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Public Health Service

Food and Drug Administration
Bethesda, MD 20205

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FROM: Director, Office of Biologics Research and Review (OBRR)
Center for Drugs and Biologics, Food and Drug Administration

SUBJECT: Additional Recommendations for Reducing Further the Number of Units of Blood and Plasma Donated for Transfusion or for Further Manufacture by Persons at Increased Risk of HTLV-III/LAV Infection

TO: All Registered Blood Establishments

This memorandum revises the categories of persons at increased risk of human lymphotropic virus, Type III/lymphadenopathy associated virus (HTLV-III/LAV) infection whose blood and components should not be used for transfusion and who should not routinely donate plasma and makes a recommendation about the manner in which donors through an expanded donor consent statement should exclude themselves from donating blood or plasma for transfusion to others or for further manufacture. A recommendation also is made that donors of blood for transfusion be offered a procedure at the time of donation through which they can designate confidentially that their blood should not be transfused to others. These recommendations were developed in part, due to consensus among members of the blood service complex that expanded language about the Acquired Immunodeficiency Syndrome (AIDS) in the signed consent is appropriate to provide additional protection of the blood supply; in part, in response to the recommendations in the Consensus Development Panel Statement (The Impact of Routine HTLV-III/LAV Antibody Testing of Blood and Plasma Donors on Public Health) and of the Blood Products Advisory Committee; and, in part, to align more closely the recommendations of the Food and Drug Administration (FDA) regarding suitability of blood and plasma donors with the general public health recommendations of the Centers for Disease Control (CDC).

Revised Categories To Be Used by Registered Blood Establishments in Determining Persons at Increased Risk of HTLV-III/LAV Infection

Information provided to potential blood and plasma donors prior to donation should indicate clearly that people in the following categories should not donate blood or blood components to be used for transfusion or routinely donate plasma for further manufacture:

- o persons with clinical or laboratory evidence of HTLV-III/LAV infection;
- o men who have had sex with another man one or more times since 1977;
- o past or present intravenous drug abusers;

- o persons emigrating since 1977 from countries where heterosexual activity is thought to play a major role in transmission of HTLV-III/LAV infection;*
- o persons with hemophilia who have received clotting factor concentrates;
- o sexual partners of any of the above; and,
- o men and women who have engaged in prostitution since 1977 and persons who have been their heterosexual partners within six months.

This revision reflects more accurately current understanding about persons who are at increased risk of transmitting AIDS by donating blood for transfusion to others.

Recommendation Regarding Expanded Donor Consent

The consent signed by blood and plasma donors should include a provision that is equivalent in meaning to the following:

> I have reviewed and understand the information provided to me regarding the spread of the AIDS virus by donated blood or plasma and, if I consider myself to be a person at risk for spreading the virus known to cause AIDS, I agree not to donate blood or plasma for transfusion to another person or for further manufacture.

It is generally agreed that blood and plasma donors should attest in writing whether they consider their donation would pose a risk for transmission of HTLV-III/LAV infection to recipients in the same manner as they attest about other medical conditions in the health questionnaire completed before donation. This recommendation aligns questions about the risk for transmission of HTLV-III/LAV infection with other questions about donor eligibility. The language permits donors of blood and blood components to answer truthfully, even if they are at increased risk for HTLV-III/LAV infection, if they confidentially designate their units not for transfusion to others by a procedure recommended below.

Recommendation About Confidential Unit Exclusion

Blood establishments collecting whole blood or blood components for transfusion should provide a procedure through which donors can indicate confidentially at the time of donation that their blood should not be transfused to others (confidential unit exclusion). These procedures should provide at a minimum:

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* e.g., Haiti, Central Africa

- o that units designated not for transfusion to others be removed from inventories and not made available for transfusion or for further manufacture unless under a specific exception granted in writing by the Director, OBRR;

- o strict confidentiality of donors' decisions and a confidential environment in which to make the decisions;

- o HTLV-III/LAV antibody testing of all donated units;

- o notification of all donors of the results of HTLV-III/LAV antibody tests considered positive by the criteria defined in the procedure manual for that establishment, without regard to whether they designated their units as acceptable for transfusion to others or excluded them from transfusion to others.

- o assurances to donors that units confidentially excluded will be used for laboratory testing.

This recommendation is made in response to both the recent consensus panel statement and to the 11 September 1986 recommendation of the Blood Products Advisory Committee. Data from blood banks that have used confidential unit exclusion strategies as defined above suggest that they are effective in meeting the needs of persons at high risk for HTLV-III/LAV infection who believe they cannot exclude themselves prior to donation and therefore donate blood. Individual establishments collecting blood or blood components for transfusion that can provide data indicating that implementing such procedures would be unlikely to improve the safety of the blood they supply may apply to the Director, OBRR, for concurrence.

Although implementing new recommendations in blood collecting establishments is difficult and requires time to develop appropriate procedures, implementation of those contained in this memorandum should be expedited in order to increase the safety of the blood supply further. We recommend that you implement the revised procedures within 30 days. You may contact the Division of Blood and Blood Products (301-496-4396, Dr. Thomas Zuck or Mrs. Ann Hoppe) if you need assistance.

GRO-C

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