TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Submissions: Through ABI/ACS						
1.280 through 1.281	N/A	1,700	7,647	12,999,900	0.167 (10 minutes)	[2] 2,170,983
Through PNSI						
1.280 through 1.281	3540 [3]	27,000	70	1,890,000	0.384 (23 minutes)	725,760
Subtotal						2,896,743
Cancellations: Through ABI/ACS						
1.282	3540	7,040	1	7,040	0.25 (15 minutes)	1,760
Through PNSI						
1.282 and 1.283(a)(5)	3540	35,208	1	35,208	0.25 (15 minutes)	8,802
Subtotal						10,562
Requests for Review and Post-hold Submissions						
1.283(d) and 1.285(j)	N/A	1	1	1	8	8
1.285(i)	N/A	263	1	263	1	263
Subtotal						271
Total				14,932,412		2,907,576

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] To avoid double-counting, an estimated 396,416 burden hours already accounted for in the Importer's Entry Notice information collection approved under OMB control number 0910–0046 are not included in this total.
[3] The term ''Form FDA 3540'' refers to the electronic submission system known as PNSI, which is available at *https://www.access.fda.gov.*

Based on our experience and the average number of prior notice submissions, cancellations, and requests for review received in the past 3 years, we have made no adjustments in our burden estimate for the information collection. We estimate that 1,700 users of ABI/ACS will submit an average of 7,647 prior notices annually, for a total of 12,999,900 prior notices received through ABI/ACS. We assume the reporting burden for a prior notice submitted through ABI/ACS to be 10 minutes, or 0.167 hour, per notice, for a total annual burden of 2,170,983 hours. This estimate takes into consideration the burden hours already counted in the information collection approval for FDA importer's entry notice (OMB control number 0910–0046), as previously discussed.

We estimate that 27,000 registered users of PNSI will submit an average of 70 prior notices annually, for a total of 1,890,000 prior notices received annually. We assume the reporting burden for a prior notice submitted through PNSI to be 23 minutes, or 0.384 hour, per notice, for a total burden of 725,760 hours.

We estimate that 7,040 users of ABI/ACS will submit an average of 1 cancellation annually, for a total of 7,040 cancellations received annually through ABI/ACS. We assume the reporting burden for a cancellation submitted through ABI/ACS to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 1,760 hours.

We estimate that 35,208 registered users of PNSI will submit an average of 1 cancellation annually, for a total of 35,208 cancellations received annually. We assume the reporting burden for a cancellation submitted through PNSI to be 15 minutes, or 0.25 hour, per cancellation, for a total burden of 8,802 hours.

We estimate that one or fewer requests for review under § 1.283(d) or § 1.285(j) will be submitted annually. We assume that it will take respondents 8 hours to prepare the factual and legal information necessary to prepare a request for review. Thus, we estimate a total reporting burden of 8 hours.

We estimate that 263 post-hold submissions under § 1.285(i) will be submitted annually. We assume that it will take about 1 hour to prepare the written notification described in § 1.285(i)(2)(i), for a total reporting burden of 263 hours.

Dated: January 29, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02371 Filed 2–5–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–D–3324]

Use of Serological Tests To Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II; Guidance for Industry; 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 final guidance entitled ''Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV–I/II).'' The guidance document provides blood collection establishments with recommendations regarding the use of

serological tests to reduce the risk of HTLV–I/II transmission by blood and blood components. The guidance announced in this notice finalizes the draft guidance entitled ''Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV–I/II)'' dated September 2018. The guidance also consolidates FDA's other previously issued recommendations on HTLV–I/II into one document. Therefore, the guidance also supersedes the recommendations specific to HTLV–1 contained in the memorandum to blood establishments entitled ''Recommendations for the Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human T-Lymphotropic Virus Type I (HTLV–I)'' dated July 1996. In addition, the guidance supersedes the memorandum to blood establishments entitled ''HTLV–I Antibody Testing, Memorandum'' dated November 1988; the memorandum to blood establishments entitled ''HTLV–I Antibody Testing, Memorandum'' dated July 1989; and the document entitled ''Guidance for Industry: Donor Screening for Antibodies to HTLV–II'' dated August 1997.

