

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

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 anytime. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (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 <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>.

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
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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 (FL-DHQ and aDHQ, respectively) and accompanying materials, version 2.0 dated February 2016, prepared by the AABB Donor History Task Force (referred to as “task force”), as an acceptable mechanism for collecting blood donor history information from donors of blood and blood components that is consistent with the FDA requirements and recommendations.¹ The FL-DHQ documents are being updated to align with the requirements promulgated in the final rule published in the *Federal Register* of May 22, 2015 entitled “Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use” (80 FR 29842), which became effective May 23, 2016, and incorporate the recommendations provided in the document entitled “Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry” dated December 2015 (Ref. 1). In the future, we may recognize other AABB donor history questionnaires and accompanying materials (referred to as “DHQ documents”) as acceptable.

This guidance supersedes the following documents entitled:

- “Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components” dated October 2006, which accepted version 1.3 of the AABB full-length DHQ (Ref. 2); and
- “Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components” dated May 2013 (Ref. 3), which accepted version 1.3 of the AABB abbreviated DHQ.

¹ See section III of this guidance for certain exceptions.

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Additionally, this guidance supersedes FDA's acceptance of the referenced donor history questionnaires and accompanying materials in the documents entitled:

- “Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products” dated May 2010 (Ref. 4), which accepted revisions to version 1.3 of the AABB full-length DHQ²; and
- “Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria” dated August 2014 (Ref. 5), which accepted revisions to versions 1.3 of the AABB full-length and abbreviated DHQ's, respectively.

The DHQ documents provides blood establishments that collect blood and blood components (referred to as “manufacturers” or “you”) with a specific process for administering questions to donors of blood and blood components (referred to as “blood donors”) to determine their eligibility to donate. (In this guidance, the term “eligibility” refers to the donor eligibility requirements described in Title 21 of the Code of Federal Regulations 630.10 and 630.15 (21 CFR 630.10 and 630.15)). Acceptable DHQ documents are those documents that FDA has determined provide manufacturers with one means of obtaining donor history information from a blood donor to determine if the donor is eligible, consistent with the requirements in 21 CFR 630.10 and 630.15.

This guidance also advises licensed manufacturers who choose to implement the acceptable DHQ documents on how to report the manufacturing change consisting of the implementation of the DHQ documents 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 630.10(c) requires the eligibility of all blood 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 infections (21 CFR 630.10(a)(1)-(2)). 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

² This guidance was updated in January 2016.

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(21 CFR 630.10(e)-(f)). 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. 6). 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. 7). As noted during public meetings 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. 8 through 10). Strategies such as using self-administered computer-assisted and abbreviated questionnaires have been implemented as approaches to improve donor understanding and satisfaction over what some view as a lengthy and time-consuming process, particularly for frequent donors (Refs. 2, 3, and 11).

A. Abbreviated Donor History Questionnaire

In the Abbreviated Donor History Questionnaire User Brochure (User Brochure), AABB defines a frequent donor as “[a] donor who has previously donated two times using the full-length Donor History Questionnaire, one donation of which occurred within the previous 6 months.” The User Brochure contains additional instructions that delineate when the aDHQ documents and FL-DHQ should be administered.

During the Blood Products Advisory Committee meeting held on March 18, 2005, the task force presented a study design for evaluating the abbreviated questionnaire post-implementation (Ref. 12). The task force also proposed to assess inappropriate use of the aDHQ documents instead of the FL-DHQ for donor screening. This study will include a review of post-donation information and data about inappropriate use of the aDHQ documents. The task force has agreed to submit the summary data to FDA once the study has been completed. Based on the outcome of the post-implementation evaluation, FDA may revise its recommendations for the use of the aDHQ.

B. DHQ Documents

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

- Full-Length Donor History Questionnaire
- 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

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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
- 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.
- Variant Creutzfeldt-Jakob Disease (vCJD) Countries of Risk – contains a list of countries identified as being at risk for vCJD.
- References

The FL-DHQ and aDHQ questionnaires are designed to be implemented together. For example, if you choose to implement the AABB Abbreviated Donor History Questionnaire, you should also implement the AABB Full-Length Donor History Questionnaire as described in the User Brochure. Both the full-length and abbreviated questionnaires are designed to be administered either by blood establishment personnel or self-administered with follow-up by establishment personnel.

III. RECOGNITION OF DHQ DOCUMENTS

We find the DHQ documents version 2.0 dated February 2016 to be acceptable for use in screening donors of blood and blood components. These documents are consistent with FDA requirements and recommendations related to donor eligibility interviews, subject to the following exception: the acceptable DHQ documents do not contain the donor questions and donor educational material related to Zika virus recommended by FDA in the document titled, "Recommendations for Donor Screening, Deferral, and Product Management to Reduce the Risk of Transfusion-Transmission of Zika Virus: Guidance for Industry," dated February 2016. Blood establishments should revise the acceptable DHQ documents to address the recommendations for Zika virus, as appropriate.

In addition, the DHQ documents contain questions related to the following donor medical history issues for which we currently do not have requirements or recommendations: cancer; certain organ, tissue, or bone marrow transplant; and bone or skin graft. By recognizing the acceptable DHQ 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 DHQ documents and omit these questions, you would still be in compliance with FDA requirements.

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While we recognize that the acceptable DHQ documents provide an effective tool for screening blood donors, we do not require that you implement the acceptable DHQ documents. You may continue to use any FL-DHQ and aDHQ and accompanying materials developed by your establishment and for licensed establishments, approved by FDA. These materials may include procedures and wording that are different from those in the DHQ documents. In the future, you may implement, consistent with § 601.12, new procedures and materials that differ from those in DHQ documents (Ref. 13).

