided to the investigator.
8. Failure to establish and maintain procedures to adequately control environmental conditions, which could reasonably be expected to have an adverse effect on product quality, as required by 21 CFR 820.70(c). For example, there is no procedure for the control of potential damage due to electrostatic discharge.
9. Failure to adequately establish procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, as required by 21 CFR 820.72(a). For example:
 - a. The [REDACTED] multimeter [REDACTED] has not been calibrated since its purchase over a year ago; and
 - b. [REDACTED] Inspection, Measuring, and Test Equipment, requires a schedule for testing and calibration; however, a schedule does not exist.

10. Failure to establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, as required by 21 CFR 820.20(b)(1). For example, the job description for the Quality Control Manager is not complete in that the responsibility and authority for the position has not been established.

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 form FDA 483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance system. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. 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. Given the serious nature of these violations of the Act, all infusion device analyzers manufactured by Datrend Systems Inc. of Delta Canada may be detained upon entry into the United States (U.S.) until these violations are corrected.

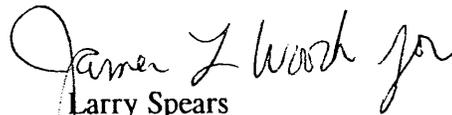
In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. We acknowledge your January 29, 2001 response to the FDA 483. Review of your response indicates that it is inadequate in that (1) you have not implemented your proposed changes, or (2) you did not submit the necessary documentation to show that adequate correction has been achieved. After we notify you that you have submitted an adequate response, it will be your responsibility to schedule an inspection of your facility. As soon as the inspection has taken place, and the implementation of your corrections have been verified, your products may resume entry into this country.

Please notify this office in writing within 15 days of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make correction to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If documentation is not in English, please provide an English translation to facilitate our review. Please address your response and any questions to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement II, General Hospital Devices Branch, HFZ-333, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Ms. Carolyn Niebauer.

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Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Ms. Leslie E. Dorsey at the letterhead address or at 301.594.4618 or FAX 301.594.4638.

Sincerely yours,

A handwritten signature in cursive script that reads "Larry Spears". The signature is written in black ink and is positioned above the printed name.

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