Use of Genetic Systems HIV-2 EIA (6/21/90)

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From: Director, Center for Biologics Evaluation and Research

Subject: Use of Genetic Systems HIV-2 EIA

To: All Registered Blood Establishments

On April 25, 1990, the Food and Drug Administration (FDA) licensed Genetic Systems Corporation, Seattle, Washington, to manufacture and distribute an enzyme immunoassay (EIA) for the detection of circulating antibodies to human immunodeficiency virus type 2 (HIV-2) in human serum or plasma. The labeled indication for the use of this test is "as an aid in the diagnosis of potential infection with Human Immunodeficiency virus Type 2 (HIV-2)." This memorandum states the FDA's position concerning the use of this test in blood and plasma establishments.

The Genetic Systems HIV-2 EIA is based on a purified whole viral lysate antigen obtained from tissue culture. The virus used in the culture is a well characterized strain of HIV-2 originally isolated by scientists at the Institut Pasteur, Paris, France, from a West African man. In clinical trials, the test has been shown to be highly reproducible, and to detect antibodies to HIV-2 in 100% of studied cases in which the antibody should have been present. The specificity of the test for HIV-2 or HIV-1 antibodies was estimated to be 99.8% in United States blood and plasma establishments. In about 60% of cases, sera with antibodies to HIV-1 crossreact with HIV-2 antigens in this test. Conversely, currently licensed whole viral lysate based tests for antibodies to HIV-1 will detect antibodies to HIV-2 in approximately 60-90% of sera with antibodies to HIV-2 (CDC, unpublished data).

The epidemiology of HIV-2 and its relevance to donor screening in the U.S. was discussed at a meeting of the FDA Blood Products Advisory Committee on March IS, 1990 in Bethesda, Maryland. Unlike HIV-1 which is widespread in the world, including a major epidemic focus in the U.S., HIV-2 has been found predominantly in some countries of West Africa with secondary spread to Europe and only sporadic cases reported in the U.S. and Canada. The CDC is" currently aware of only 18 well documented cases in North America. The country of origin is known for 14 of these cases; 13 occurred in persons from West Africa and one occurred in a U.S. citizen. Surveillance studies carried out since 1987 have failed to demonstrate widening spread of this infection or any

highly endemic focus in a U.S. population. Based on initial screening with HIV-1 antibody test kits in studies done in U.S. blood banks, no cases of HIV-2 infection were identified in over 5 million donations. Even allowing for the limited sensitivity

of the HIV-1 tests to detect HIV-2 antibodies, these studies suggest that the true prevalence of HIV-2 infection in blood donors is quite low.

In view of the extremely low prevalence of HIV-2 infections in the U.S. population, there appears to be no public health need at this time to screen donors of blood or source plasma for antibodies to HIV-2 with this test. for this reason the FDA currently does not recommend routine use of the Genetic Systems HIV-2 EIA in blood establishments. Recommendations concerning donor screening for antibodies to HIV-2 will be updated, as necessary, based on the results of surveillance studies or other new developments.

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