DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2836]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Donor Risk Assessment Questionnaire for the Food and Drug Administration/National Heart, Lung, and Blood Institute-Sponsored Transfusion-Transmissible Infections Monitoring System—Risk Factor Elicitation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Submit written comments (including recommendations) on the collection of information by August 12, 2020.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0841. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Donor Risk Assessment Questionnaire for FDA/National Heart, Lung, and Blood Institute (NHLBI)-Sponsored Transfusion-Transmissible Infections Monitoring System (TTIMS)—Risk Factor Elicitation (RFE)

OMB Control Number 0910–0841—Revision

FDA intends to interview blood donors to collect risk factor information associated with testing positive for a TTI. This collection of information is part of a larger initiative called TTIMS, which is a collaborative project funded by FDA, the NHLBI of the National Institutes of Health (NIH), and the Department of Health and Human Services (HHS) Office of the Assistant Secretary of Health with input from other Agencies in HHS, including the Centers for Disease Control and Prevention (CDC). FDA will use these scientific data collected through such interview-based risk factor elicitation of blood donors to monitor and help ensure the safety of the U.S. blood supply.

Previous assessments of risk factor profiles among blood donors found to be positive for human immunodeficiency virus (HIV) were funded by CDC for approximately 10 years after implementation of HIV serologic screening of blood donors in the mid-1980s, whereas studies of Hepatitis C virus (HCV) seropositive donors, funded by NIH, were conducted in the early 1990s. Information on current risk factors in blood donors as assessed using analytical study designs was next evaluated by the Transfusion-Transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors Study conducted by the NHLBI Retrovirus Epidemiology Donor Study-II (REDS–II) approved under OMB control number 0925–0630. Through a risk factor questionnaire, this study elicited risk factors in blood donors who tested confirmed positive for one of four transfusion-transmissible infections: HIV, HCV, Hepatitis B virus (HBV), and Human T-cell Lymphotropic virus. The study also elicited risk factors from donors who did not have any infections (controls) and compared their responses to those of the donors with confirmed infection (cases). Results from the REDS–II study were published in 2015.

FDA recently revised the currently approved collection instrument for the collection of information and have included recently issued Agency guidance. On April 2, 2020, FDA issued a revised guidance document entitled ''Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products; Guidance for Industry'' dated April 2020 (available at: *https://www.fda.gov/media/92490/download*), which changed the blood donor criterion for men who have sex with men (MSM) from a 12-month deferral to a 3-month deferral since last MSM contact. The impact of this change in the deferral criteria requires a national monitoring effort as part of TTIMS to assess if the relative proportions of risk factors for infection in blood donors have changed following the adoption of the 3-month donor deferral for MSM. We also made a change to the Risk Factor Assessment interview questionnaire to keep the TTIMS interview relevant with the current deferral. TTIMS will use similar procedures as the ones used in the REDS–II study to monitor and evaluate risk factors among HIV-positive donors and recently HCV or HBV infected donors as well as controls.

This study will help identify the specific risk factors for TTI and their prevalence in blood donors and help inform FDA on the proportion of incident (new) infections among all HIV positive blood donors. Donations with incident infections have the greatest potential transmission risk because they could be missed during routine blood screening. The study will help FDA evaluate the effectiveness of screening strategies in reducing the risk of HIV transmission from at-risk donors and to evaluate if there are unexpected consequences associated with the recent change in donor deferral policy such as an increase in HIV incidence among donors. These data also will inform FDA regarding future blood donor deferral policy options to reduce the risk of HIV transmission, including the feasibility of moving from the existing time-based deferrals related to risk behaviors to alternate deferral options, such as the use of individual risk assessments, and to inform the design of potential studies to evaluate the feasibility and effectiveness of such alternative deferral options.

