TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
516.161; content and format of a request for modification of an indexed drug	3	1	3	4	12
516.163; information to be contained in a request to FDA to transfer ownership of a drug's index file to another person	1	1	1	2	2
516.165; requires drug experience reports and distributor statements to be submitted to FDA	10	10	100	5	500
Total					5,223

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
516.141, requires the qualified expert panel leader to maintain a copy of the written report and all notes or minutes relating to panel deliberations that are submitted to the requestor for 2 years after the report is submitted.	30	2	60	0.5 (30 minutes)	30
516.165, requires the holder of an indexed drug to maintain records of all information pertinent to the safety or effectiveness of the indexed drug, from foreign and domestic sources.	10	2	20	1	20
Total					50

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We based our estimates in tables 1 and 2 on our experience with the MUMS indexing program and the requests for eligibility for indexing and for addition to the index, as well as the periodic drug experience reports submitted during the past 3 years.

Our estimated burden for the information collection reflects an overall increase of 351 reporting hours and a corresponding increase of 85 responses. We attribute this adjustment, generally, to an increase in the number of submissions we received over the last few years. We also reduced our burden hour estimate for drug experience reports and distributor statements under § 516.165 from 8 hours per submission to 5 hours per submission based on our experience with this type of reporting.

Dated: January 2, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00042 Filed 1–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–5971]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recommendations To Reduce the Risk of Transfusion-Transmitted of Infection in Whole Blood and Blood Components; Agency Guidance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments concerning establishment notification of a consignee and consignee notification of a recipient's physician of record regarding a possible increased risk of transfusion-transmitted infection.

DATES: Submit either electronic or written comments on the collection of information by March 9, 2020.

ADDRESSES: You may submit comments as follows. Please note that late untimely filed comments will not be considered. Electronic comments must be submitted on or before March 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2019–N–5971 for ''Use of Serological Tests to Reduce the Risk of the Transfusion-Transmitted Infection in Whole Blood and Blood Components; Agency Guidance.'' Received comments, those filed in a timely manner (see **ADDRESSES**) 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.

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: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Recommendations To Reduce the Risk of Transfusion-Transmitted Infection in Whole Blood and Blood Components; Agency Guidance

OMB Control Number 0910–0681—Extension

Under § 630.3(h) (21 CFR 630.3(h)), a list is set forth of relevant transfusion-transmitted infections (RTTIs) (§ 630.3(h)(1)) and the conditions under which a transfusion-transmitted infection (TTI) would meet the definition of an RTTI (§ 630.3(h)(2)). The list of RTTIs under § 630.3(h)(1) includes, among other things, the following: *Trypanosoma cruzi* (Chagas), Creutzfeldt Jacob Disease (CJD)/variant Creutzfeldt Jacob Disease (vCJD), *plasmodium* species (malaria), and West Nile virus. The RTTIs FDA has identified thus far under § 630.3(h)(2) include Zika virus and babesiosis. In addition, FDA has determined Ebola virus to be a TTI identified under § 630.3(*l*). FDA has issued several guidance documents with recommendations regarding the RTTIs or TTIs including Chagas, babesiosis, Zika virus, West Nile virus Ebola virus, malaria, CJD and vCJD, human immunodeficiency virus (HIV) and human T-lymphotropic virus, types I and II (HTLV).

The Chagas, babesiosis, Zika virus and West Nile virus, and HTLV guidance documents provide recommendations for consignee and physician notification relating to donors that tested reactive for these infections.

In addition, a blood establishment may receive information from a donor following collection that reveals the donor had a risk factor for a RTTI or TTI at the time of collection and should have been deferred for the risk factor. FDA has recommended, in the following guidance documents, that such a blood collection establishment notify the consignee regarding the distributed blood components that are potentially at-risk for a RTTI or TTI. In some cases,

we recommend that if the blood was transfused, the consignee notify the transfusion recipient's physician of record regarding the potential risk. This recommendation is included in Ebola virus, malaria, CJD and vCJD, and HIV guidance documents. These guidance documents are available from our website at *https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/blood-guidances.*

Although such notifications are rare, we believe that these notification practices would be part of the usual and customary business practice for blood establishments and consignees in addressing the RTTIs or TTIs under the regulations. In addition, we believe respondents would have already developed standard operating procedures for notifying consignees and the recipient's physician of record regarding distributed blood components potentially at risk for a TTI. Therefore, for the purpose of estimating burden under the PRA, we provide an estimate of one response and one burden hour annually.

As other relevant transfusion-transmitted infections are determined under § 630.3, we may continue to issue guidance accordingly, and, if approved, intend the information collections to be included under this OMB control number.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimates. These guidance documents, as applicable, also refer to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR parts 601 and 640, and Form FDA 356h have been approved under OMB control number 0910–0338; the collections of information in 21 CFR parts 606 and 630 have been approved under OMB control number 0910–0116; the collections of information in 21 CFR 606.171 have been approved under OMB control number 0910–0458.

Dated: December 31, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–00034 Filed 1–6–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–0366]

Agency Information Collection Activities; Proposed Collection; Comment Request; Advisory Committee Nomination Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on advisory committee nomination Applications.

DATES: Submit either electronic or written comments on the collection of information by March 9, 2020.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before March 9, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 9, 2020. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

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–2017–N–0366 for ''Advisory Committee Nomination Applications.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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