TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Part 1141 and activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Original Submission (Initial Plan) Records	59	1.5	89	3	267
Total					267

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

FDA estimates that 59 recordkeepers will keep a total of about 89 records at 3 hours per record for a total of 267 hours. As stated previously, these estimates are based on FDA's experience with information collections for other tobacco product plans (*i.e.,* smokeless, OMB control number 0910–0671 and cigars, OMB control number 0910–0768). Based on our estimates for the submission of one-time, initial plans and supplements (*i.e.,* that all respondents will submit one-time, initial plans and about half of respondents will submit supplements to FDA-approved plans), we estimate that each recordkeeper will keep an average of 1.5 records.

FDA concludes that the required warnings for cigarette packages and cigarette advertisements in § 1141.10 are not subject to review by OMB because they do not constitute a ''collection of information'' under the PRA (44 U.S.C. 3501–3521). Rather, these labeling statements are a ''public disclosure'' of information originally supplied by the Federal Government to the recipient for the purpose of ''disclosure to the public'' (5 CFR 1320.3(c)(2)).

Since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: April 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08280 Filed 4–18–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1168]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products

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 (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 the information collection associated with statutory and regulatory requirements that govern certain human cells, tissues, and cellular and tissue-based products (HCT/Ps).

DATES: Either electronic or written comments on the collection of information must be submitted by June 20, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 20, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2023–N–1168 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products.'' 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, 240–402–7500.

- 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.gpoinfo.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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–994–7399, *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.

Human Cells, Tissues, and Cellular and Tissue-Based Products—21 CFR Part 1271

OMB Control Number 0910–0543—Extension

This information collection helps support the implementation of statutory and regulatory requirements that govern certain human cells, tissues, and cellular and tissue-based products (HCT/Ps). Manufacturers of HCT/Ps regulated solely under the authority of section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264) are required to register and list HCT/Ps pursuant to part 1271 (21 CFR part 1271) whether or not the HCT/P enters into interstate commerce. Manufacturers of HCT/Ps regulated as drugs, devices and/or biological products under section 351 of the PHS Act (42 U.S.C. 262) and/or section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321), are required to register and list HCT/Ps following the procedures in part 207 (21 CFR part 207) (if a drug and/or biological product) or part 807 (21 CFR part 807) (if a device). Information collection associated with the registration and listing requirements in parts 207 and 807 are currently approved in OMB control numbers 0910–0045 and 0910–0625, respectively.

Agency regulations in part 1271 set forth general provisions applicable to HCT/Ps in subpart A (§§ 1271.1 through 1271.20). Those HCT/Ps that are regulated solely under the authority of section 361 of the PHS Act are described in § 1271.10. Provisions in part 1271, subpart B (§§ 1271.21 through 1271.37), establish procedures for registration and listing including format and content elements along with scheduled timeframes for the submission of certain information and action by FDA. The regulations also provide for waivers from the electronic format requirement, amendments to establishment registration, and requesting information on registration and listing from FDA.

Registrants use Form FDA 3356, Establishment Registration and Listing for HCT/Ps, to submit HCT/P establishment registration and listing information to the Electronic Human Cell and Tissue Establishment Registration System (eHCTERs). Electronic submission of HCT/P establishment and product listing information is required under § 1271.22. However, a request for waiver of the electronic submission requirement may be submitted pursuant to § 1271.23. If the waiver request is granted, Form FDA 3356 (and accompanying instructions) may be downloaded to complete and submit by mail. The Tissue Establishment Registration page (*https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/tissue-establishment-registration*) provides access to eHCTERs, instructions for using eHCTERs, and other resource information that may be helpful to respondents.

Provisions in part 1271, subpart C (§§ 1271.45 through 1271.90), establish requirements for determining donor eligibility, including donor screening and testing, explaining these requirements are a component of current good tissue practice (CGTP) requirements set forth in part 1271, subpart D (§§ 1271.145 through 1271.320). The provisions in part 1271, subparts C and D, govern the methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution.

The regulations in part 1271, subpart E and subpart F (§§ 1271.330 through 1271.440), establish additional requirements for establishments described in § 1271.10, including inspection and enforcement provisions, and recordkeeping requirements providing for the retention, notification to third parties, and disclosure of such records to FDA.

Description of Respondents: Respondents to this information collection are establishments that recover, process, store, label, package, or distribute any HCT/P that is regulated solely under section 361 of the PHS Act and regulations in part 1271 or perform donor screening or testing.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section; reporting activities	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [2]
1271.10(b)(1) and 1271.21(b); register and submit list of each HCT/P manufactured by existing establishments.	2,374	1	2,374	0.5 (30 minutes) ...	1,187
1271.10(b)(1) and (2), 1271.21(a), and 1271.25(a) and (b); register and submit list of each HCT/P manufactured by new establishments.	157	1	157	0.75 (45 minutes)	118
1271.10(b)(2), 1271.21(c)(2)(ii), and 1271.25(c); update list.	566	1	566	0.5 (30 minutes) ...	283
1271.23; request electronic format waiver	1	1	1	1	1
1271.26; location/ownership amendments	346	1	346	0.25 (15 minutes)	87
1271.155(a); request exemption or alternative to any requirement.	18	1.333	24	3	72
1271.350(a)(1) and (3); investigate and report adverse actions.	15	14.266	214	1	214
1271.420(a); notify FDA (imports)	200	2.8	560	0.25 (15 minutes)	140
Total		23.399	4,242		2,102

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Rounded to the nearest whole number.

