FDA Recommendations for Donor Deferral (12/12/91)

Date: December 12, 1991

From: Acting Director, Center for Biologics Evaluation and Research

Subject: Clarification of FDA Recommendations for Donor Deferral and Product Distribution Based on the Results of Syphilis Testing

To: All Registered Blood Establishments

Background

For at least 30 years, a screening test for syphilis has been performed as part of routine laboratory testing on every unit of blood or blood component for transfusion. Most, if not all, states have required reporting of reactive screening results to the Department of Health, and confirmatory testing has usually been done by health departments rather than blood centers. Whole blood and red blood cells with reactive screening results and negative confirmatory results are usually discarded, although FDA has stated that use is acceptable if units are labeled with both the reactive screening test result of record and the negative confirmatory test. Source Plasma collected prior to receipt of screening test results has been considered acceptable for further manufacturing. Donors whose blood or plasma tested reactive were not in the past deferred for any specific time period, but were often asked to provide evidence of treatment before donating again.

FDA regulations require that Source Plasma donors be tested for syphilis on the day of first medical examination for plasmapheresis and at least every four months thereafter. The regulations do not require the labeling of each unit with the screening test results. FDA has not recommended product retrieval when repeat donors test reactive for syphilis because transmission of syphilis has not been considered a health risk for plasma derivatives. For continued Source Plasma collection from a donor who is known to have a reactive test for syphilis, documentation of medical treatment is required (21 CFR 640.65)(2)(iv).

In the memorandum to all blood establishments dated December 5, 1990, the Food and Drug Administration (FDA) recommended that blood establishments defer potential blood and plasma donors who provide positive responses to a question about having had or having been treated for syphilis or gonorrhea during the preceding 12 months. Since publication of this recommendation, a number of blood establishments have sought clarification as to whether this additional donor suitability criterion has altered the way in which tests for syphilis should be used as a basis for

donor deferral, removal of product from use channels, or recipient tracing. The purpose of this memorandum is to clarify FDA's recommendations on the use of tests for syphilis in regard to AIDS-related risk.

Rationale for Change

Asking donor history questions concerning risk factors and performing serological tests for markers of infectious diseases are each important elements to better assure the safety of the blood supply. In recommending that donors who have a history of diagnosis or treatment for syphilis or gonorrhea in the last 12 months be deferred, the FDA intended to broaden the donor deferral criteria to exclude additional individuals who might be at increased risk of HIV infection due to heterosexual transmission. Although recommendations for management of units or donors based on the results of serological testing for syphilis were not specifically addressed earlier, it cannot be ignored that a confirmed positive screening test for syphilis is in most cases evidence of recent or untreated syphilis and that this information can supplement the use of donor history questions in making deferral decisions.

Donor Deferral Recommendation

To ensure a uniform approach to these issues, FDA is now making an additional recommendation that may be implemented immediately. Concurrent with implementation, licensed establishments should revise their standard operating procedures and submit a statement to their license application file containing the information indicated in the attached example. This statement indicates that a revised standard operating procedure consistent with the following recommendation has been implemented:

> Donors who are found to have a reactive screening test for syphilis by the Automated Reagin Test (ART), the Rapid Plasma Reagin Test (RPR), the Venereal Disease Research Laboratory Slide Technique (VDRL), or other screening test, should be temporarily deferred pending the outcome of a confirmatory test such as the Fluorescent Treponemal Antibody Absorption Test (FTA). Donors who are found to have a positive FTA (or other confirmatory test), or for whom no additional test result is available, should be deferred for 12 months. (In the event that a history of therapy for syphilis in the last 12 months is established, the 12 month deferral period may be calculated from the established date of diagnosis.) After 12 months, deferred donors may be requalified if they have a negative screening test. For cases in which the positive serology was confirmed, evidence of adequate treatment for syphilis, documented by a

letter from a physician or public health clinic, should also be obtained.

The following additional points of clarification are intended to resolve confusion which may exist regarding current recommendations:

1. FDA is not recommending at this time that extant units of whole blood, blood components, and Source Plasma be removed from use channels if previously collected from donors who subsequently provide a history of syphilis or gonorrhea within the last 12 months, or who are found subsequently to have reactive or confirmed tests for syphilis and have no other disqualifying history or test results, nor is FDA recommending that the blood center notify hospitals for the purpose of tracing recipients of such products.

2. For Source Plasma, current collection and labeling requirements related to the results of serologic tests are found in 21 CFR 640.65 and 21 CFR 640.70. FDA is not recommending that the frequency of serological testing for syphilis for Source Plasma be altered (i.e., initially, then every four months) and Source Plasma collected before serologic test results are received may be used for further manufacturing.

3. For whole blood and blood components, otherwise suitable units may be released for transfusion if they were obtained from donors who tested reactive for syphilis by screening tests but had negative results of confirmatory testing by FTA or equivalent methods on the same collection. For units to be released for transfusion, the confirmatory test should be performed on every donation for which there is a reactive screening test (i.e., prior negative confirmatory results are insufficient to qualify a collection with a reactive screening test). Such units should be labeled as reactive by a screening test for syphilis and negative by FTA (or other confirmatory test).

4. In cases of autologous donation of blood or components, collections with reactive screening tests which are either positive by FTA, or not further tested, may be used for transfusion provided that they bear both an "Autologous Use Only" label and a biohazard label. A written report of the test results should be provided to the patient's physician before transfusion. Guidance on proper labeling of autologous blood and components may be found in memoranda dated March 15, 1989 and February 12, 1990. Biohazard labels are described in the current Guideline for the Uniform Labeling of Blood and Components.

   It should be noted that the recommendation on labeling of autologous blood and components reactive for syphilis

differs from FDA recommendations issued on March 15, 1989, with respect to restrictions on the use of autologous blood which is positive for other infectious disease markers. For release of autologous units found to be repeatedly reactive for anti-HIV or HBsAg, the physician's written request remains necessary.

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Dear Dr. Quinnan:

In response to your recent recommendations for revision of STS positive donor deferral and product distribution procedures affirm that:

_____ Our program is in complete compliance with FDA's recent recommendations included in the memorandum to all registered blood establishments dated Dec. 5, 1990.

_____ A revised standard operating procedure consistent with the recommendations has been implemented.

Date implemented: _____

Please add this information to the license file for facility:

License No. _____

Registration No. _____

Facility Name _____

Address _____

_____

Responsible Person: Name _____

Telephone No. _____

Date of response _____

Sincerely yours,

_____

Signature