Guidance for Industry

Implementation of an Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance recognizes the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 1.2 dated September 2012, prepared by the Plasma Protein Therapeutics Association (PPTA) as an acceptable mechanism that is consistent with the Food and Drug Administration's (FDA's) requirements and recommendations for collecting Source Plasma donor history information. In the future, we, FDA, may recognize other Source Plasma donor history questionnaires and accompanying materials as acceptable. We intend to make the current recognized versions of the Source Plasma donor history questionnaires and accompanying materials (referred to as "SPDHQ documents") available on the FDA website.

The SPDHQ documents will provide blood establishments that collect Source Plasma (referred to as "manufacturers" or "you"), with a specific process for administering questions to Source Plasma donors (referred to as "donors") to determine their eligibility to donate. We are using the term "eligibility" in this guidance to refer to the donor suitability requirements described in Title 21 Code of Federal Regulations 640.63 (21 CFR 640.63). Acceptable SPDHQ documents are those documents that FDA has determined will provide Source Plasma manufacturers with one means of obtaining donor history information from a Source Plasma donor to determine if the donor is eligible consistent with the requirements in 21 CFR 640.63.

This guidance also advises Source Plasma manufacturers who choose to implement the acceptable SPDHQ documents on how to report the manufacturing change consisting of the implementation of the SPDHQ under 21 CFR 601.12 (§ 601.12).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, these guidances describe the FDA's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements

are cited. The use of the word *should* in FDA's guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Section 640.63(a) requires the eligibility of Source Plasma donors to be determined on the day of collection. (We interpret "day of collection" to permit clarifying a donor's response to the donor history questionnaire or obtaining omitted responses to questions within 24 hours of the time of collection.[1]) Such determination is intended to ensure a donor's overall good health and prevent transmission of diseases transmissible by blood and blood components (21 CFR 640.63(a-d)). A donor's eligibility to donate blood and blood components is determined in part by a physical assessment and the donor's answers to questions concerning medical history and risk factors for diseases transmissible by blood and blood components. The donor screening interview is especially important in identifying risks for diseases and conditions for which there are no adequate laboratory tests or for which tests are unable to identify early stage or window period infection.

The first formal uniform questionnaire developed for the purpose of blood donor screening was implemented nearly sixty years ago (Ref. 1). Though the donor interview process is helpful in excluding ineligible donors, errors in this process do occur because some information may not be understood or captured during the screening process (Ref. 2). As noted during workshops sponsored by FDA to discuss this issue, the blood donor screening process should consider such factors as question complexity, donor recall ability, donor health and safety, donor satisfaction and willingness to return, any further processing which a product may undergo prior to use, and risk to the end user/recipient of blood and blood components (Refs. 3 and 4). Strategies such as using self-administered computer-assisted and abbreviated questionnaires have been suggested as approaches to improve donor understanding and satisfaction over what some view as a lengthy and time-consuming process, particularly for frequent donors (Refs. 3 through 5). FDA has previously issued a guidance documented entitled "Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires," dated July 2003 (Streamlining Donor Interview guidance) explaining how blood and plasma establishments may simplify the donor screening process by allowing certain donors to use self-administered donor questionnaires (Ref. 6).

The full-length and abbreviated questionnaires are designed to be implemented together. For example, if you choose to implement the Abbreviated PPTA Donor History Questionnaire, you should also implement the Full-Length PPTA Donor History Questionnaire as described in the

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[1] See FDA guidance documented entitled "Guidance for Industry: Recommendations for Blood Establishments: Training of Back-Up Personnel, Assessment of Blood Donor Suitability and Reporting Certain Changes to an Approved Application," dated November 2010 for additional information on donor suitability procedures, available at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm235785.htm.

Directions for Use. Both the full-length and abbreviated questionnaires are designed to be administered either by Source Plasma establishment personnel or self-administered with follow-up by establishment personnel.

The SPDHQ documents include the following materials and are intended to be used in their entirety, with the exceptions noted in Section IV.A.2.:

