Handling of Human Blood Source Materials (12/23/87)

DATE : December 23, 1987

FROM : Director, Office of Biologics Research and Review

SUBJECT: Handling of Human Blood Source Materials

TO : Licensed in-vitro diagnostic manufacturers

On December 6, 1985, FDA's Center for Devices and Radiological Health (CDRH) issued guidelines for labeling human blood derived in-vitro diagnostic devices concerning HIV testing status. The Office of Biologics Research and Review (OBRR) also issued recommendations for labeling and shipping HIV-antibody positive blood products on December 9, 1985 (copies attached).

It has recently come to the attention of the OBRR that the labels for some licensed and unlicensed reagents intended for blood bank use have failed to provide the HIV testing status of the source material (blood, plasma or serum) as well as appropriate precautionary statements. Therefore, in order to minimize any risk of transmission of HIV to laboratory workers and others who cone in contact with these materials, we are recommending the following:

1) All source material used in the manufacture of licensed and unlicensed in-vitro diagnostic reagents for blood bank use should be tested for the presence of antibody to HIV;

2) No source material positive for antibody to HIV should be utilized in the manufacture of such reagents unless there is no alternate source material; and

3) The labeling (container, package and circular) of the final product should bear additional labeling statements as provided in CDRH letter of December 6, 1985.

With regard to the acquisition (in accordance with 2lCFR 601.22) of unlicensed human source biological products for further manufacturing, e.g.,cord blood samples, the OBRR recommends that the final product manufacturer assure that the following are maintained by the source supplier:

1. Detailed procedures implemented by the source supplier related to the handling and preparation of the product for shipment, including tests performed for infectious agents, e.g., HBsAg and Anti-HIV.

2. Explicit information regarding informed consent

from the donor for the required HBsAg and Anti-HIV tests.

3. Procedures for follow-up of any positive results.

Questions concerning labeling requirements on this matter may be addressed to the Division of Blood and Blood Products (301-496-4396) or the Division of Product Certification (301-443-5433).

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