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

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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-1342.

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 e-mail address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
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Contains Nonbinding Recommendations

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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 April 2020, prepared by the AABB Donor History Task Force[1]. This guidance also provides recommendations to licensed establishments on how to report implementation of the acceptable AABB donor history questionnaires and accompanying materials (DHQ documents) under Title 21 of the Code of Federal Regulations 601.12 (21 CFR 601.12).

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

This guidance supersedes the document entitled, "Implementation of Acceptable Full-Length and Abbreviated Donor History Questionnaires and Accompanying Materials for Use in Screening Donors of Blood and Blood Components," dated May 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 is in good health and that the donor is free from transfusion-transmitted infections (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 DHQ documents include the following materials:

- Full-Length Donor History Questionnaire (FL-DHQ)
- Full-Length Donor History Questionnaire User Brochure – includes glossary; describes how questions can be administered.
- Full-Length Donor History Questionnaire Flow Charts – contain follow-up questions as a method to obtain additional information 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 Donor History Questionnaire (aDHQ)
- Abbreviated Donor History Questionnaire User Brochure – includes glossary and references; describes which donors may complete the aDHQ questionnaire and how questions can be administered.
- Abbreviated Donor History Questionnaire Flow Charts – contain follow-up questions as a method to obtain additional information to further evaluate a potential donor's response to capture questions.
- Medication Deferral List – contains a list of medications that may serve as a basis for donor deferral.
- Blood Donor Educational Material – educates the donor about certain risks and conditions that are a basis for deferral.
- References

The DHQ Flowcharts are intended as a resource, and their use is not required if the blood establishment has an equivalent method for evaluating responses to the DHQ. The FL-DHQ and aDHQ are designed to be implemented together. For example, if you choose to implement the AABB aDHQ, you should also implement the AABB FL-DHQ, as described in the User Brochure. Both the FL-DHQ and aDHQ are designed for self-administration by the donor with follow-up by establishment personnel or may be administered by a health historian.

III. RECOGNITION OF DHQ DOCUMENTS

We, FDA, find the DHQ documents, version 2.1 dated April 2020, acceptable for use in screening donors of blood and blood components. These documents are consistent with FDA requirements and recommendations for donor eligibility.

Note, the DHQ documents contain questions related to the following donor history factors for which we currently do not have requirements or recommendations, including: cancer; certain organ, tissue, or bone marrow transplant; and bone or skin graft. By recognizing the acceptable DHQ documents, we are not requiring or recommending that donors be screened or deferred for these factors. If you choose to implement the acceptable DHQ documents and omit these questions, you would still be in compliance with FDA requirements.

While we recognize that the acceptable DHQ documents provide an effective tool for screening blood donors, we do not require that you implement these DHQ documents. You may continue to use any FL-DHQ and aDHQ and accompanying materials developed by your establishment and for licensed establishments, as approved by FDA. These materials may include procedures and wording that are different from those in the DHQ documents developed by AABB.

IV. REPORTING IMPLEMENTATION OF ACCEPTABLE DHQ DOCUMENTS

Licensed establishments must report the implementation of the acceptable DHQ documents to FDA under 21 CFR 601.12 as follows:

1. If the acceptable DHQ documents are implemented without modifications and in their entirety, as a complete process for administering questions to blood donors, the change is considered to be minor. You must report the change to FDA in your annual report under 21 CFR 601.12(d), noting the date the process was implemented.

2. If the acceptable DHQ documents are implemented in their entirety, but modified by: (a) adding additional, more restrictive eligibility criteria that are specific to your establishment; or (b) omitting questions related to cancer; organ, tissue, or bone marrow transplant; or, bone or skin graft, which FDA has not required or recommended for determining donor eligibility, the changes are considered to be minor. You must report the change 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 questions that were omitted from your questionnaire.

3. If the acceptable DHQ 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 flow charts, other than changes incorporating donor eligibility criteria that are stricter than that required or recommended by FDA. 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 DHQ documents.

4. If the acceptable DHQ documents are implemented in their entirety but are modified by reformatting any of the acceptable DHQ 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 DHQ 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 DHQ documents.

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

6. Implementation of the acceptable DHQ documents that have been modified other than as described in sections IV.2-4 of this guidance is considered a major change. You must report the change as a Prior Approval Supplement 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 written standard operating procedure (SOP) describing the donor questions and questionnaire process.
    d. The donor history questionnaires and accompanying document(s). Please highlight the modifications.

Unlicensed blood establishments do not need to report implementation of the acceptable DHQ to FDA.

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 DHQ documents, contact AABB Regulatory Affairs at regulatory@aabb.org, or by phone at 301-907-6977.

The acceptable DHQ documents are accessible at http://www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx.

VI. REFERENCES

1. Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires, July 2003. Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/streamlining-donor-interview-process-recommendations-self-administered-questionnaires.