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

---

Guidance for Industry

This guidance is for immediate implementation.

FDA is issuing this guidance for immediate implementation in accordance with 21 CFR 10.115(g)(4)(i). Submit one set of either electronic or written comments on this guidance at any time. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. You should identify all comments with docket number FDA-2016-D-1533.

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-8010, or email ocod@fda.hhs.gov, or from the Internet at https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances.

For questions on the content of this guidance, contact OCOD at the phone numbers or email address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
May 2020

Table of Contents

Contains Nonbinding Recommendations

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

Guidance for Industry

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance recognizes the standardized full-length and abbreviated donor history questionnaires and accompanying materials, version 2.1 dated May 2020, prepared by the Plasma Protein Therapeutics Association (PPTA).[1] This guidance also advises Source Plasma manufacturers on how to report implementation of the acceptable PPTA Source Plasma donor history questionnaires and accompanying materials (SPDHQ documents) under Title 21 of the Code of Federal Regulations 601.12 (21 CFR 601.12).

The SPDHQ documents provide establishments that collect Source Plasma with a specific process for administering questions to donors to determine their eligibility to donate. Acceptable SPDHQ documents are those documents that FDA has determined provide Source Plasma collection establishments with one means of obtaining donor history information to determine if a donor is eligible, consistent with FDA requirements and recommendations. The SPDHQ documents have been updated to align with FDA's current requirements and recommendations for donor eligibility.

This guidance supersedes the document entitled "Implementation of an Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Source Plasma" dated July 2016.

In general, 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.

[1] See section III of this guidance for certain exceptions.

II. BACKGROUND

Section 630.10(c) requires the eligibility of all donors to be determined on the day of donation and before collection, with certain exceptions (21 CFR 630.10(c)(1)-(2)). Such determination is intended to ensure a donor's overall good health and that the donor is free from transfusion-transmitted infection (21 CFR 630.10(a)). 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 associated with exposure to, or clinical evidence of a relevant transfusion-transmitted infection and other conditions that may adversely affect the health of the donor or the safety, purity, or potency of the blood or blood components or any product manufactured from the blood or blood components.

The SPDHQ documents include the following materials:

- Full-Length PPTA Donor History Questionnaire.
- 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. ("Capture" questions ask a general question about a donor's history or behavior and are followed up by obtaining additional information about the donor if needed.)
- Abbreviated PPTA Donor History Questionnaire.
- 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 Poster – educates the donor about risks and conditions that are a basis for donor deferral.

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

III. RECOGNITION OF SPDHQ DOCUMENTS

We, FDA, find the SPDHQ documents version 2.1 dated May 2020, to be acceptable for use in screening Source Plasma donors. These documents are consistent with FDA requirements and recommendations related to donor eligibility.

Note, the SPDHQ documents contain questions related to the following donor medical history factors for which we currently do not have requirements or recommendations, including: cancer; certain organ, tissue, or bone marrow transplant; bone or skin graft; nervous system disease; diabetes; history of fainting, seizures or convulsions; relapsing disease; surgery, diagnostic or dental procedures; or acupuncture. 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 factors. If you choose to implement the acceptable SPDHQ documents and omit these questions, you would still be in compliance with FDA requirements.

In addition, the acceptable SPDHQ documents include a donor acknowledgement statement. Note, the use of this statement alone does not meet the requirements for donor acknowledgement as described in 21 CFR 630.10(g)(2). You must establish procedures in accordance with 21 CFR 606.100 to ensure that the requirements in 21 CFR 630.10(g)(2) have been satisfied.

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 use full-length and abbreviated donor history questionnaires and accompanying materials developed by your establishment and approved by FDA. These materials may include procedures and wording that are different from those in the acceptable SPDHQ documents.

IV. REPORTING IMPLEMENTATION OF ACCEPTABLE SPDHQ DOCUMENTS

Licensed establishments must report the implementation of the acceptable SPDHQ documents to FDA under 21 CFR 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. You must report such changes to FDA in your annual report under 21 CFR 601.12(d), noting the date the process was implemented.

2. If the acceptable SPDHQ documents are implemented in their entirety, but modified by: (a) adding additional, more restrictive selection criteria that are specific to your establishment; (b) omitting questions not required or recommended by FDA for determining donor eligibility including those related to: cancer; organ, tissue, or bone marrow transplant, except for xenotransplantation; bone or skin graft; nervous system disease; diabetes; history of fainting, seizures or convulsions; relapsing disease; surgery, diagnostic or dental procedures; or acupuncture; or (c) omitting the donor acknowledgement statement and using your own materials to satisfy the requirements in 21 CFR 630.10(g)(2), the changes are considered to be minor. You must report such changes to FDA in your annual report under 21 CFR 601.12(d), noting the date the process was implemented and describing the additional criteria or the questions or statements that were omitted from your questionnaire.

3. If the acceptable SPDHQ documents are implemented in their entirety but modified by displaying the flow charts in another format that is compatible with your current process,

the changes are considered minor, provided there is no change to the content in the SPDHQ flow charts, other than changes incorporating donor deferral criteria that are stricter than the FDA required/recommended donor deferral criteria. You must report such changes to FDA in your annual report under 21 CFR 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 are 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 to be minor, provided you do not change the wording and the order of content in the acceptable SPDHQ documents. You must report such changes to FDA in your annual report under 21 CFR 601.12(d), noting the date the process was implemented and describing how you modified the acceptable SPDHQ documents.

5. If the acceptable SPDHQ documents are implemented using a computer-assisted interactive interview procedure, this is considered a moderate change. You must report the change as a Changes Being Effected in 30 Days (CBE30) supplement under 21 CFR 601.12(c). For recommendations on preparing the CBE30 for the computer-assisted interactive interview procedure, see the document entitled, "Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires," dated July 2003 (Ref. 1).

   Note, if you are already approved to implement a computer-assisted interactive interview procedure and you are revising your procedures to incorporate the accepted SPDHQ documents as described in sections IV. 1-4 of this guidance, you must report this change in your Annual Report under 21 CFR 601.12(d).

6. Implementation of the acceptable SPDHQ documents that have been modified other than as specifically described in sections IV. 2-4 of this guidance is considered a major change. If you wish to implement the acceptable SPDHQ documents modified in a manner other than as described in sections IV. 2-4 of this guidance, you must report such changes as a Prior Approval Supplement (PAS) under 21 CFR 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 https://www.fda.gov/AboutFDA/ReportsManualsForms/Forms/default.htm;
   b. A cover letter describing the request and the contents of the submission;
   c. A Standard Operating Procedure (SOP) describing the donor questions and questionnaire process; and
   d. The donor history questionnaires and accompanying document(s). Please highlight the modifications.

V. FOR MORE INFORMATION

If you have questions regarding this guidance, contact OCOD at the phone numbers or email address provided in this guidance.

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

The acceptable SPDHQ documents can be accessed on the PPTA website at http://www.pptaglobal.org/safety-quality/donor-history-questionnaire.

VI. REFERENCES

1. Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires, July 2003. Available at https://www.fda.gov/media/70688/download.