1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)) became effective:* May 25, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 25, 2012.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service Act (42 U.S.C. 262):* December 17, 2015. FDA has verified the applicant's claim that the biologics license application (BLA) for ANDEXXA (BLA 125586) was initially submitted on December 17, 2015.

3. *The date the application was approved:* May 3, 2018. FDA has verified the applicant's claim that BLA 125586 was approved on May 3, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 661 days, 693 days, or 1,066 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: November 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26251 Filed 12–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0731]

Agency Information Collection Activities; Proposed Collection; 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 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 requirements for FDA regulations related to human cells, tissues, and cellular and tissue-based products (HCT/Ps) involving establishment registration and listing; eligibility determination for donors; and current good tissue practice (CGTP).

DATES: Submit either electronic or written comments on the collection of information by February 3, 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 February 3, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 3, 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–2013–N–0731 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Eligibility Determination for Donors; and Current Good Tissue Practice.'' 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.gpo.gov/fdsys/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.

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 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 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)) identifies the required initial registration and HCT/P listing information. Section 1271.21(b), in brief, requires an annual update of the establishment registration. Section 1271.21(c)(ii) requires establishments to submit HCT/P listing updates if a change as described in § 1271.25(c) has occurred. Section 1271.25(c) identifies the required HCT/P listing update information. Section 1271.26 (21 CFR 1271.26) requires establishments to submit an amendment if ownership or location of the establishment changes, or if there is a change in the U.S. agent's name, address, telephone number, or email address. FDA requires the use of an electronic registration and listing system entitled ''eHCTERs'' (Electronic Human Cell and Tissue Establishment Registration System) to submit the required information (§§ 1271.10, 1271.21, 1271.25, and 1271.26)). Under § 1271.23 (21 CFR 1271.23), manufacturers may request a waiver from the requirements in 21 CFR 1271.22 that information must be provided to FDA in electronic format.

II. Eligibility Determination for Donors

In brief, FDA requires certain HCT/P establishments described in § 1271.1(b) to determine donor eligibility based on donor screening and testing for relevant communicable disease agents and diseases except as provided under 21 CFR 1271.90. The documented determination of a donor's eligibility is made by a responsible person as defined in § 1271.3(t) (21 CFR 1271.3(t)) and is based on the results of required donor screening, which includes a donor medical history interview (defined in § 1271.3(n)), and testing (§ 1271.50(a) (21 CFR 1271.50(a)). Certain records must accompany an HCT/P once the donor-eligibility determination has been made (§ 1271.55(a) (21 CFR 1271.55(a))). This requirement applies both to an HCT/P from a donor who is determined to be eligible as well as to an HCT/P from a donor who is determined to be ineligible or where the donor-eligibility determination is not complete if there is a documented urgent medical need, as defined in § 1271.3(u) (§§ 1271.60 and 1271.65 (21 CFR 1271.60 and 1271.65)). Once the donor-eligibility determination has been made, the HCT/P must be accompanied by a summary of records used to make the donor-eligibility determination (§ 1271.55(b)), and a statement whether, based on the results

of the screening and testing of the donor, the donor is determined to be eligible or ineligible (§ 1271.55(a)(2)). Records used in determining the eligibility of a donor, *i.e.,* results and interpretations of testing for relevant communicable disease agents, the donor-eligibility determination, the name and address of the testing laboratory or laboratories, and the name of the responsible person (defined in § 1271.3(t)) who made the donor-eligibility determination and the date of the determination, must be maintained (§ 1271.55(d)(1)). If any information on the donor is not in English, the original record must be maintained and translated to English and accompanied by a statement of authenticity by the translator (§ 1271.55(d)(2)). HCT/P establishments must retain the records pertaining to a particular HCT/P at least 10 years after the date of its administration, or, if the date of administration is not known, then at least 10 years after the date of the HCT/P's distribution, disposition, or expiration, whichever is latest (§ 1271.55(d)(4)).