DATES: The announcement of the guidance is published in the **Federal Register** on February 6, 2020.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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–3324 for ''Use of Serological Tests to Reduce the Risk of Transfusion Transmitted Human T-Lymphotropic Virus Types I and II (HTLV–I/II).'' 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.govinfo.gov/content/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 guidance to 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 the office in processing your requests. The 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: Melissa Segal, 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 document entitled ''Use of Serological Tests to Reduce the Risk of Transfusion-Transmitted Human T-Lymphotropic Virus Types I and II (HTLV–I/II).'' The guidance document provides blood collection establishments with recommendations regarding the use of serological tests to reduce the risk of HTLV–I/II transmission by blood and blood components.

In the **Federal Register** of September 25, 2018 (83 FR 48448), FDA announced the availability of the draft guidance entitled ''Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV–I/II)'' dated September 2018. FDA received a few comments on the draft guidance and those comments

were considered as the guidance was finalized.

The guidance announced in this notice finalizes the draft guidance entitled ''Recommendations for Requalification of Blood Donors Deferred Because of Reactive Test Results for Antibodies to Human T-Lymphotropic Virus Types I and II (anti-HTLV–I/II)'' dated September 2018. The guidance also consolidates FDA's other previously issued recommendations on HTLV–I/II into one document. Therefore, the guidance also supersedes the recommendations specific to HTLV–1 contained in the memorandum to blood establishments, entitled ''Recommendations for the Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), and Human T-Lymphotropic Virus Type I (HTLV–I)'' dated July 1996. In addition, the guidance supersedes the memorandum to blood establishments entitled ''HTLV–I Antibody Testing, Memorandum'' dated November 1988; the memorandum to blood establishments entitled ''HTLV–I Antibody Testing, Memorandum'' dated July 1989; and the document entitled ''Guidance for Industry: Donor Screening for Antibodies to HTLV–II'' dated August 1997.

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 the use of serological tests to reduce the risk of transfusion-transmitted human T-lymphotropic virus types I and II. 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.

II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3521). 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 parts 610 and 606 have been approved under OMB control number 0910–0116.

III. Electronic Access

Persons with access to the internet may obtain the guidance at either *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances* or *https://www.regulations.gov.*

Dated: February 3, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–02373 Filed 2–5–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Ending the HIV Epidemic (EHE), OMB No. 0906–xxxx—New

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than March 9, 2020.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

A 60-day notice was published in the **Federal Register** on October 15, 2019, vol. 84, No. 199; pp. 55163–64. There was one public comment.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Ending the HIV Epidemic (EHE) Triannual Module, OMB No. 0906–xxxx—New.

Abstract: HRSA's Ryan White HIV/AIDS Program (RWHAP) funds and coordinates with cities, states, and local clinics/community-based organizations to deliver efficient and effective HIV care, treatment, and support to low income people with HIV. Nearly two-thirds of clients (patients) live at or below 100 percent of the federal poverty level and approximately three-quarters of RWHAP clients are racial/ethnic minorities. Since 1990, the RWHAP has developed a comprehensive system of safety net providers who deliver high quality direct health care and support services to over half a million people with HIV—more than 50 percent of all people with diagnosed HIV in the United States.

Ending the HIV Epidemic: A Plan for America

In February 2019, the Administration announced a new initiative, *Ending the HIV Epidemic: A Plan for America* (EHE). Authorized by section 311(c) and title XXVI of the Public Health Service Act, this 10-year initiative beginning in FY 2020 seeks to achieve the important goal of reducing new HIV infections in the United States to fewer than 3,000 per year by 2030. EHE will focus on 48 counties, Washington, DC, San Juan, Puerto Rico, and 7 states that have a substantial rural HIV burden. By focusing on these jurisdictions in the first phase of the EHE, HHS plans to reduce new HIV infections by 75 percent within 5 years. Across the United States, the EHE will promote and implement four Pillars to substantially reduce HIV transmissions—diagnose, treat, prevent, and respond. EHE is a collaborative effort among key HHS agencies, primarily HRSA, the Centers for Disease Control and Prevention, the National Institutes of Health, the Indian Health Service, and the Substance Abuse and Mental Health Services Administration. RWHAP will focus on implementing activities in the *Pillar Two: Treat* and supporting *Pillar Four: Respond* for this important initiative.

HRSA identified proposed data collection needs to support HRSA's efforts toward ending the HIV epidemic. To reach this goal, HRSA needs to have the ability to monitor initiative activities including funding allocations, expenditures, service utilization, and clients served; and assess progress toward meeting national goals for ending the HIV epidemic. HRSA proposes that recipients and service providers (subrecipients) who receive EHE initiative funding report on the