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

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I. INTRODUCTION

In November 2009, we, FDA, issued a draft guidance entitled "Recommendations for the Assessment of Blood Donor Suitability, Blood Product Safety, and Preservation of the Blood Supply in Response to Pandemic (H1N1) 2009 Virus," dated November 2009 ("Pandemic (H1N1) 2009 Virus Draft Guidance") (November 19, 2009, 74 FR 59982). This guidance finalizes that draft guidance. Note that while the recommendations that FDA is finalizing were proposed in the Pandemic (H1N1) 2009 Virus Draft Guidance, the finalized recommendations are applicable regardless of the existence of a pandemic or other emergency situation.

This guidance is intended for establishments that manufacture Whole Blood and blood components intended for use in transfusion and for further manufacture, including recovered plasma, Source Plasma, and Source Leukocytes. Within this document, "you" refers to blood establishments; "we" refers to FDA.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe 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 guidance means that something is suggested or recommended, but not required.

II. BACKGROUND

As discussed above, the Pandemic (H1N1) 2009 Virus Draft Guidance was issued in November 2009. At that time, we anticipated that the rapid spread of pandemic (H1N1) 2009 virus had the potential to cause disruptions in the blood supply. In addition, at that time, there was limited

information available on pandemic (H1N1) 2009 virus viremia and the potential for transmission of the virus through blood transfusion. Furthermore, as explained in the Pandemic (H1N1) 2009 Virus Draft Guidance, it was anticipated that the usual practices for ensuring blood availability in response to local disasters (i.e., hurricanes) would not be applicable or sufficient under a severe pandemic scenario.

Since we issued the Pandemic (H1N1) 2009 Virus Draft Guidance, the H1N1 influenza pandemic has waned in the United States and disruptions in the blood supply have not been observed. The April 26, 2009 declaration of a public health emergency by the Department of Health and Human Services in response to H1N1 influenza expired on June 23, 2010.[1] Therefore, we are not finalizing those recommendations set forth in the draft guidance that referred to blood donor deferral and blood product management specific to the pandemic (H1N1) 2009 virus.

Instead, in this document, we are finalizing those recommendations contained in the Pandemic (H1N1) 2009 Virus Draft Guidance that are of general applicability (i.e., regardless of the existence of a pandemic or other emergency situation) as to training of back-up personnel, assessing blood donor suitability and reporting certain changes to an approved application for licensed blood establishments under Section 601.12 of Title 21, Code of Federal Regulations (21 CFR 601.12).

III. RECOMMENDATIONS

A. Training of Back-Up Personnel

Under 21 CFR 211.25 and 21 CFR 606.20, personnel performing critical functions in blood establishments must be adequate in number, educational background, training and experience, including professional training as necessary, or combination thereof, to assure competent performance of their assigned functions. We recommend that you have adequate back-up personnel in the event of personnel shortages which could occur during incidents such as influenza pandemics, local natural disasters or as a result of bioterrorism. To assure continued operations, we further recommend that you train more than one back-up person for each critical function where appropriate. Any such back-up personnel should be trained pursuant to your existing training program. We also recommend that as provided in your training program, you document this training and/or re-training.

B. Blood Donor Suitability

In general, a donor's medical history is obtained at the time of blood collection. However, under 21 CFR 640.3(a) and 21 CFR 640.63(a), the suitability of a donor as a source of Whole Blood or Source Plasma, must be made on the *day of collection* from the donor. These regulations do not explicitly define the term *day of collection.*

[1] http://www.flu.gov/news/h1n1pheexpiration.html, accessed November 16, 2010.

Occasionally, a donor's responses to the donor questions presented before collection are found to be incomplete upon review by the blood establishment. In such instances, you may clarify a donor's response to the donor history questionnaire or obtain omitted responses to questions within 24 hours of the time of collection.

Licensed blood establishments that currently have approved standard operating procedures (SOPs) for clarifying or obtaining a donor's response to the donor history questionnaire after the donor has left the collection establishment do not have to report this change to FDA under 21 CFR 601.12. However, if you are a licensed blood establishment that lacks such SOPs, and you now wish to implement such procedures, you must submit a supplement and receive our approval before making this change in accordance with 21 CFR 601.12(b) (See FDA's Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture," (July 2001) ("July 2001 Guidance"), section III.A.2, (Ref. 1)).

C. Changes to an Approved Application

As provided under 21 CFR 601.12(c)(5), we have determined that the following changes to an approved application for licensed blood establishments may be submitted as a "Supplement-Changes Being Effected (CBE)."

- Use of a different outside test lab, provided the test lab is registered with FDA and has been performing donor testing.[2]
- Implementation of a written or audio/visual presentation of a self-administered, pre-donation donor history questionnaire with respect to the high-risk behavior questions, provided you are using your currently approved questionnaire and you follow the critical control points described in FDA's "Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires" (July 2003) ("July 2003 Guidance")(Ref. 2)), and the submission contains the content recommended for these self-administered procedures as outlined in the July 2003 Guidance.[3] Note that if you change your donor interview process to include a self-administered, computer-assisted interactive interview procedure with respect to the high-risk behavior questions, as described in section IV of the July 2003 Guidance, you must report this change to us as a "Supplement-Changes Being Effected in 30 Days (CBE-30)" under 21 CFR 601.12(c), as recommended in the July 2003 Guidance.[4]

[2] Note that the temporary use of a previously approved alternate or back-up contractor to perform a manufacturing step should continue to be described in an annual report. See section VI.C.2 in Ref. 1.
[3] As discussed in section II of the July 2003 Guidance, in an audio/visual presentation, the donor reviews the questions by listening to a recording or watching a video and documents the answers on a printed questionnaire.
[4] As discussed in section II of the July 2003 Guidance, in a computer-assisted interactive interview, the donor reviews the questions on a computer screen and enters the answers electronically.

Note that the recommendations set forth above supersede the recommendations set forth in FDA's July 2001 Guidance at section IV.C.1 and the July 2003 Guidance at section IV.A, respectively (in both of these guidances, we previously had determined that these changes would require a CBE-30).

IV. IMPLEMENTATION

This guidance is for immediate implementation

V. REFERENCES

1. Guidance for Industry: Changes to an Approved Application: Biological Products: Human Blood and Blood Components Intended for Transfusion or for Further Manufacture (July 2001). http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm076729.htm, accessed November 16, 2010.

2. Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires (July 2003). http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Blood/ucm062910.pdf, accessed November 16, 2010.