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 Dockets Management Staff (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 240-402-8010, 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 email address listed above.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
April 2024

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Contains Nonbinding Recommendations

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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

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 4.0.0, dated January 2024 (Version 4.0.0 Standard). The Version 4.0.0 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 3.0.0, dated March 2013.

The Version 4.0.0 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 June 2014.

In general, 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

The International Council for Commonality in Blood Banking Automation (ICCBBA) prepared and submitted to FDA for review the Version 4.0.0 Standard. The ICCBBA requested that the Version 4.0.0 Standard replace the Version 3.0.0 Standard currently in use for container labels for blood and blood components.

III. RECOGNITION OF THE VERSION 4.0.0 STANDARD

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 4.0.0 Standard, dated January 2024, and finds it acceptable for use on the container labels of blood or blood components. We believe that conformance to the Version 4.0.0 Standard will help facilitate the use of a uniform container label for blood or blood components in the United States and internationally.

IV. REPORTING IMPLEMENTATION OF THE VERSION 4.0.0 STANDARD

Licensed manufacturers who implement the Version 4.0.0 Standard must report changes in labeling to FDA under 21 CFR 601.12 as follows:

1. If you implement the Version 4.0.0 Standard 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 you implement the Version 4.0.0 Standard with modifications, the change is 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 or Abbreviated New Drug or Biologic for Human Use" which may be obtained at https://www.fda.gov/about-fda/reports-manuals-forms/forms.
    b. A cover letter describing the request and the contents of the submission.
    c. The modified labels.

Unlicensed blood establishments are not required to report this change to FDA.

V. SUPLEMENTARY INFORMATION

Interested persons may obtain the Version 4.0.0 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 4.0.0 Standard at www.isbt128.org.