Date: June 8, 1995

From: Director, Center for Biologics Evaluation and Research

Subject: Recommendations for the Deferral of Current and Recent Inmates of Correctional Institutions as Donors of Whole Blood, Blood Components, Source Leukocytes, and Source Plasma

To: All Registered Blood Establishments

The Food and Drug Administration (FDA) has periodically issued recommendations to blood establishments on donor deferral to prevent the transmission of infectious diseases, including Human Immunodeficiency Virus (HIV), Hepatitis B Virus, and Hepatitis C Virus, by blood and blood products. In April 1992, FDA issued two memoranda: "Revised Recommendations for the Prevention of Human Immunodeficiency Virus (HIV) Transmission by Blood and Blood Products", and "Recommendations for Testing Whole Blood, Blood Components, Source Plasma and Source Leukocytes for Antibody to Hepatitis C Virus Encoded Antigen (Anti-HCV)". These recommendations have not addressed the collection and use of Whole Blood, blood components, Source Leukocytes, and Source Plasma from inmates of correctional institutions. This topic has been reviewed recently by the FDA due to a series of recent reports.

One of the known risk factors associated with the transmission of HIV and hepatitis viruses is the use of illicit intravenous drugs involving needle sharing[1-5]. Reports by the U.S. Department of Justice[6-14], the Centers for Disease Control and Prevention[15-20], and others[21-26], indicate that a significant proportion of inmates of correctional institutions are at increased risk of infectious diseases because of their use of illicit intravenous drugs prior to incarceration. In a study of almost 17,000 intravenous drug users (IVDU) conducted between 1987 and 1989, 83% reported having been incarcerated in a prison or jail, and 78% reported sharing drug-injection equipment with another IVDU[16]. These data correlate with a high rate of infection with blood borne agents, including HIV and hepatitis viruses, and other transmissible agents in inmates entering or incarcerated in correctional facilities[6-10,14,15,17-20,27-38]. Consistent with this observation, the aggregate Acquired Immunodeficiency Syndrome incidence rate for State and Federal correctional systems in a 1992-1993 survey was 362 cases per

100,000 compared with 18 cases per 100,000 U.S. population[8]. Other risk factors for HIV and hepatitis transmission, such as tattooing[39-41], and high risk sexual activity[8,41,42], have been reported for inmates of prisons or jails. Although reports vary on the rate of seroconversion for HIV in the prison setting[8,43-45], transmission of HIV and HBV have been reported in the prison environment.[8,43,44,46]

This information suggests that a history of incarceration in a correctional institution is associated with behaviors, such as intravenous drug abuse, that indicate an increased risk for transfusion-transmitted infections. In addition, for current inmates the nature of the prison environment may lead to a denial of behavioral risk factors by those seeking to donate blood products, because of secondary gains.[47]

The FDA therefore recommends that:

1. Current inmates of correctional institutions (including jails and prisons) and individuals who have been incarcerated for more than 72 consecutive hours during the previous 12 months be deferred as donors of Whole Blood, blood components, Source Leukocytes, and Source Plasma for 12 months from the last date of incarceration.

2. Blood establishments supplement the AIDS education and self-exclusion material to include self-deferral from Whole Blood, blood components, Source Leukocytes and Source Plasma donations for donors who were incarcerated at a correctional institution for more than 72 consecutive hours within the previous 12 month period.

3. Blood establishments revise donor suitability standard operating procedures (SOPs) to incorporate these recommendations.

FDA recognizes that special public health needs may require collections from high risk donors. Establishments seeking approval for Whole Blood, blood components, Source Leukocytes or Source Plasma collections from inmates of correctional institutions and persons incarcerated for more than 72 hours within the previous 12 month period should submit Product and Establishment License applications or supplements for such

collections. FDA will consider approval of such applications for in-vitro, or other special uses, when there are no alternative sources, consistent with its existing policy on collections from high risk donors. See, "Guideline for Collection of Blood or Blood Products from Donors with Positive Tests for Infectious Disease Markers ('High Risk' Donors)", 1989.

The recommendations contained in this memorandum may be implemented as soon as feasible, without prior approval from the Agency. For licensed establishments, a copy of the revised SOP should be submitted to the license file and should include the date of implementation.

For further information, contact Mary Gustafson, Director, Division of Blood Applications (HFM-375), FDA, 1401 Rockville Pike, Rockville, MD. 20852. (301) 594-2012.

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