NEW INFORMATION and GUIDELINES FOR USE of the CIRCULAR

NEW INFORMATION
AABB is pleased to report new information that is consistent with FDA’s current thinking on the Circular of Information (the Circular). AABB’s Circular of Information Task Force (the AABB Task Force) has the following considerations for safe and effective implementation that is consistent with FDA’s stated expectation that the Circular should be distributed “to physicians, transfusionists, caregivers, and other health care professionals in any setting in which questions may arise regarding blood transfusion. If the environment includes blood transfusion, the circular should be available.”

Considering this new information, AABB has identified acceptable options for use of an electronic version of the Circular that will meet the regulatory requirements of 21 CFR 606.122.

GUIDELINES FOR USE OF THE CIRCULAR

1) AABB’s Task Force is making this electronic version of the Circular available for use.
   • In a manner consistent with FDA regulations at §606.122, as well as:
     o the agency’s stated expectations, including the Q&A from the 2017 Ask the FDA Session provided below, and
     o as described in FDA’s December 2017 guidance formally recognizing the October 2017 Circular as acceptable for use.
   • Without revising the content that is currently protected to help prevent changes to language accepted by FDA as part of a formal review process.
   • Consistent with FDA’s expectation that blood collection establishments will make a hard copy of the Circular available to customers as follows:
     o on a yearly basis, or
     o whenever a change is made to the Circular, or
     o upon request from your customers.
   • By a blood collection establishment that follows SOP’s that will help ensure compliance with FDA regulations for safe and effective use of the Circular, (including the electronic version) which remains the sole responsibility of the establishment.
   • To promote wider access to healthcare providers in any setting in which questions may arise regarding blood transfusion and in every environment that includes blood transfusion, the Circular should be “available” to provide “information about the product, including information on how the product is prepared, test results, instructions for use and side effects and hazards.”
   • With updates for FDA required information on the designated pages, found at the front of the Circular, making the new information readily available to the user.

2) Updates to the electronic version of the Circular:
   • It is possible that your computer will require that you first open the electronic version as a PDF document to add FDA required updates in the designate area.
   • The three pages prior to the Table of Contents are designated for FDA required updates.
   • These three designated pages contain editable text boxes that permit additions and revisions.
   • The Table of Contents and all pages that follow are “locked” to protect the content of this controlled document.
• The “locked” protected content prevents inadvertent changes and ensures that the content approved by the AABB Task Force and formally accepted by FDA is not revised.

3) The following list provides some examples to guide you in the use of the Circular:

**Acceptable:**

A hard copy *Circular* with local modifications is sent by the blood collector to hospital blood banks. In addition to a hard copy *Circular*, local modifications are added to the electronic version of the *Circular*.

The electronic version of the *Circular* (with local modifications) is sent by the blood collector to the hospital blood bank.

The electronic version of the *Circular* (with local modifications) is downloaded and printed by the blood collector.

A link to the electronic version of the *Circular* (with local modifications) is posted on the blood collector’s website with all required information regarding current ZIKV testing.

A transfusion service requests additional copies of the *Circular* from the blood collector for distribution to a provider of emergency transport services.

The watermarked version without local modifications posted on AABB’s website is used as a reference or teaching tool rather than an extension of container labeling.

A hard copy with local modifications is sent each year AND whenever the *Circular* is updated with new information.

**Unacceptable:**

A hard copy or electronic version of the *Circular* without local modifications provided to a transfusion service as part of the extension of labeling as required under §606.122.

The electronic version of the *Circular* is revised to change the content approved by the AABB Task Force and formally accepted by FDA.

A transfusion service purchases and distributes the hard copy *Circular*, to serve as an extension of container labeling for blood products they did not manufacture.

A hard copy of the *Circular* with local modifications dated November 2013 is used to meet the labeling requirements under §606.122.

A blood collector decides to use only the electronic version of the *Circular* without a hard copy version first.

A blood collector does not provide an additional copy of the *Circular* when requested by a customer.

**INFORMATION ON THE CIRCULAR PROVIDED AT THE 2017 ASK THE FDA SESSION**
The following information clarifies FDA’s expectations as provided by the agency in the Ask the FDA Session at AABB’s October 2017 Annual Meeting:

**Question 1.** Regulations at §606.122 describe requirements for the Circular of Information as an extension of labeling and state:

“A circular of information must be available for distribution if the product is intended for transfusion...”