TTIMS will include a comprehensive interview-based epidemiological study of risk factor information for viral infection-positive blood donors at the American Red Cross (ARC), Blood Systems, Inc. (BSI), New York Blood Center (NYBC), and OneBlood that will identify the current predominant risk factors and reasons for virus-positive donations. The TTIMS program establishes a new, ongoing donor hemovigilance capacity that currently does not exist in the United States. Using procedures developed by the REDS–II study, TTIMS will establish this capacity in greater than 50 percent

of all blood donations collected in the country.

As part of the TTIMS project, a comprehensive hemovigilance database will be created that integrates the risk factor information collected through interviews of blood donors with the resulting data from disease marker testing and blood components collected by participating organizations into a research database. Following successful initiation of the risk factor interviews, the TTIMS network is poised to be expanded to include additional blood centers and/or refocused on other safety threats as warranted. In this way, the TTIMS program will maintain standardized, statistically, and scientifically robust processes for applying hemovigilance information across blood collection organizations.

The specific objectives are to:

- Determine current behavioral risk factors associated with all HIV infections, incident HBV, and incident HCV infections in blood donors (including parenteral and sexual risks) across the participating blood collection organizations using a case-control study design.
- Determine infectious disease marker prevalence and incidence for HIV, HBV, and HCV overall and by demographic characteristics of donors in the majority of blood donations collected in the country. This will be accomplished by forming epidemiological databases consisting of harmonized operational data from ARC, BSI, NYBC, and OneBlood.
- Analyze integrated risk factor and infectious marker testing data concurrently because when taken together these may suggest that blood centers are not achieving the same degree of success in educational efforts to prevent donation by donors with risk behaviors across all demographic groups.

The respondents will be persons who donated blood in the United States and these participants will be defined as cases and controls. The estimated number of respondents is based on an overall expected participation in the risk factor survey. We estimate a case-to-control ratio of 1:2 (200 to 400) with a 50 percent case enrollment.

In the **Federal Register** of January 8, 2020 (85 FR 922), we published a 60-day notice requesting public comment on the proposed collection of information. We received two comments that were generally supportive of the collection. One comment also contained a specific suggestion that, in analyzing the data after it is collected, we utilize an ''underreporting correction factor'' identified by the commenter. The comment did not suggest that we make any changes to the Donor Risk Assessment Questionnaire or the information collection requirements. We appreciate the commenter's interest in the accuracy of the TTIMS and will consider the ''underreporting correction factor'' identified by the commenter when analyzing the data.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Questionnaire/survey	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Cases and controls [2]	600	1	600	0.5 (30 minutes)	300

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Cases consist of virus-positive donations and controls represent uninfected donors.

We have adjusted our burden estimate, which has resulted in a decrease to the currently approved burden. Based on experience with this survey, we decreased the average burden per response from 45 to 30 minutes, resulting in a change from 450 to 300 total hours.

Dated: July 7, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–15009 Filed 7–10–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–1253 (formerly FDA–1987–N–0054)]

Pentaerythritol Tetranitrate; Final Decision on Proposal To Withdraw Approval From New Drug Applications and Abbreviated New Drug Applications; Availability of Final Decision

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the initial decision of the Administrative Law Judge (ALJ), to withdraw approval of new drug applications (NDAs) and abbreviated new drug applications (ANDAs) for pentaerythritol tetranitrate (PETN), is the final decision of the Commissioner of Food and Drugs (the Commissioner) by operation of law. In the initial decision, the ALJ found that PETN had not been shown to be supported by substantial evidence consisting of adequate and well-controlled studies to be effective for prophylactic treatment of angina pectoris and ordered the withdrawal of approval for all NDAs and ANDAs. Several parties to the hearing filed exceptions to the ALJ's initial decision; however, all parties who submitted exceptions have since voluntarily withdrawn them, or FDA has deemed them withdrawn after their associated NDA or ANDA was withdrawn. Consequently, the proceeding is in the same procedural position as if no exceptions to the ALJ's initial decision had been filed. Therefore, the ALJ's initial decision has become the final decision of the Commissioner by operation of law.

Applicable Date: This notice is applicable July 13, 2020.

ADDRESSES: For access to the docket, 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 between 9 a.m. and 4 p.m., Monday