M E M O R A N D U M DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE December 10, 1993

FROM Director, Center for Biologics Evaluation and Research

SUBJECT: Guidance Regarding Post Donation Information Reports

TO All Registered Blood and Plasma Establishments

PURPOSE

The purpose of this memorandum is to provide guidance to blood establishments concerning process control procedures that should be established and maintained for the receipt, evaluation, investigation, and follow-up of post donation information reports. Post donation information includes information provided by the donor or other source and received by telephone or other means of communication following a donation.

BACKGROUND

During the past three years, there has been a significant increase in the number of error and accident reports submitted to the Center for Biologics Evaluation and Research (CBER). In fiscal year 1991, CBER received 3,834 error and accident reports. Post donation information reports represented 19% (725) of the total reports submitted in 1991. In fiscal year 1992, CBER received 10,456 reports, and 44% (4553) of these reports were related to post donation information. In fiscal year 1993, CBER received 8,991 reports, and 40% (3564) of these reports were related to post donation information.

This increase is believed to be due in part to the implementation of the guidance contained in the December 5, 1990, memorandum "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products," recommending direct questioning about high risk behavior, and to the March 20, 1991, memorandum "Responsibilities of Blood Establishments Related to Errors & Accidents in the Manufacture of Blood & Blood Components," regarding reporting of errors and accidents to CBER.

GUIDANCE

Blood establishments should have control procedures that provide for: (1) the receipt and documentation of post donation information reports that identify the source of the information (e.g., from a donor, competent health care professional, etc.); (2) the prompt medical evaluation by a qualified physician, following established criteria, to ensure that potential risks are consistently assessed and investigated for all donations potentially affected; (3) the timely investigation of the reports to determine if an error or accident in manufacturing occurred and if the safety, purity, or potency (hereafter, "quality") of blood and blood components may have been affected, (4) appropriate consignee notification and determination regarding the disposition of all affected products (in-date and expired) including those intended for transfusion and those intended for further manufacturing use where the quality of the final manufactured product may be compromised, and (5) assessment of the donor's suitability to serve as a donor in the future.

Written standard operating procedures (SOPs) are required for all steps to be followed that are part of the established control process (21 CFR 606.100, 211.192, and 211.198). Blood establishment SOPs should also include procedures to obtain more detailed information and further clarification in a confidential manner when a donor calls and reports that his or her blood should not be used, but does not provide further information. If more detailed information or clarification cannot be obtained and thus a medical evaluation cannot be made, blood establishments should attempt to retrieve products. SOPs should be followed regardless of whether the product(s) was released and distributed by the blood establishment or whether the specific event is reported to CBER. Blood establishment records must be as detailed as necessary to provide a complete history of the decisions made for each post donation information report received and evaluated (21 CFR 606.160).

Blood establishments should submit post donation information reports to CBER if the product was made available for distribution by the blood establishment and if: (1) the donor should have been deferred had the information been known at the time of donation (e.g., per regulation or CBER recommendation) and the product quality may be affected, or (2) the medical evaluation otherwise suggests that product quality may be affected, or (3) the information is insufficient to conclude that product quality is not compromised. These events are required to be reported to CBER by licensed blood establishments (21 CFR 600.14), and unlicensed, registered establishments are requested to report these events.

Blood establishments do not need to submit post donation information reports to CBER when the information leads to a conclusion that the donor should not have been deferred at the time of donation (e.g., per regulation or CBER recommendation), and the medical evaluation (as referred to in item #2 above) indicates that product quality is not affected. For example, blood establishments do not need to submit post donation information reports for donors who call the blood center and report post donation cold or flu symptoms, or other conditions that do not compromise product quality.

Distribution of products associated with post donation information reports may be viewed as an accident and not an error, provided that the review and evaluation of the facts relating to manufacturing and distribution reveal no deficiencies from established standards. Blood establishments should immediately and consistently respond to post donation information reports according to established SOPs. The agency does not ordinarily intend to evaluate these actions as recalls, provided that the blood establishment adhered to applicable regulations and SOPs.

However, if the blood establishment's investigation of a post donation information report determines that regulations or SOPs for donor deferral, donor screening, or other control processes were not followed, the agency intends to evaluate the incident as an error and possible recall.

During inspections, FDA Investigators will assess the blood establishment's system for processing post donation information reports, and may review written SOPs relating to receipt and evaluation of post donation information, documentation for all steps followed in the decision making process, notification of consignees, product disposition determination, and reporting to CBER. Investigators may also evaluate whether personnel are properly trained and follow the established procedures. Failure to: (1) establish and maintain control procedures for the receipt and evaluation of post donation information reports, or (2) develop and implement effective corrective action(s) in response to errors revealed through investigations of post donation information, may result in enforcement action.

Reports should be forwarded to:

Food & Drug Administration
Center for Biologics Evaluation and Research
Office of Compliance
Division of Inspections and Surveillance (HFM-650)
1401 Rockville Pike, 200N
Rockville, Maryland 20852-1448

Questions may be addressed to CBER/Division of Inspections & Surveillance at (301) 594-1191.

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