



Certified/Return Receipt Requested

April 29, 1998

Food and Drug Administration  
Kansas City District Office  
11630 West 80th Street  
P.O. Box 15905  
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

**WARNING LETTER**

Clifford W. Illig, President &  
Chief Operating Officer  
Cerner Corporation  
2800 Rockcreek Parkway  
Kansas City, MO 64117-2551

Ref. # - KAN-98-017

Dear Mr. Illig:

During an inspection of your firm located in Kansas City, Missouri, on March 2 through 16, 1998, our investigators determined that your firm manufactures and distributes blood bank computer software. PathNet HNA™ Clinical Systems, which include Blood Bank Donor and Blood Bank Transfusion software, is a device as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (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 current good manufacturing practice (CGMP) requirement of the Quality System Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to implement effective corrective and preventative actions to address recurring software malfunctions stemming from failures to reinitialize program working storage variables [21 CFR 820.20(a)(3) and 820.162]. This would also be a violation of the Quality System Regulation, 21 CFR 820.100. Examples include:
  - a. A software malfunction occurred on 2/5/98 at a blood bank using Blood Bank Transfusion 306, wherein the DIS program failed to validate the compatibility of a blood product being issued to a patient of unknown blood group/type. The expected screen warning regarding the dispensing of an incompatible unit failed to display, and two units of incompatible B NEG red blood cells were

administered to a patient in an emergency transfusion (Hazard Report HZ-98-1). This software malfunction was later found to be due to failure to reinitialize a working storage variable in the DIS program.

- b. Since the last inspection, the DIS program has undergone six code modifications (PIM's 30776, 30989, 32132, 32228, 32589, and 33103). Each of these code modifications was implemented after a Software and Test Case Review Checklist was completed by checking off the item "Ensure that all variables added to Working Storage are initialized as needed."

However, none of these six code reviews detected the variable reinitialization problem within DIS which was subsequently reported in Hazard Report HZ-98-1, and led to the current recall #B-650-8.

- c. In response to the previous FDA inspection of your facility, your firm committed to a code inspection project to address the failure to properly initialize storage variables. The project was to be completed by July 9, 1997. The current inspection found that your firm did not implement written procedures for the retrospective review of the blood bank product source code for proper initialization of memory variables until SOP #9.16, Initialization Project, became effective November 3, 1997.
- d. To date only 2 of the 133 programs which comprise Blood Bank Transfusion and Blood Bank Donor have been subjected to code inspections under SOP #9.16. Of these, no defects were reported in program ADU; and multiple initializing problems were reported in program FDE, which is still under going review and code correction.
- e. The selection of programs for code inspection under SOP#9.16 is not based on a statistical rationale. Your firm has implemented initialization code inspections under SOP #9.16 only on programs which are scheduled for code revisions for other reasons (Enhancement PIM's and Production PIM's). There is no schedule to assure all programs in Blood Bank Transfusion and Blood Bank Donor will be subjected to a code review for proper initialization of variables.
- f. SOP #9.16, Initialization Project, does not require periodic review of findings by a responsible individual to assure the corrective action is effective.



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This letter is not intended to be an all-inclusive list of deficiencies at your facility. Violations were previously brought to your attention in a Warning Letter issued to your firm on May 14, 1993. 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 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.

Your response of March 26, 1998, to the Form FDA 483 issued at the close of the inspection was received and reviewed. Corrective actions addressed in your letter may be referenced in your response to this letter, as appropriate. While we acknowledge your commitment to correct the identified deficiencies, we note that your firm has in the past, promised to correct deficiencies noted during FDA inspections, and our subsequent inspections, in particular the most recent inspection, have found your efforts to be ineffective.

Therefore, in order to facilitate FDA in making the determination that such corrections have been made and thereby enabling FDA to withdraw its advisory to other federal agencies concerning the award of government contracts, and to resume marketing clearance for Class III devices for which a 510(k) has been submitted, and export clearance for products manufactured at your facility, we are requesting that you submit to this office on the schedule below, authentication by an outside expert consultant, that it has conducted an audit of your firm's PathNet HNA™ Clinical Systems, Blood Bank Donor and Blood Bank Transfusion software, relative to the requirements of the Quality System Regulation, 21 CFR, Part 820. This audit should include:

- Thorough examination of the software products using appropriate methods, techniques and tools in order to establish the dependability of the software under its intended conditions of use.
- Ensure that software faults and related problems identified during the audit are either corrected, or scheduled for correction following suitable plans.
- Ensure there are appropriate procedures, instructions and personnel in place which will assure proper maintenance of the software products throughout its commercial life span.

You should also submit a copy of the consultant's report which should include a review of the software products' quality level, a description of the tasks performed, the coverage obtained, the problems identified, and the corrections made and planned. This report should

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be certified by you, that you have reviewed the consultant's report, and that your firm has initiated or completed all corrections called for in the report. The attached guidance may be helpful in selecting an appropriate consultant.

The initial certification of audit and corrections should be submitted to this office by Friday, November 6, 1998. A timeframe should be provided for corrections and subsequent audits that will be completed after November 6, 1998.

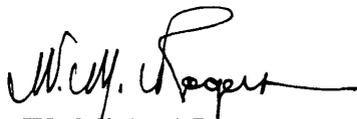
Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no requests for Certificates For Products For Export will be approved until the violations related to the subject 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 FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Please notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you will be taking to comply with our request.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

A handwritten signature in black ink, appearing to read "W. Michael Rogers", with a long horizontal flourish extending to the right.

W. Michael Rogers  
District Director  
Kansas City District

Attachment - Selecting a Consultant?