Software Used in Blood Establishments (3/31/94)

Date: March 31, 1994

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike
Rockville, MD 20852-1448

To: Blood Establishment Computer Software Manufacturers

Dear Sir/Madam:

The purpose of this letter is to advise you that the Food and Drug Administration (FDA) considers software products intended for use in the manufacture of blood and blood components or for the maintenance of data that personnel use in making decisions regarding the suitability of donors and the release of blood or blood components for transfusion or further manufacture to be devices under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. 321(h)].

These software products are designed to receive and store data used by blood establishments during the manufacturing process, from determining donor suitability through component processing, testing, and labeling to product release. They are designed to receive and store data regarding blood donor status, including donors' answers to health history questions and the results of laboratory tests, including blood grouping and typing, hepatitis, and antibody to the human immunodeficiency virus (anti-HIV). Blood establishment personnel later access and use the data to determine whether donors are suitable and whether blood or blood components are free from disease-causing agents transmissible by blood, such as hepatitis and HIV. In addition, the data are used to label blood and blood components prior to release for use in hospitals and other health care facilities or for further manufacturing. Because they aid in the prevention of disease (e.g., hepatitis, HIV, etc.) by identifying unsuitable donors and preventing release of unsuitable blood and blood components for transfusion or for further manufacturing use, these software products meet the definition of device under the Act.

Facilities that manufacture and distribute these software products are subject to the device provisions of the Act and FDA's device regulations, including establishment registration, product listing, premarket notification or approval, Current Good Manufacturing Practices (CGMP), and adverse event reporting. FDA's CGMP regulations for devices appear at Title 21, Code of Federal Regulations (CFR), Part 820 and the MDR regulations at 21 CFR, Part 803.

According to FDA's information, your facility manufactures software intended for use in the manufacture of blood and blood components. Consequently, you are required under the Act to register your establishment and list your devices. In addition, your manufacturing operations are required to be in compliance with CGMP for devices, and you must report adverse events and other problems as required by FDA's Medical Device Reporting (MDR) regulations.

We are enclosing a registration package for your convenience. We will forward a device listing package to you in the near future. When completing the device listing form (Form FDA 2892), identify your product as Software, Blood-Bank, Stand Alone Products, Product Code 75MMH. The registration form should be submitted within 60 days of receipt of this letter if you intend to continue to distribute software products to blood establishments for use in manufacturing.

In addition, you are required to submit a premarket notification or application for premarket approval for each of your devices unless you can demonstrate that you commercially distributed the devices in interstate commerce prior to May 28, 1976 (the date of enactment of the Medical Device Amendments) and have continued to do so without any significant changes to these devices. If you claim such preamendment status for any product(s), please complete only the registration form, and send it to: Center for Devices and Radiological Health (HFZ-300), 2098 Gaither Road, Rockville, MD, 20850.

If you do not intend to submit a premarket submission, and intend to submit proof of the claimed preamendment distribution, this information should be sent to: Center for Biologics Evaluation and Research (CBER), Division of Blood Applications (HFM-370), 1401 Rockville Pike, Rockville, MD, 20852-1448. Finally, if you do not currently manufacture software products for blood establishments, please advise CBER promptly.

When we forward the product listing information to you, we will include guidance on how to prepare your premarket submissions. If you have questions about the content or format of a premarket submission once you have reviewed our guidance, CBER staff are available to help answer such questions. Premarket submissions should be submitted to CBER no later than March 31, 1995.

In the interim, FDA will continue to conduct inspections of blood establishment software vendors. These inspections will include, among other things, a review of your standards for software development, testing, validation, and quality assurance. The primary focus of these inspections will be to assess compliance with the CGMP regulations for devices (21 CFR, Part 820).

The agency will also review and assess your procedures for investigating reports of product problems and defects and for implementing and evaluating corrective actions. We will also

review and assess your procedures for notifying your customers and the agency when you take corrective actions.

Please be advised that during this interim period if a manufacturer of software products for blood establishments is not making good faith efforts to comply with the Act and FDA's regulations as stated above, the agency will not hesitate to take appropriate steps to bring the firm into compliance.

If you have questions concerning: (1) the preparation of the establishment registration and device listing notification, contact Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ-220), at 301-443-6597, or (2) guidance for premarket submissions, contact Center for Biologics Evaluation and Research, Division of Blood Applications (HFM-370), at 301-594-2012.

Sincerely yours,

Kathryn C Zoon, Ph.D.
Director,
Center for Biologics Evaluation
  and Research

Enclosure