- Full-Length Donor History Questionnaires
  - Questionnaire I – to be used by Source Plasma establishments that use an approved test to detect HIV-1 Group O variant.
  - Questionnaire II – to be used by Source Plasma establishments that do not use an approved test to detect HIV-1 Group O variant.
- Full-Length PPTA Donor History Questionnaire Directions for Use – includes glossary, flow charts and references; describes how questions can be administered; and contains follow-up questions to further evaluate a potential donor's response to "capture questions."[2]
- Abbreviated Donor History Questionnaire – to be used by frequent Source Plasma donors.
- Abbreviated PPTA Donor History Questionnaire Directions for Use – includes glossary, flow charts and references, describes which donors may complete the questionnaire and how the questions can be administered, and contains follow-up questions to further evaluate a potential donor's response to capture questions.
- Medication List – contains a list of medications that may serve as a basis for donor deferral.
- Risk Posters – educate the donor about risks and conditions that are a basis for donor deferral.
  - Poster I – to be used by Source Plasma establishments that use an approved test to detect HIV-1 Group O variant.
  - Poster II – to be used by Source Plasma establishments that do not use an approved test to detect HIV-1 Group O variant.
- Travel Posters – identify countries endemic for diseases that can be transmitted by blood and blood components.
  - Travel Poster I – to be used by Source Plasma establishments that use an approved test to detect HIV-1 Group O variant.
  - Travel Poster II – to be used by Source Plasma establishments that do not use an approved test to detect HIV-1 Group O variant.

III. RECOGNITION OF PPTA SPDHQ DOCUMENTS

We find the SPDHQ documents (version 1.2) to be acceptable for use in screening Source Plasma donors. These documents are consistent with FDA requirements and recommendations

[2] Capture questions ask general questions about a potential donor's history and are followed up by more specific questions if needed.

related to donor eligibility interviews, subject to the following exception. The SPDHQ documents contain questions related to the following donor medical history issues for which we currently do not have requirements or recommendations: cancer; organ, tissue, or bone marrow transplant; bone or skin graft; and pregnancy. By recognizing the acceptable SPDHQ documents as one way to satisfy FDA's regulatory requirements, we are not requiring or recommending that donors be screened or deferred for these issues. If you choose to implement the acceptable SPDHQ documents and omit these questions, you would still be in compliance with FDA requirements.

While we recognize that the acceptable SPDHQ documents provide an effective tool for screening donors, we do not require that you implement the acceptable SPDHQ documents. You may continue to use the full-length and abbreviated donor history questionnaires and accompanying materials developed by your establishment and previously approved by FDA. These materials may include procedures and wording that are different from those in the SPDHQ documents. In the future, you may implement, consistent with § 601.12, new procedures and materials that differ from those in SPDHQ documents (Ref. 7).

IV. REPORTING TO FDA THE IMPLEMENTATION OF ACCEPTABLE DONOR HISTORY QUESTIONNAIRES AND ACCOMPANYING MATERIALS

As indicated above, we recommend that the full-length and abbreviated questionnaires be used together. For example, if you choose to implement the Abbreviated PPTA Donor History Questionnaire, we recommend that you also implement the Full-Length PPTA Donor History Questionnaire.

A. Implementation of the Acceptable SPDHQ Documents

You must report the implementation of the acceptable SPDHQ documents to FDA under § 601.12 as follows:

1. If the acceptable SPDHQ documents are implemented without modifications and in their entirety as a complete process for administering questions to Source Plasma donors, the change is considered to be minor, with a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product. You must report such changes to FDA in your annual report under § 601.12(d), noting the date the process was implemented. If donors will be allowed to self-administer the acceptable SPDHQ documents, see section IV.B.

2. If the acceptable SPDHQ documents are implemented in their entirety, but modified (a) by adding additional, more restrictive selection criteria that are specific to your establishment; or (b) by omitting questions related to cancer; organ, tissue, or bone marrow transplant; bone or skin graft; and pregnancy, which FDA has not required or recommended for determining donor eligibility, the changes are considered to be minor. Report such changes to FDA in your annual report under § 601.12(d), noting

the date the process was implemented and describing the additional criteria or the questions that were omitted from your questionnaire.

3. If you make changes to the format or wording in the SPDHQ flow charts but the content remains consistent with FDA required/recommended donor deferral criteria or if you adopt stricter donor deferral criteria, the changes are considered to be minor. You must report such changes to FDA in your annual report under § 601.12(d), noting the date the process was implemented and describing how you modified the acceptable SPDHQ documents.

4. If the acceptable SPDHQ documents are implemented in their entirety, but modified by reformatting any of the acceptable SPDHQ documents (other than the flow charts) to be consistent with your current process, the changes are considered minor, provided you do not change the wording and the order of content in the acceptable SPDHQ documents. Report such changes to FDA in your annual report under § 601.12(d), noting the date the process was implemented and describing how you modified the acceptable SPDHQ documents.

