breach or (2) preventing, minimizing, or remedying the risk of harm to individuals, the recipient agency or entity (including its information systems, programs, and operations), the federal government, or national security, resulting from a suspected or confirmed breach.

Additional Circumstances Affecting All Routine Use Disclosures: To the extent that the subject individual claims records in this system contain Protected Health Information (PHI) as defined by HHS regulation ''Standards for Privacy of Individually Identifiable Health Information'' (45 CFR parts 160 and 164, Subparts A and E), disclosures of such PHI that are otherwise authorized by these routine uses may only be made if, and as, permitted or required by the ''Standards for Privacy of Individually Identifiable Health Information'' (see 45 CFR 164.512(a)(1)).

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

The records are secured across both physical and digital environments. Hard-copy records are maintained in restricted, locked facilities accessible only to authorized personnel. Electronic records are safeguarded using industry-standard encryption, firewalls, and multi-factor access controls. Portable electronic media containing personal data are strictly encrypted. All records are subject to strict retention schedules and are permanently destroyed or de-identified when no longer required.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Information may be retrieved by any of these personal identifiers: provider's TIN (which could be an SSN); NPI; CMS Certification Number (CCN); Patient's SSN or a Beneficiary's HICN; a patient's or beneficiary's name in combination with the patient's or beneficiary's date of birth.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

The applicable schedule approved by the National Archives and Records Administration (NARA) is DAA–0440–2015–0007–0001 (Bucket 5, Beneficiary Records), which provides for beneficiary claims records to be cut off at the end of the calendar year and destroyed no sooner than 10 years after cutoff unless longer retention is authorized; however, beneficiary claims records are currently subject to a document preservation order and must be preserved indefinitely pending further notice from the U.S. Department of Justice.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Safeguards conform to the HHS Information Security and Privacy Program, *https://www.hhs.gov/ocio/securityprivacy/index.html.* Information is safeguarded in accordance with applicable laws, rules and policies, including the HHS Policy for Information Security and Privacy Protection (IS2P); the E-Government Act of 2002, which includes the Federal Information Security Modernization Act (FISMA) of 2014, 44 U.S.C. 3551 through 3558; all pertinent National Institutes of Standards and Technology (NIST) Special Publications (SP), and OMB Circular A–130, Managing Information As a Strategic Resource.

Records are protected from unauthorized access through appropriate administrative, physical, and technical safeguards. These safeguards include protecting the facilities where records are stored or accessed with security guards, badges and cameras, securing hard-copy records in locked file cabinets, file rooms or offices during off-duty hours, limiting access to electronic databases to authorized users based on roles and two-factor authentication (or user identification (ID) and password), using a secured operating system protected by encryption, firewalls, and intrusion detection systems, requiring encryption for records stored on removable media, and training personnel in Privacy Act and information security requirements. Records that are eligible for destruction are disposed of using destruction methods prescribed by NIST SP 800–88, as revised.

RECORD ACCESS PROCEDURES:

An individual seeking access to records about the individual in this system of records must submit a written access request to the System Manager identified in the ''System Manager(s)'' section. An access request must contain the individual's full name, current address, email address or other contact information, and, for identity verification purposes, signature and date and place of birth. In addition, to verify the requester's identity, the signature must be notarized, or the request must include the individual's written certification that the individual is the person the individual claims to be and understands that the knowing and willful request for or acquisition of a record pertaining to an individual under false pretenses is a criminal offense subject to a fine of up to $5,000. An individual may also request an accounting of disclosures that have been made of the records about the individual, if any.

CONTESTING RECORD PROCEDURES:

An individual seeking to amend a record about the individual in this system of records must submit a written amendment request to the System Manager identified in the ''System Manager(s)'' section. The request must contain the same information required for an access request, and must reasonably identify the record, specify the information contested, state the corrective action sought, provide the reasons for the amendment, and include any supporting justification or documentation. The individual must verify his or her identity in the same manner required for an access request. The right to contest records is limited to information that is factually inaccurate, incomplete, irrelevant, or untimely (obsolete).

NOTIFICATION PROCEDURES:

An individual who wishes to know if this system of records contains records about the individual must submit a written request to the System Manager identified in the ''System Manager(s)'' section. The request must contain the same information required for an access request, and the individual must verify their identity in the same manner required for an access request.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

HISTORY:

79 FR 19341 (Apr. 8, 2014); 83 FR 6591 (Feb.14, 2018)

[FR Doc. 2026–18316 Filed 9–8–26; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No FDA–2026–N–9638]

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 reinstatement 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 November 9, 2026.

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 November 9, 2026. 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–2026–N–9638 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.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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Stephen Chang, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–2287, *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 reinstatement 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—Reinstatement

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 that 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, subparts E and 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 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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

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 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.

We therefore retain our currently approved burden estimates.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–18333 Filed 9–8–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2024–E–4125; FDA–2024–E–4128; FDA–2024–E–4129; FDA–2024–E–4130; and FDA–2024–E–4131]

Determination of Regulatory Review Period for Purposes of Patent Extension; ANKTIVA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for ANKTIVA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of patents which claim that human biological product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect must submit either electronic or written comments and ask for a redetermination by November 9, 2026. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by March 8, 2027. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 November 9, 2026. 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:

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