Guidance for Industry

Recognition and Use of a Standard for Uniform Blood and Blood Component Container Labels

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 No. FDA-1998-D-0067 (formerly Docket No. 1998D-0965).

Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD), 10903 New Hampshire Avenue, Bldg. 71, rm. 7301, Silver Spring, MD 20993-0002, or by calling 1-800-835-4709 or 240-402-7800, 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 email address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
June 2014

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Contains Nonbinding Recommendations

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

We, FDA, Center for Biologics Evaluation and Research (CBER), are recognizing as acceptable for use by you, manufacturers of blood and blood components, subject to United States statutes and regulations, the document entitled "United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128," Version 3.0.0, dated March 2013 (Version 3.0.0 Standard). The Version 3.0.0 Standard is the revised version of the "United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128," Version 2.0.0, dated November 2005 (the Version 2.0.0 Standard).

The Version 3.0.0 Standard describes a system of uniform container labels for blood and blood components intended for transfusion or for further manufacturing use. We believe that this uniform container label standard will assist manufacturers in complying with the container label requirements under Title 21 of the Code of Federal Regulations 606.121 (21 CFR 606.121). This guidance supersedes the guidance of the same title dated September 2006.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, 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

On March 29, 2013, the International Council for Commonality in Blood Banking Automation (ICCBBA) prepared and submitted to FDA for review the Version 3.0.0 Standard. The ICCBBA requested that the Version 3.0.0 Standard replace the Version 2.0.0 Standard currently in use for container labels for blood and blood components.

The Version 3.0.0 Standard is considerably reorganized and expanded from the Version 2.0.0 Standard. However, there are only limited substantive revisions when compared to the Version 2.0.0 Standard. Specific revisions in the Version 3.0.0 Standard when compared to the Version 2.0.0 Standard include:

- Providing for the abbreviation of certain words to reduce the amount of printing space needed on a label;
- Providing that the Donation Identification Number be printed such that all characters are the same font, color, and print size;
- Providing that blood products collected from autologous donors that are not eligible for crossover be encoded with an "X" or a "1" in the product code;
- Specifying that the term "OPEN SYSTEM" be printed on the label if the product is manufactured in an open system;
- Including instructions for labeling products containing platelet additive solutions; and
- Clarifying when the name and location of a modifying facility (if different from that of the collection facility) needs to be printed on the label.

Furthermore, note that many more examples of labels and text are included in Version 3.0.0 Standard.

III. FDA REVIEW AND CONCLUSIONS

Under 21 CFR 606.121(c)(13), the container label of blood or blood components intended for transfusion must bear encoded information in a format that is machine-readable and approved for use by the Director, CBER. The Director of CBER has reviewed the Version 3.0.0 Standard and finds it acceptable for use on the container labels of blood or blood components. We believe that conformance to the Version 3.0.0 Standard will help facilitate the use of a uniform container label for blood or blood components in the United States and internationally.

IV. REPORTING REQUIREMENTS FOR LICENSED ESTABLISHMENTS

Licensed manufacturers who implement the Version 3.0.0 Standard must report changes in labeling to FDA under 21 CFR 601.12 as follows:

1. If the Version 3.0.0 Standard is implemented for your approved products without modification and in its entirety, the change is considered to be minor. You must report such changes in your annual report consistent with 21 CFR 601.12(f)(3), noting the date the process was implemented.

2. If the Version 3.0.0 Standard is implemented for your approved products but modified, the changes are considered to be major. You must report such changes and submit a Prior Approval Supplement consistent with 21 CFR 601.12(f)(1). We recommend 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 (optional for eSubmitter submissions) describing the request and the contents of the submission.
    c. The modified labels.

V. SUPLEMENTARY INFORMATION

Interested persons may obtain the Version 3.0.0 Standard from:

The International Council for Commonality in Blood Banking Automation, Inc.
P.O. Box 11309
San Bernardino, CA 92423-1309

Persons with access to the Internet may obtain the Version 3.0.0 Standard at www.iccbba.org.

VI. THE VERSION 3.0.0 STANDARD

Below is a copy of the "United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128," dated March 2013, that we, through this guidance document, recognize as acceptable.