What are FDA’s expectations of the blood donor centers that must make the hard copy Circular “available for distribution”? Please clarify FDA’s expectation for the frequency of and method for distribution of the Circular.

**FDA:** “Thank you. I will give a very brief historical background on the Circular as part of the response to this question:

**HISTORICAL BACKGROUND:**

The current circular of information was developed in the 1970s to provide for safe handling and administration of blood components and to provide uniform labeling to facilitate regional and interregional sharing of the Nation’s blood supply. In 1974, the Commission for Commonality in Blood Banking Association (CCBBA) was created. It consisted of volunteers from different areas of the medical community and FDA personnel. At the time, labeling varied in format and wording depending on the collector. Blood banking computerization did not yet exist. CCBBA undertook a review of the container label requirements for blood and blood components in order to recommend a revised simplified container label suitable for use by all establishments, to include machine readable code, and to select key information for inclusion on the container label. In support of these efforts, FDA issued a Guideline for the Uniform Labeling of Blood and Blood components which described suitable labeling for blood and blood components and then promulgated labeling regulations in 1985. Many of the information elements that were removed from the simplified container label recommended by CCBBA were included in the instruction circular. New cautionary statements and instructions to users were included in the circular when the agency determined that the information was necessary. Because the revised, simplified container label was intended for use with the circular, the instruction circular must be available concurrent with the use of the container label. With that said.......................

The Circular of Information for the Use of Human Blood and Blood Components is considered to be labeling. It was developed as an extension of blood bag container labels, because the space on those labels is limited.

FDA believes that the circular should be distributed to customers. We believe availability of a hard copy circular should be part of your overall distribution process in accordance with 606.122, to include distribution on a yearly basis, or whenever a change is made to the circular, or upon request from your customers.”

Question 2. The requirements of §606.122 also state:
“The circular of information must provide adequate directions for use, including the following information:...”

As you know, this extension of labeling is

- developed by the Circular of Information Task Force.
- reviewed and formally recognized by FDA as acceptable to meet the long list of requirements in §606.122(a)-(n).
- The printed copy is available for purchase from AABB and distribution of electronic copies is not yet an option.

Specifically, §606.122 requires the Circular to provide information critical to the work performed from collection to transfusion, by the blood donor center, transfusion service, prescribing physician, and nursing staff, including:

- Instructions to mix the product before use, to use a filter in the administration equipment
- A statement "Do Not Add Medications" or an explanation concerning allowable additives.
- A description of the product, its source, and preparation, including the name and proportion of the anticoagulant used in collecting the Whole Blood from each product is prepared.
- A statement about testing for RTTIs, and the related warnings.
- The use of the product, indications, contraindications, side effects and hazards, warnings, dosage and administration recommendations for handling and transfusion of...
- Instructions for administration.

What is the purpose of this extension of labeling and what are FDA’s expectations for the handling of the Circular once received by the transfusion service?

**FDA:** “The circular of information is an extension of the information on the blood bag label and is intended to provide information about the product, including information on how the product is prepared, test results, instructions for use and side effects and hazards. The circular also contains educational information for the user. The transfusion services should be familiar with the information in the circular including the instructions for use.”

Question 3. Do the requirements of §606.122 apply solely to the blood collection establishments or do the requirements also apply to transfusion services to make the Circular available to prescribing physicians prior to and/or at the time of issue?

**FDA:** “FDA believes that the Circular should be available for prescribing physicians, transfusionists, and other health care professionals for when questions arise regarding blood transfusion. In the
preamble to the final rule in 1985, FDA explained that “while it is often unnecessary to consult the instruction circular during the routine operation of a transfusion service, the circular is useful in providing necessary information when a question arises concerning characteristics of a blood product or its proper administration.”

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**Question 4.** Is it FDA’s expectation that the *Circular* be made available at the time of issue for transfusions in a private practice or other setting, and for emergency use if needed during patient transport by air or ground etc.?

**FDA:** “Again, FDA believes that the *Circular* should be available for distribution to physicians, transfusionists, caregivers, and other health care professionals in any setting in which questions may arise regarding blood transfusion. If the environment includes blood transfusion, the *Circular* should be available.”