4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-4308]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen Typing Results

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, or Agency) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, Fax: 202-395-7285, or emailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title "Draft Guidance for Industry: Labeling of Red Blood Cell Units with Historical Antigen Typing Results." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Labeling of Red Blood Cell Units with Historical Antigen Typing Results

OMB Control Number 0910-NEW

The draft guidance document provides establishments that collect blood and blood components for transfusion with recommendations for labeling RBC units with non-ABO/Rh(D) antigen typing results obtained from previous donations (historical antigen typing results). The draft guidance provides recommendations to transfusion services for managing RBC units labeled with historical antigen typing results. The guidance also provides licensed blood collection 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.

Description of Respondents: Establishments that collect blood and blood components intended for transfusion.

Burden Estimate: We believe that the information collection provisions in the draft guidance do not create a new burden for respondents and are part of usual and customary business practices. 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.

The guidance also recommends establishments that collect blood and blood components for transfusion should convey to transfusion services the practices for repeating historical RBC typing results on current donations and for labeling RBC units with historical RBC antigen typing results.

We believe that collection establishments have already developed standard operating procedures for including the non-ABO/Rh(D) historical antigen typing results on a tie-tag or directly on the container label, and for conveying any change in their antigen typing or labeling practices to their consignees, including practices for repeating historical RBC typing results on current donations and for labeling RBC units with historical RBC antigen typing results.

In the *Federal Register* of January 3, 2017 (82 FR 130), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received six comments on the guidance; however, no comments were related to the collection of information.

The draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 601.12 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 0910-116.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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