When a product is shipped in quarantine, as defined in § 1271.3(q), before completion of screening and testing, the HCT/P must be accompanied by records identifying the donor (*e.g.,* by a distinct identification code affixed to the HCT/P container) stating that the donor-eligibility determination has not been completed and stating that the product must not be implanted, transplanted, infused, or transferred until completion of the donor-eligibility determination, except in cases of urgent medical need, as defined in § 1271.3(u) (§ 1271.60(c)). When an HCT/P is used in cases of documented urgent medical need, the results of any completed donor screening and testing, and a list of any required screening and testing that has not yet been completed also must accompany the HCT/P (§ 1271.60(d)(2)). When a HCT/P is used in cases of urgent medical need or from a donor who has been determined to be ineligible (as permitted under § 1271.65), documentation by the HCT/P establishment is required, showing that the recipient's physician received notification that the testing and screening were not complete (in cases of urgent medical need), and upon the completion of the donor-eligibility determination, of the results of the determination (§§ 1271.60(d)(3) and (4), and 1271.65(b)(3)).

An HCT/P establishment is also required to establish and maintain procedures for all steps that are performed in determining eligibility (§ 1271.47(a) (21 CFR 1271.47(a)), including the use of a product from a donor of viable, leukocyte-rich cells or tissue testing reactive for cytomegalovirus (§ 1271.85(b)(2) (21 CFR 1271.85(b)(2))). The HCT/P establishment must record and justify any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of its occurrence (§ 1271.47(d)).

III. Current Good Tissue Practice (CGTP)

FDA requires HCT/P establishments that manufacture HCT/Ps that are regulated solely under section 361 of the PHS Act to follow CGTP (§ 1271.1(b)). Section 1271.155(a) (21 CFR 1271.155(a)) permits the submission of a request for FDA approval of an exemption from or an alternative to any requirement in subpart C or D of part 1271. Section 1271.290(c) (21 CFR 1271.290(c)) requires establishments to affix a distinct identification code to each HCT/P that they manufacture that relates the HCT/P to the donor and to all records pertaining to the HCT/P. Whenever an establishment distributes an HCT/P to a consignee, § 1271.290(f) requires the establishment to inform the consignee, in writing, of the product tracking requirements and the methods the establishment uses to fulfill these requirements. Non-reproductive HCT/P establishments described in § 1271.10 are required under § 1271.350(a)(1) and (3) (21 CFR 1271.350(a)(1) and (3)) to investigate and report to FDA adverse reactions (defined in § 1271.3(y)) using Form FDA–3500A (§ 1271.350(a)(2)). Form FDA–3500A is approved under OMB control number 0910–0291. Section 1271.370(b) and (c) (21 CFR 1271.370(b) and (c)) requires establishments to include specific information either on the HCT/P label or with the HCT/P.

The standard operating procedures (SOP) provisions under part 1271 include the following: (1) Section 1271.160(b)(2) (21 CFR 1271.160(b)(2)) (receiving, investigating, evaluating, and documenting information relating to core CGTP requirements, including complaints, and for sharing information with consignees and other establishments); (2) § 1271.180(a) (21 CFR 1271.180(a)) (to meet core CGTP requirements for all steps performed in the manufacture of HCT/Ps); (3) § 1271.190(d)(1) (21 CFR 1271.190(d)(1)) (facility cleaning and sanitization); (4) § 1271.200(b) (21 CFR 1271.200(b)) (cleaning, sanitizing, and maintenance of equipment); (5) § 1271.200(c) (calibration of equipment); (6) § 1271.230(a) and (c) (21 CFR 1271.230(a) and (c)) (validation of a process and review and evaluation of changes to a validated process); (7) § 1271.250(a) (21 CFR 1271.250(a)) (controls for labeling HCT/Ps); (8) § 1271.265(e) (21 CFR 1271.265(e)) (receipt, predistribution shipment, availability for distribution, and packaging and shipping of HCT/Ps); (9) § 1271.265(f) (suitable for return to inventory); (10) § 1271.270(b) (21 CFR 1271.270(b)) (records management system); (11) § 1271.290(b)(1) (21 CFR 1271.290(b)(1)) (system of HCT/P tracking); and (12) § 1271.320(a) (21 CFR 1271.320(a)) (review, evaluation, and documentation of complaints as defined in § 1271.3(aa)).

