initially submitted on December 20, 2016.

3. *The date the application was approved:* August 17, 2017. FDA has verified the applicant's claim that BLA 761040 was approved on August 17, 2017.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 654 days, 703 days, or 1,099 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: October 16, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–22958 Filed 10–19–18; 8:45 am]

BILLING CODE 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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry: Labeling of Red Blood Cell Units With Historical Antigen Typing Results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 November 21, 2018.

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.

[FR Doc. 2018–22959 Filed 10–19–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Committee on Vital and Health Statistics: Hearing

Pursuant to the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) announces the following advisory committee hearing.

Name: National Committee on Vital and Health Statistics (NCVHS), Subcommittee on Standards.

Date and Times: Wednesday, December 12, 2018: 9 a.m.–5 p.m. (EST); Thursday, December 13, 2018: 9 a.m.–1 p.m. (EST).

Place: Omni Shoreham Hotel, 2500 Calvert Street NW, Washington, DC 20008.

Status: Open. There will be a public comment period during the final 15 minutes of both days of the meeting.

Purpose: Health Insurance Portability and Accountability Act (HIPAA) legislation from 1996, as amended,[1] directed the Secretary of Health and Human Services (HHS) to publish regulations adopting standards, code sets and identifiers to support the exchange of electronic health information between covered entities. The standards are for retail pharmacy and medical transactions.

In its capacity to advise the HHS Secretary on health data, statistics, privacy, national health information policy, and HIPAA, NCVHS is in the final stages of the development of a standards update and adoption roadmap, referred to as the Predictability Roadmap. The development of the Predictability Roadmap has been a year and a half long process, achieved in collaboration with industry stakeholders and the standards development organizations (SDOs). The overall vision for the Predictability Roadmap is that:

- HIPAA covered entities and their business associates use the adopted standards and operating rules in a consistent way to exchange health information and conduct business; and
- Standards are reliably updated and adopted so that covered entities know when they will need to, and/or be able to update systems and business processes.

To accomplish this goal, NCVHS conducted several information gathering activities and stakeholder engagement meetings and workshops: In June 2017 the Subcommittee on Standards met with each of the standards development organizations (SDOs) to learn about their individual maintenance processes; in August 2017 the Subcommittee held a visioning exercise with the SDOs and Designated Standards Maintenance Organization (DSMO); and in May 2018, the Subcommittee conducted a CIO Forum with 21 health care technology experts and senior corporate officers representing a cross-section of organizations that were end-users of the HIPAA and ACA administrative standards. The goal of this Forum was to elicit input for improving the standards development, update and adoption process, and address barriers to use of those standards. Based on this work, the Subcommittee on Standards developed a draft Predictability Roadmap comprised of 23 recommendations organized under three major focus areas. The draft recommendations were presented at the September 13–14 NCVHS meeting and are posted on the website at: *https://ncvhs.hhs.gov/wp-content/uploads/2018/09/Presentation-NCVHS-Draft-Predictability-Roadmap-Recs-Coussoule-and-Goss.pdf.*

The purpose of this Subcommittee hearing is to obtain input from stakeholders on the draft recommendations designed to improve the processes for updating, adopting and using standards and operating rules, and developing a formal Predictability Roadmap. The Subcommittee will use the feedback received at this hearing to finalize recommendations to the Secretary of HHS.

Individuals and representatives of organizations interested in submitting written testimony are invited to respond to the following questions:

In general,

1. Would these recommendations as a whole improve the predictability of the adoption of administrative standards and operating rules?

2. What additional recommendations are critical to achieve predictability?

And specifically,

3. What is the value proposition of each recommendation and what improvements to the current state do you believe will arise from each recommendation/group of similar recommendations?

4. Are there potential unintended consequences? What are those and how can they be mitigated with modifications to the recommendations?

The questions outlined above can be used to guide written submissions to the Subcommittee. Written submissions should be sent electronically to *NCVHSmail@cdc.gov* with ''Predictability Roadmap'' in the subject line no later than November 20, 2018.

The times and topics for this meeting are subject to change. Please refer to the posted agenda at *www.ncvhs.hhs.gov* for any updates.

Contact Persons for More Information: Substantive program information may be obtained from Rebecca Hines, MHS, Executive Secretary, NCVHS, National Center for Health Statistics, Centers for Disease Control and Prevention, 3311 Toledo Road, Hyattsville, Maryland 20782, telephone (301) 458–4715. Information pertaining to meeting content may be obtained from Lorraine Doo, MSW, MPH, (410) 786–6597; and/or Geanelle G. Herring, MSW, (410) 786–4466; Centers for Medicare & Medicaid Services, Office of Information Technology, Division of National Standards, 7500 Security Boulevard, Baltimore, Maryland, 21244. Summaries of meetings and a roster of Committee members are available on the NCVHS website: *www.ncvhs.hhs.gov* where further information including an agenda and instructions to access the live audio broadcast of the meeting will be posted.

Should you require reasonable accommodation, please contact the CDC Office of Equal Employment Opportunity on (770) 488–3210 as soon as possible.

Sharon Arnold,

Associate Deputy Assistant Secretary for Planning and Evaluation, Science and Data Policy, Office of the Assistant Secretary for Planning and Evaluation.

[FR Doc. 2018–22952 Filed 10–19–18; 8:45 am]

BILLING CODE 4151–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

[1] Along with Section 1104(c) of the Patient Protection and Affordable Care Act (ACA) of 2010.