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 written comments on this guidance at anytime to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. You should identify all comments with Docket No. 1998D-0965.

Additional copies of this guidance are available from the Office of Communication, Training and Manufacturers Assistance (HFM-40), 1401 Rockville Pike, Suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or from the Internet at http://www.fda.gov/cber/guidelines.htm.

For questions on the content of this guidance, contact the Office of Blood Research and Review at 301-827-3543.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research
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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, recognize as acceptable, except where inconsistent with the regulations,[1] the standard for blood and blood component container labels, "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 2.0.0 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 1.2.0, dated November 1999 (the Version 1.2.0 Standard).

The Version 2.0.0 Standard contains only minor revisions of the Version 1.2.0 Standard. These revisions include adding more label illustrations, adding to the database more blood component products, and adding examples of how division information is to be included in eye-readable format. Division information is additional information on how divided units of blood and blood components are coded for the International Society of Blood Transfusion (ISBT). In addition, some of the minor revisions in the Version 2.0.0 Standard include changing pooled platelets to pooled products to allow for labeling of other pooled products, standardizing the terminology in the document, revising label and testing wording to comply with FDA requirements, and clarifying the usage of data structures.

[1] In June 2000, we recognized the Version 1.2.0 Standard as acceptable for use except where inconsistent with the regulations. We identified two inconsistencies between the Version 1.2.0 Standard and the container label regulations in 21 CFR 606.121 regarding: (1) the name of the applicable anticoagulant immediately preceding the proper name (21 CFR 606.121(e)(1)(ii)); and (2) printing specific information in solid red (21 CFR 606.121(d)(2)). After we issued the June 2000 guidance, we revised the regulations in 21 CFR 606.121(d)(2) by providing a choice of printing specific information in solid red or solid black. This change in the regulation removed the inconsistency between 21 CFR 606.121(d)(2) and the Version 1.2.0 Standard. However, the inconsistency with 21 CFR 606.121(e)(1)(ii) remains as of the date of issuance of this guidance.

The Version 2.0.0 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 label requirements under Title 21 Code of Federal Regulations 606.121 (21 CFR 606.121).

This guidance supersedes the guidance entitled "Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components" dated June 2000.

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 November 15, 2005, the International Council for Commonality in Blood Banking Automation (ICCBBA) prepared and submitted to FDA for review the Version 2.0.0 Standard. The ICCBBA requested that the Version 2.0.0 Standard replace the Version 1.2.0 Standard currently in use for container labels for blood and blood components intended for transfusion or for further manufacturing use.

III. FDA REVIEW AND CONCLUSIONS

Under 21 CFR 606.121(c)(13), the container label for blood and blood components intended for transfusion must bear encoded information in a format that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research (CBER). The Director, CBER, has reviewed the information regarding the Version 2.0.0 Standard and finds it acceptable for use on the container labels of blood and blood components intended for transfusion or for further manufacturing use, except where inconsistent with 21 CFR 606.121(e)(1)(ii). We believe that conformance to the Version 2.0.0 Standard will help facilitate the use of a uniform container label for blood and blood components intended for transfusion in the United States and internationally.

Until the current inconsistency between 21 CFR 606.121(e)(1)(ii) and the Version 2.0.0 Standard is corrected, a manufacturer that intends to follow the Version 2.0.0 Standard instead of 21 CFR 606.121(e)(1)(ii) must seek approval of an exception or alternative for a container label under 21 CFR 640.120. If the alternative is approved, a manufacturer may use the Version 2.0.0 Standard to produce labels. Manufacturers previously approved for an exception to or an alternative for a container label under 21 CFR 640.120 for the Version 1.2.0 Standard would not need to reapply to use the Version 2.0.0 Standard.

IV. REPORTING REQUIREMENTS FOR LICENSED ESTABLISHMENTS

Licensed establishments who implement the Version 2.0.0 Standard must submit labels for licensed products consistent with reporting requirements in 21 CFR 601.12(f)(1).

V. SUMMARY

Except where inconsistent with the regulations, FDA recognizes as acceptable 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, for container labels of blood and blood components intended for transfusion or for further manufacturing use. Any modifications to the Version 2.0.0 Standard are not recognized by FDA as acceptable for use until reviewed and found acceptable by the Director, CBER, and then issued as guidance. However, minor modifications to the Version 2.0 0 Standard document (e.g., 2.0.1, 2.0.2, 2.2, or 2.3, etc.) made to correct spelling or format errors in the document itself would be acceptable, and would not require review and acceptance by the Director, CBER.

VI. SUPPLEMENTARY INFORMATION

You may also access copies of the Version 2.0.0 Standard from:

The International Council for Commonality in Blood Banking Automation, Inc.
1615 Orange Tree Lane, Suite 200
Redlands, CA 92374
USA
www.iccbba.org