Section 1271.155(f) requires an establishment operating under the terms of an exemption or alternative to maintain documentation of FDA's grant of the exemption or approval and the date on which it began operating under the terms of the exemption or alternative. Section 1271.160(b)(3) requires the quality program of an establishment that performs any step in the manufacture of HCT/Ps to document corrective actions relating to core CGTP requirements. Section 1271.160(b)(6) requires documentation of HCT/P deviations. Section 1271.160(d) requires, in brief, documentation of validation of computer software if the establishment relies upon it to comply with core CGTP requirements. Section 1271.190(d)(2) requires documentation of all cleaning and sanitation activities performed to prevent contamination of HCT/Ps. Section 1271.195(d) requires documentation of environmental control and monitoring activities. Section 1271.200(e) requires documentation of all equipment maintenance, cleaning, sanitizing, calibration, and other activities. Section 1271.210(d) (21 CFR 1271.210(d)) requires, in brief, documentation of the receipt, verification, and use of each supply or reagent. Section 1271.230(a) requires documentation of validation activities and results when the results of processing described in 21 CFR 1271.220 cannot be fully verified by subsequent inspection and tests. Section 1271.230(c) requires that when changes to a validated process subject to § 1271.230(a) occur, documentation of the review and evaluation of the process and revalidation, if necessary, must occur. Section 1271.260(d) and (e) (21 CFR 1271.260(d) and (e)) requires documentation of any corrective action taken when proper storage conditions are not met and documentation of the storage temperature for HCT/Ps. Section 1271.265(c)(1) requires documentation

that all release criteria have been met before distribution of an HCT/P. Section 1271.265(c)(3) requires documentation of any departure from a procedure relevant to preventing risks of communicable disease transmission at the time of occurrence. Section 1271.265(e) requires documentation of the activities in paragraphs (a) through (d) of that section, which must include identification of the HCT/P and the establishment that supplied the HCT/P, activities performed and the results of each activity, date(s) of activity, quantity of HCT/P subject to the activity, and disposition of the HCT/P. Section 1271.270(a) requires documentation of each step in manufacturing required in part 1271, subparts C and D. Section 1271.270(e) requires documentation of the name and address, and a list of responsibilities of any establishment that performs a manufacturing step for the establishment. Section 1271.290(d) and (e) require documentation of a method for recording the distinct identification code and type of each HCT/P distributed to a consignee to enable tracking from the consignee to the donor and to enable tracking from the donor to the consignee or final disposition. Section 1271.320(b) requires an establishment to maintain a record of each complaint that it receives. The complaint file must contain sufficient information about each complaint for proper review and evaluation of the complaint and for determining whether the complaint is an isolated event or represents a trend.

Section 1271.420(a) (21 CFR 1271.420(a)) requires importers of HCT/Ps to notify the FDA District Director having jurisdiction over the port of entry through which the HCT/Ps are offered for import. The HCT/Ps must be held intact or transported under quarantine until they are inspected and released by FDA.

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 or perform donor screening or testing. The estimates provided below are based on most recent available information from FDA's database system and trade organizations. The hours per response and hours per record are based on data provided by the Eastern Research Group, or FDA experience with similar recordkeeping or reporting requirements.