Based on current data from eHCTERS, we estimate there are 2,374 HCT/P current registrants and 157 new registrants, for a total of 2,531 respondents annually. Information collection provisions that include reporting activities are identified in table 1. The estimated burden for each of the individual reporting activities was calculated based on the annual number of submissions, averaged among respondents, and based on informal communications with industry.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 1271; establish and maintain records	Number of recordkeepers	Number of records per recordkeeper [2]	Total annual records	Average burden per recordkeeping [2]	Total hours [3]
1271.47; Establishing SOPs	157	1	157	48	7,536
1271.47; Updating SOPs	2,374	1	2,374	24	56,976
1271 Subpart C & Subpart D: Establishing and maintaining records documenting methods used in, and the facilities and controls used for, the manufacture of HCT/Ps, including but not limited to all steps in recovery, donor screening, donor testing, processing, storage, labeling, packaging, and distribution.	2,531	3,311.36	8,381,049	0.26 (~15 minutes)	2,170,493
Total			8,383,580		2,235,005

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Decimals rounded to the nearest hundredth.
[3] Rounded to the nearest whole number.

To calculate burden associated with the establishment and maintenance of operating procedures in accordance with applicable CGTP requirements, we assume twice the time is necessary for new establishments. Burden we attribute to recordkeeping activities associated with the remaining provisions in part 1271 is assumed to be distributed among the individual elements and averaged among respondents.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part 1271—human cells, tissues, and cellular and tissue-based products; activity	Number of respondents	Number of disclosures per respondent [2]	Total annual disclosures	Average burden per disclosure [2]	Total hours
Disclosing information as required under applicable good manufacturing practices/CGTP provisions.	1,611	4,984.75	8,030,435	0.30 (~18 minutes)	2,389,226

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Decimals rounded to the nearest hundredth.

As part of the recordkeeping requirements, certain provisions in part 1271 require the disclosure of information to third parties, particularly as it pertains to the distribution of HCT/Ps. We estimate a proportion of the respondents to the information collection (1,611) will incur burden resulting from these disclosures and have therefore accounted for burden that may be attributable to these distinct activities.

Our estimated burden for the information collection reflects an overall reduction of 150,137 hours and 347,843 responses annually, which corresponds to a decrease in the number HCT/P establishments and a decrease in the number HCT/Ps distributed since our last evaluation.

Dated: April 14, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–08277 Filed 4–18–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Self-Governance Planning Cooperative Agreement Program

Announcement Type: New.

Funding Announcement Number: [HHS–2023–IHS–TSGP–0001].

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.444.

Key Dates

Application Deadline Date: June 20, 2023.

Earliest Anticipated Start Date: July 18, 2023.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for cooperative agreements for the Tribal Self-Governance Planning Cooperative Agreement Program. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). The Assistance Listings section of *SAM.gov* (*https://same.gov/content/home*) describes this program under 93.444.

Background

The Tribal Self-Governance Program (TSGP) is more than an IHS program; it is an expression of the Government-to-Government relationship between the United States (U.S.) and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions, and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP affords Tribes the most flexibility to tailor their health care needs by choosing one of three ways to obtain health care from the Federal Government for their citizens. Specifically, Tribes can choose to: (1) receive health care services directly from the IHS; (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-Determination Contracting); and (3) compact with the IHS to assume control over health care programs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances.

The TSGP is a tribally-driven initiative and strong Federal-Tribal partnerships are essential to the program's success. The IHS established the Office of Tribal Self-Governance (OTSG) to implement the Self-Governance authorities under the ISDEAA. The primary OTSG functions are to: (1) serve as the primary liaison and advocate for Tribes participating in the TSGP; (2) develop, direct, and implement TSGP policies and procedures; (3) provide information and technical assistance to Self-Governance Tribes; and (4) advise the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN), designated by the IHS Director to act on his or her behalf, who has authority to negotiate Self-Governance Compacts and Funding Agreements. Tribes interested in participating in the TSGP should contact their respective ALN to begin the Self-Governance planning and negotiation process. Tribes currently participating in the TSGP that are interested in expanding existing or adding new PSFAs should also contact their respective ALN to discuss the best methods for expanding or adding new PSFAs.

Purpose

The purpose of this Planning Cooperative Agreement is to provide resources to Tribes interested in entering the TSGP and to existing Self-Governance Tribes interested in assuming new or expanded PSFAs. Title V of the ISDEAA requires a Tribe or Tribal organization (T/TO) to complete a planning phase to the satisfaction of the Tribe. The planning phase must include legal and budgetary research and internal Tribal government planning and organizational preparation relating to the administration of health care programs. See 25 U.S.C. 5383(d).

The planning phase is critical to negotiations and helps Tribes make informed decisions about which PSFAs to assume and what organizational changes or modifications are necessary to successfully support those PSFAs. A thorough planning phase improves timeliness and efficient negotiations and ensures that the Tribe is fully prepared to assume the transfer of IHS PSFAs to the Tribal health program.

A Planning Cooperative Agreement is not a prerequisite to enter the TSGP and a Tribe may use other resources to meet the planning requirement. Tribes that receive Planning Cooperative Agreements are not obligated to participate in the TSGP and may choose to delay or decline participation based on the outcome of their planning activities. This also applies to existing Self-Governance Tribes exploring the option to expand their current PSFAs or assume additional PSFAs.

II. Award Information

Funding Instrument—Cooperative Agreement

Estimated Funds Available

The total funding identified for fiscal year (FY) 2023 is approximately $900,000. Individual award amounts are anticipated to be $180,000. The funding available for competing awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

The IHS anticipates issuing approximately five awards under this program announcement.

Period of Performance

The period of performance is for 1 year.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as grants. However, the funding agency, IHS, is anticipated to have substantial programmatic involvement in the project during the