5. Donor screening is important to the safety of blood components and screening procedures have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of blood and blood components as they may relate to the safety or effectiveness of the product. Therefore, the implementation of the acceptable SPDHQ documents that have been modified other than as specifically described in sections IV.A.2-4, will be a major change. If you wish to implement the acceptable SPDHQ documents modified in a manner other than as described in sections IV.A.2-4, you must report such changes as a Prior Approval Supplement (PAS) under § 601.12(b). We recommend that you include the following in the submission:

    a. FDA Form 356h "Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use" which may be obtained at http://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm;
    b. A cover letter describing the request and the contents of the submission;
    c. A written SOP describing the donor questions and questionnaire process; and
    d. The donor history questionnaires and accompanying document(s). Please highlight the modifications.

For assistance in preparing the supplement, please refer to FDA's guidance entitled "Guidance for Industry: For the Submission of Chemistry, Manufacturing and Controls and Establishment Description Information for Human Blood and Blood Components Intended for Transfusion or for Further Manufacture and for the Completion of the Form FDA 356h 'Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use,'" dated May 1999 (Ref. 8).

B. Implementation of Self-Administered Acceptable SPDHQ Documents

In July 2003, we issued the Streamlining Donor Interview guidance (Ref. 6), advising licensed blood establishments to submit procedures for self-administering the donor history questionnaire to FDA as a Changes Being Effected in 30 days supplement (CBE30) under § 601.12(c). We determined in the Streamlining Donor Interview guidance that a CBE30 was an appropriate supplement to ensure that controls were in place to manage this process. However, we have since determined that when acceptable DHQ documents include instructions for controlling the self-administration process, such as in the SPDHQ Directions for Use, this change may be reported in an annual report or, in some situations, as a CBE30, as described in IV.B.1 and IV.B.2 below. These recommendations modify those stated in the Streamlining Donor Interview guidance. Licensed manufacturers planning to implement self-administration of a questionnaire other than the acceptable SPDHQ documents should continue to consult the Streamlining Donor Interview guidance (Ref. 6).

Licensed manufacturers must report implementation of self-administered acceptable SPDHQ documents under § 601.12 as follows:

1. If you choose to implement self-administration of the acceptable SPDHQ documents using the written form or audio/visual presentation methods described in the acceptable SPDHQ documents, this is considered a minor change. Report such a change to FDA in your annual report under § 601.12(d), noting the date the process was implemented.

2. If you choose to implement the acceptable SPDHQ documents using a computer-assisted interactive interview procedure, report this change to FDA as a Supplement – Changes Being Effected in 30 Days (CBE30) under § 601.12(c). This change presents a moderate potential to adversely affect the identity, strength, quality, purity, or potency of blood and blood components, as they may relate to the safety or effectiveness of the product, because of concerns that the presentation of the questions and information may not be easily readable in all conditions and by all potential users. Additionally, implementation for the first time of a computer-assisted interactive interview procedure may raise new issues that should be evaluated, such as the management of electronic records. Therefore, we cannot conclude at this time that the implementation of a computer-assisted interactive interview procedure will be a minor change.

For assistance in implementing and reporting the use of self-administered questionnaires other than as described above, and for preparing the supplement for the computer-assisted interactive interview procedure, see the Streamlining Donor Interview guidance (Ref. 6).

V. RECOGNITION AND IMPLEMENTATION OF FUTURE ACCEPTABLE SPDHQ DOCUMENTS

In the future, we may issue regulations or guidance documents concerning donor deferrals when we identify new infectious diseases, medical conditions, behaviors, geographic exposures or medications that have the potential to affect the donor's safety or the safety, purity, and potency of Source Plasma. Implementation of new safeguards would change your donor interview SOPs,

and involve amending accepted SPDHQ documents (typically by adding a question at the end of the questionnaire in the area designated for additional questions or by implementing new or revised SPDHQ documents). If you do not use the acceptable SPDHQ documents, this would involve amending your own questionnaire. We anticipate that in the event we recommend a new donor deferral criterion, we will, in the same guidance, provide recommendations concerning implementing and reporting to FDA the manufacturing changes associated with this change in procedure. If revised SPDHQ documents are available and found acceptable, we also intend to recognize those SPDHQ documents as acceptable in the guidance document addressing the donor deferrals. We intend to make all acceptable SPDHQ documents available on the FDA website.

We recommend that you have a procedure in place for implementing updated donor questionnaire documents in all your facilities.

VI. FOR MORE INFORMATION

If you have questions regarding this guidance and FDA policies for implementing the acceptable SPDHQ documents, call OCOD at the numbers provided above.

If you have questions regarding the SPDHQ documents, contact PPTA by phone at 202-789-3100, fax at (410) 263-2298 or online at http://www.pptaglobal.org/contact/default.aspx.

You may view the SPDHQ documents that FDA has recognized as acceptable on the FDA website at http://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/BloodDonorScreening/ucm255235.htm.

VII. REFERENCES

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