Control of Unsuitable Blood and Blood Components (4/6/88)

DATE: April 6, 1988

TO: ALL REGISTERED BLOOD ESTABLISHMENTS

SUBJECT: Control of Unsuitable Blood and Blood Components

FROM: Director, Center for Biologics Evaluation and Research

A number of errors recently have resulted in the inappropriate release of blood and blood components not suitable for transfusion or use in the further manufacturing of injectable products. We are requesting all blood bank directors to immediately review procedures and employee training programs to determine that safeguards adequate to prevent the release of blood and blood components not meeting Food and Drug Administration (FDA) requirements, including untested components such as recovered plasma from autologous donors, are in place and are equivalent to these procedures.

QUARANTINE: Blood that is collected in accordance with acceptable procedures must be placed immediately into quarantine in appropriate storage temperatures, pending results of testing that will permit labeling and distribution or destruction. When testing is complete, the blood and blood components may be removed from quarantine storage and, if appropriate, labeled for distribution and placed into a storage area designated for release. All blood and blood components that, as a result of testing or other information, are found not suitable for transfusion or for further manufacturing must be stored in separate quarantine from blood and blood components for which testing has not been done and from blood and blood components suitable for distribution. The identity of each unit quarantined should be confirmed from the container label by a second person to assure clerical accuracy before release of the remainder of the batch for distribution.

The procedure by which blood and blood components are released from quarantine for transfusion purposes or for further manufacture should include safeguards, (e.g., two employee check or supervisory review) to prevent inappropriate release. Blood and blood components determined to be ineligible for release for any purpose must be promptly quarantined for destruction. When some blood components from a single donation are suitable for release but others are not, the disposition record must detail the number of components prepared and the actual disposition of each one. Record keeping must include identification of the person responsible for each critical step in the labeling and release of blood and blood components including appropriate review.

DESTRUCTION: Destruction of ALL BLOOD COMPONENTS having a single donation number should be accomplished simultaneously. For the

unusual situation where one of the components may be suitable for further manufacturing, e.g., recovered plasma that is anti-HBc positive, special recording must be made to show that failure to destroy that blood component was deliberate and distribution made only after a second review of all testing records disclosed no limitation on its shipment for further manufacturing. The identity of the component, the name and address of the consignee, and the date of shipment should be recorded.

The method of destruction of blood and blood components should be either by total incineration or by steam under pressure at 121.5oC for at least 60 minutes. The adequacy of sterilization by steam under pressure (autoclaving) should be routinely evaluated using appropriate biological indicator systems. The record of destruction shall include the identity of each component in the load. Proper notations regarding final disposition of all blood and blood components quarantined must be entered on the appropriate record after destruction is complete or when other disposition occurs.

ERRORS AND ACCIDENTS: If any component prepared from a unit improperly tested, not tested, or tested properly but improperly interpreted for ABO or for infectious diseases is accidentally labeled and released for transfusion, fractionation, reagent production, research or other use, immediate effort must be made to locate and quarantine all components until satisfactory resolution occurs.

If a whole blood unit or any blood component has been transfused prior to recognition of the error, the medical director of the blood collection facility should be immediately notified. If the blood is collected outside the patient's hospital blood bank, appropriate medical staff from the collection facility should notify the patient's hospital blood bank director who should document in turn that the patient's physician is suitably notified. Thorough ana complete documentation must be made as to these actions, including the signature of the highest level of supervisory review, as soon as possible after the error has been recognized.

Errors and accidents that result in shipment of unsuitable blood and blood components must be reported to the FDA promptly by the licensed establishment as required by Title 21, Code of Federal Regulations, Part 600.14(a) (21 CFR600.14(a)). Registered (including licensed) establishments that notify users and attempt to retrieve distributed blood and blood components as described above should notify immediately the local FDA District Office (per 2l CFR7.46).

Questions regarding this memorandum should be addressed to: K. Sazama, M.D., Chief, BBPL, Division of Blood and Blood Products, 301/496-0952.

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