IV. REPORTING TO FDA THE IMPLEMENTATION OF ACCEPTABLE FULL-LENGTH AND ABBREVIATED DONOR HISTORY QUESTIONNAIRE AND ACCOMPANYING MATERIALS

As discussed in section II of this guidance, we recommend that the FL-DHQ and aDHQ be used together. For example, if you choose to implement the FL-DHQ, we recommend that you also implement the aDHQ.

A. Implementation of Acceptable DHQ Documents

Licensed manufacturers must report the implementation of the acceptable DHQ documents to FDA under § 601.12 as follows:

1. If the acceptable DHQ documents are implemented without modifications and in their entirety, except as described below, as a complete process for administering questions to blood 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 acceptable DHQ documents, see section IV.B of this guidance.
2. If the acceptable DHQ documents are implemented in their entirety, but modified by: (a) revising the DHQ documents to include FDA recommendations related to Zika virus; (b) adding additional, more restrictive selection criteria that are specific to your establishment; or (c) omitting questions related to cancer; organ, tissue, or bone marrow transplant, except for xenotransplantation; 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 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 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

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the content in the 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 § 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 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 § 601.12(d), noting the date the process was implemented and describing how you modified the acceptable DHQ documents.
5. Donor 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 DHQ documents that have been modified other than as specifically described in sections IV.A.2-4 of this guidance is considered a major change. If you wish to implement the acceptable DHQ documents modified in a manner other than as described in sections IV.A.2-4 of this guidance, 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 standard operating procedure (SOP) describing the donor questions and questionnaire process.
 - d. The donor history questionnaires and accompanying document(s). Please highlight the modifications.

For assistance in preparing the supplement, please refer to the document 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. 14).

B. Implementation of Self-Administered Acceptable DHQ Documents

In July 2003, we issued a document entitled “Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires” (Streamlining Donor Interview guidance) (Ref. 11) advising licensed blood

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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 User Brochure, this change may be reported in an annual report or in some situations as a CBE30, as described in sections IV.B.1 and IV.B.2 of this guidance. These recommendations modify those in the Streamlining Donor Interview guidance. Licensed manufacturers planning to implement self-administration of a questionnaire other than the acceptable DHQ documents should continue to consult the Streamlining Donor Interview guidance (Ref. 11).

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

1. If you choose to implement self-administration of the acceptable DHQ documents using the written form or audio/visual presentation methods described in the acceptable DHQ documents, this is considered a minor change. You must 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 DHQ documents using a computer-assisted interactive interview procedure, you must report this change to FDA as a 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 recommendations on the implementation and reporting of the use of self-administered questionnaires other than as described above, and for preparing the CBE30 for the computer-assisted interactive interview procedure, see the Streamlining Donor Interview guidance (Ref. 11).

Unlicensed blood establishments do not need to report implementation of the DHQ (as described in sections IV.A and IV.B of this guidance) to FDA.

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V. RECOGNITION AND IMPLEMENTATION OF FUTURE ACCEPTABLE DHQ DOCUMENTS

In the future, we may issue regulations or guidance documents concerning donor eligibility. For example, we may recommend revised eligibility criteria with respect to transfusion-transmitted infections, medical conditions, behaviors, geographic exposures or medications. Implementation of new eligibility criteria would change your donor interview SOPs, and involve amending the accepted DHQ 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 DHQ documents)³. We note that the User Brochure describes how to add and administer revised DHQ documents.

We anticipate that in the event we recommend a new donor eligibility 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 the revised DHQ documents are available and found acceptable, we also intend to recognize those DHQ documents as acceptable in the guidance document addressing the new criterion.

We recommend that you have a procedure in place for implementing updated acceptable DHQ documents in all of your facilities.

VI. FOR MORE INFORMATION

If you have questions regarding this guidance and FDA policies for implementing acceptable DHQ documents, contact OCOD at the phone numbers or email address provided in this guidance.

If you have questions regarding the DHQ documents, contact AABB by phone at 301-907-6977, by fax at 301-907-6895 or by email at aabb@aabb.org to the attention of the AABB Donor History Task Force.

The acceptable DHQ documents can be accessed on the AABB website at <http://www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx>.

³ If you do not use the acceptable DHQ documents, this would involve amending your own donor history questionnaire.

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VII. REFERENCES

1. Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry, December 2015. Available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM446580.pdf>.
2. Guidance for Industry: Implementation of Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Donors of Blood and Blood Components, 71 FR 63327 (October 30, 2006).
3. Guidance for Industry: Implementation of an Acceptable Abbreviated Donor History Questionnaire and Accompanying Materials for Use in Screening Frequent Donors of Blood and Blood Components,” 78 FR 26785 (May 8, 2013).
4. Guidance for Industry: Revised Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Blood and Blood Products, 75 FR 29768 (May 27, 2010).
5. Guidance for Industry: Recommendations for Donor Questioning, Deferral, Reentry and Product Management to Reduce the Risk of Transfusion-Transmitted Malaria, August 2014. Available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/UCM080784.pdf>.
6. American Association of Blood Banks, *Technical Methods and Procedures of the American Association of Blood Banks*, pp. 3-5, Minneapolis: Burgess Publishing Co., 1953.
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13. Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture, November 2014. Available at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm354559.htm>.
14. 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

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“Application to Market a New Drug, Biologic or an Antibiotic Drug for Human Use,” May 1999. Available at

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm077087.htm>.