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.

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, 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 an 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 an 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.*

In the **Federal Register** of January 7, 2020 (85 FR 716), we published a 60-day notice requesting public comment on the proposed collection of information. For purposes of estimating burden under the PRA, we provided an estimate of one response and one burden hour annually. As we discussed in our 60-day notice, 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. No comments were received in response to our 60-day notice, and we therefore retain this estimate. 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 estimate. These guidance documents, as applicable, also refer to previously approved FDA collections of information. 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: March 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06986 Filed 4–2–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–2066]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Certification of Identity for Freedom of Information Act and Privacy Act Requests

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 May 4, 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 0910–0832. 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.

Certification of Identity; Form FDA 3975

OMB Control Number 0910–0832—Extension

This information collection supports Form FDA 3975 entitled ''Certification of Identity,'' which is used by FDA to identify an individual requesting a particular record under the Freedom of Information Act (FOIA) and the Privacy Act. The form is available from our website at: *https://www.fda.gov/*

RegulatoryInformation/FOI/default.htm, although if an individual requests one, we will send it by mail or email. The form is required only if an individual makes an FOIA request or Privacy Act request for records about himself and has not provided sufficient assurances of identity in the incoming FOIA or Privacy Act request.

The FOIA grants the public a right to access Federal records not normally prepared for public distribution. The Privacy Act grants a right of access to members of the public who seek access to one's own records that are maintained in an Agency's system of records (*i.e.,* the records are retrieved by that individual's name or other personal identifier). The statutes overlap, and individuals who request their own records are processed under both statutes. The Agency may need to confirm that the individual making the FOIA or Privacy Act request is indeed the same person named in the Agency records. Respondents to the information collection are asked for certain information including name, citizenship status, social security number, address, date of birth, place of birth, signature, and date of signature.

In the **Federal Register** of November 22, 2019 (84 FR 64539), we published a 60-day notice requesting public comment on the proposed collection of information. One comment was received stating it was important that FDA retain the information collection to help protect against potential identity fraud. The comment also suggested that the associated burden for completing and submitting Form FDA 3975 may be lower than estimated, but did not provide alternative figures for us to consider. We therefore retain our burden estimate, which is as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
3975; Certification of Identity	50	1	50	0.17 (10 minutes)	8.5

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

Based on Agency data, we have received no more than 50 submissions since establishing the collection in 2017.

Dated: March 26, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06996 Filed 4–2–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0731]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice

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 May 4, 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 0910–0543. 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.

Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice

OMB Control Number 0910–0543–Extension

Under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), FDA may issue and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases between the States or possessions or from foreign countries into the States. As derivatives of the human body, all human cells, tissues, and cellular and tissue-based products (HCT/Ps) pose some risk of carrying pathogens that could potentially infect recipients or handlers. FDA has issued regulations related to HCT/Ps involving electronic establishment registration and listing using an electronic system, eligibility determination for donors, and current good tissue practice (CGTP).

I. Electronic Establishment Registration and Listing

The regulations in part 1271 (21 CFR part 1271) require domestic and foreign establishments that recover, process, store, label, package, or distribute an HCT/P regulated solely under section 361 of the PHS Act and described in § 1271.10(a) (21 CFR 1271.10(a)), or that perform screening or testing of the cell or tissue donor, to register electronically with FDA (§§ 1271.1(a) (21 CFR 1271.1(a)) and 1271.10(b)(1)) and submit a list electronically of each HCT/P manufactured (§§ 1271.1(a) and 1271.10(b)(2)). Section 1271.21(a) (21 CFR 1271.21(a)) requires an establishment to follow certain procedures for initial registration and listing of HCT/Ps, and § 1271.25(a) and (b) (21 CFR 1271.25(a) and (b)) identify the required initial registration and HCT/P listing information. Section 1271.21(b), in brief, requires an annual update of the establishment registration.