I. Background

FDA is announcing the availability of a document entitled ''Labeling of Red Blood Cell Units with Historical Antigen Typing Results; Guidance for Industry.'' The guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling RBC units with historical antigen typing results. The guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. This guidance also provides licensed blood establishments that choose to implement labeling of RBC units with historical antigen typing results instructions regarding how to report the manufacturing and labeling changes under 21 CFR 601.12. The guidance does not apply to test results for ABO and Rh(D) antigens. For ABO and Rh(D) antigens, establishments must follow FDA requirements in 21 CFR 640.5(b) and (c), and 606.121(c)(9) and (13), as well as all other applicable requirements.

FDA's Blood Products Advisory Committee discussed this topic on December 4, 2012, and supported the concept of using historical RBC antigen typing results to label RBC units. AABB has revised its standards to include accommodations for labeling RBC units with historical RBC typing results. According to the 30th edition of the AABB Standards for Blood Banks and Transfusion Services, RBC units may be labeled as RBC antigen negative without testing the current donation if two previous separate donations were tested by the collection facility and results of RBC typing were found to be concordant. The standards indicate that facilities have the option to put the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label.

In the **Federal Register** of January 3, 2017 (82 FR 130), FDA announced the availability of the draft guidance of the same title dated January 2017. FDA received several comments on the draft guidance and those comments were considered as the guidance was finalized. In addition, editorial changes were made to improve clarity. The guidance announced in this notice finalizes the draft guidance dated January 2017.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on labeling of red blood cell units with historical antigen typing results. 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. This guidance is not subject to Executive Order 12866.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The guidance refers to the collections of information for putting the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label. These collections of information have been approved under OMB control number 0910–0862. The guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 601 and Form FDA 356h have been approved under OMB control number 0910–0338; and the collections of information in 21 CFR part 606 have been approved under OMB control number 0910-*0*116.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *https://www.regulations.gov.*

Dated: December 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–27654 Filed 12–20–18; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–4455]

Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data; Draft Guidance for Industry and Other Stakeholders; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data.'' This draft guidance is being developed under the 21st Century Cures Act (Cures Act), which directs FDA to issue guidance on how a person seeking to develop and submit a proposed draft guidance relating to patient experience data for consideration by FDA may submit such proposed draft guidance to the Agency.

DATES: Submit either electronic or written comments on the draft guidance by March 21, 2019 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–D–4455 for ''Developing and Submitting Proposed Draft Guidance

Relating to Patient Experience Data.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)). Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1144, Silver Spring, MD 20993–0002, 301–796–0684, Fax: 301–847–8443, *pujita.vaidya@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and other stakeholders entitled ''Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data.'' This draft guidance in being developed under section 3002(c)(5) of the Cures Act, which directs FDA to issue guidance on how a person seeking to develop and submit a proposed draft guidance relating to patient experience data for consideration by FDA may submit such proposed draft guidance to the Agency (see the Cures Act, *https://www.congress.gov/114/plaws/publ255/PLAW-114publ255.pdf*

Patient experience data should be collected and analyzed in a methodologically sound and fit-for-purpose manner. There are several options for contributing patient experience data to the medical product development and regulatory decision-making process. One option is for stakeholders to submit proposed recommendations and considerations informed by patient experience data in the form of a proposed draft guidance. Proposed draft guidance relating to patient experience data that is developed and submitted by external stakeholders can be helpful in bringing the patient's perspective into medical product development and regulatory decision-making.

As stated previously, submitting proposed draft guidance for FDA's consideration is not the only option for contributing patient experience data. Patients, caregivers, patient and disease advocacy groups, and other stakeholders with knowledge of or access to the patient community, may be well-positioned to also make broader contributions to advance medical product development. Recognizing that stakeholders may be interested in pursuing other pathways to contribute patient experience data, this draft guidance addresses questions relating to both guidance development and other potential pathways for contributing patient experience data.

In FDA's ''Plan for Issuance of Patient-Focused Drug Development Guidance'' (Plan), available at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM563618.pdf,* the Agency proposed issuing a draft guidance addressing this topic described in section 3002 of the Cures Act during the second quarter of 2018. FDA recognized that, like the other patient-focused drug development guidances described in the Plan, developing this draft guidance would also benefit from public input from the wider community of patients, patient advocates, academic researchers, expert practitioners, drug developers, and other stakeholders before FDA's drafting of the guidance. On March 19, 2018, FDA conducted a public workshop to discuss this topic. After the public workshop, FDA considered stakeholder input from the workshop and the public docket and is now publishing this draft guidance.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data.'' 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. This guidance is not subject to Executive Order 12866.

II. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *https://www.regulations.gov.*

Dated: December 18, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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