Guidance for Industry

Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
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GUIDANCE FOR INDUSTRY[1]

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I. INTRODUCTION

The Food and Drug Administration (FDA) is recognizing as acceptable, except where inconsistent with the regulations, the labeling standard "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 1.2.0 Standard describes a system of uniform labeling for blood, blood components for transfusion, Source Plasma, and other components for further manufacturing use. The FDA, Center for Biologics Evaluation and Research (CBER), believes that this uniform labeling standard will assist manufacturers in complying with labeling requirements under 21 CFR 606.121.

II. BACKGROUND

The International Council for Commonality in Blood Banking Automation (ICCBBA) prepared and submitted to FDA a draft document entitled "United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using *ISBT 128,"* draft version 1.2.0 (draft Standard). ICCBBA requested that the draft Standard replace the 1985 "Guideline for the Uniform Labeling of Blood and Blood Components" that utilizes the machine Codabar" currently in use for labeling blood and blood components. On November 21, 1998, FDA made a copy of the draft Standard of Version 1.2.0 available on its web site for public comment and in the Federal Register of November 28, 1998 (63 FR 65600), published a notice of availability of the draft Standard. FDA received 16 comments, 11 of which strongly supported the implementation of the draft Standard. Three of the comments expressed a few concerns, including the cost of implementing this program. One comment asked for some clarification.

[1] This guidance document represents the agency's current thinking on the use of a labeling standard for all licensed human blood and blood components intended for transfusion or for further manufacturing use. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. FDA REVIEW AND CONCLUSIONS

Under 21 CFR 606.121(c)(13), the container label for blood and blood components may bear encoded information in a form of machine-readable symbols approved for use by the Director, CBER. The Director, CBER, has reviewed the information regarding the Version 1.2.0 Standard and finds it acceptable for use in the labeling of blood and blood components, except where inconsistent with the regulations. FDA believes that conformance to the Version 1.2.0 Standard will help facilitate the use of a uniform container label for blood and blood components in the United States and internationally. Although FDA finds the system acceptable, FDA has identified two inconsistencies between the Version 1.2.0 Standard and the Federal regulations at 21 CFR 606.121 regarding: (1) the name of the anticoagulant 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). Therefore, if a manufacturer intends to follow the Version 1.2.0 Standard in lieu of sections 21 CFR 606.121(e)(1)(ii) and 21 CFR 606.121(d)(2), a manufacturer should seek an approval for exceptions or alternatives under 21 CFR 640.120. If the application for alternatives is approved, a manufacturer may use the Version 1.2.0 Standard to produce labels that meet FDA's labeling requirements. Some blood establishments already have obtained exceptions that allow for printing certain phrases, such as "Volunteer Donor," in black instead of solid red as prescribed in 21 CFR 606.l21(d)(2). In the future, such applications for alternatives may not be necessary. FDA published a Direct Final Rule, "Revisions to the Requirements Applicable to Blood, Blood Components, and Source Plasma," in the Federal Register of a August 19, 1999 (64 FR 45366). If the rule is finalized, a prior approval of an exception to the regulation will no longer be required for the printing of these specific phrases in solid black.

FDA is recognizing as acceptable, except where inconsistent with the regulations, the Version 1.2.0 Standard. Any modifications to the Version 1.2.0 Standard do not constitute FDA guidance until reviewed and found acceptable by the Director, CBER, and then issued as guidance.

IV. REPORTING REQUIREMENTS FOR LICENSED ESTABLISHMENTS

Licensed establishments who implement the Version 1.2.0 Standard must submit labels for licensed products consistent with reporting requirements in 21 CFR 601.12(f)(1).

V. SUMMARY

The FDA is recognizing as acceptable, except where inconsistent with the regulations, 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, for use in labeling blood and blood components in the United States.

VI. SUPPLEMENTARY INFORMATION

Address of Standards Organization from which the Version 1.2.0 Standard can be obtained:

The International Council for Commonality in Blood Banking Automation, Inc.
2083 Springwood Road, Suite 179
York, PA 17403
USA
Persons with access to the Internet may obtain the document using the World Wide Web (WWW) at "http://www.iccbba.com".

The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. Persons with access to the Internet may obtain the document using the World Wide Web (WWW) at "http://www.fda.gov/cber/guidelines.htm".