There are an estimated 2,736 HCT/P establishments (conventional tissue, eye tissue, peripheral blood stem cell, stem cell products from cord blood, reproductive tissue, and sperm banks), including 1,004 manufacturers of HCT/Ps regulated under the Federal Food, Drug, and Cosmetic Act and section 351 of the PHS Act (42 U.S.C 262), that have registered and listed with FDA. In addition, we estimate that 193 new establishments have registered with FDA (§§ 1271.10(b)(1) and (2) and 1271.25(a) and (b)). There are an estimated 1,062 listing updates (§§ 1271.10(b)(2), 1271.21(c)(ii), and 1271.25(c)) and 358 location/ownership amendments (§ 1271.26).

Under § 1271.23, FDA estimates an average of one waiver request annually.

Under § 1271.55(a), an estimated total of 2,594,415 HCT/Ps (which include conventional tissues, eye tissues, hematopoietic stem cells/progenitor cells, and reproductive cells and tissues), and an estimated total of 2,454,415 non-reproductive cells and tissues (total HCT/Ps minus reproductive cells and tissues) are distributed per year by an estimated 1,632 establishments (2,736 − 1,104 = 1,632).

Under § 1271.60(c) and (d)(2), FDA estimates that 1,611 establishments shipped an estimated 572,000 HCT/P under quarantine, and that an estimated 15 establishments requested 64 exemptions from or alternative to any requirement under part 1271, subpart C or D, specifically under § 1271.155(a).

Under §§ 1271.290(c) and 1271.370(b) and (c), the estimated 2,109 non-reproductive HCT/P establishments label each of their 2,441,644 HCT/Ps with certain information. These establishments are also required to inform their consignees in writing of the requirements for tracking and of their established tracking system under § 1271.290(f).

FDA estimates 13 HCT/P establishments submitted 188 adverse reaction reports with 162 involving a communicable disease (§ 1271.350(a)(1)).

FDA estimates that 193 new establishments will create SOPs, and that 2,736 establishments will review and revise existing SOPs annually.

FDA estimates that 1,368 HCT/P establishments (2,736 × 50 percent = 1,368) and 1,055 non-reproductive HCT/P establishments (2,109 × 50 percent = 1,055) record and justify a departure from the procedures (§§ 1271.47(d) and 1271.265(c)(3)).

Under § 1271.50(a), HCT/P establishments are required to have a documented medical history interview about the donor's medical history and relevant social behavior as part of the donor's relevant medical records for each of the estimated total of 109,019 donors (which include conventional tissue donors, eye tissue donors, peripheral and cord blood stem cell donors, and reproductive cell and tissue donors), and the estimated total of 103,419 non-reproductive cells and tissue donors (total donors minus reproductive cell and tissue donors).

FDA estimates that 821 HCT/P establishments (2,736 × 30 percent = 821) document an urgent medical need of the product to notify the physician using the HCT/P (§§ 1271.60(d)(3) and 1271.65(b)(3)).

FDA also estimates that 2,189 HCT/P establishments (2,736 × 80 percent = 2,189) have to maintain records for an average of 2 contract establishments to perform their manufacturing process (§ 1271.270(e) and 1,687 HCT/P establishments (2,109 × 80 percent = 1,687) maintain an average of 5 complaint records annually (§ 1271.320(b)).

FDA estimates that under § 1271.420(a), 200 establishments will submit 560 reports of HCT/Ps offered for imports.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR part 1271; human cells, tissues, and cellular and tissue-based products	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [3]
1271.10(b)(1) and 1271.21(b) [2]	2,736	1	2,736	0.5 (30 minutes)	1,368
1271.10(b)(1) and (2), 1271.21(a), and 1271.25(a) and (b) [2].	193	1	193	0.75 (45 minutes)	145
1271.10(b)(2), 1271.21(c)(2)(ii) and 1271.25(c) [2]	1,062	1	1,062	0.5 (30 minutes)	531
1271.23	1	1	1	1	1
1271.26 [2]	358	1	358	0.25 (15 minutes)	90

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

21 CFR part 1271; human cells, tissues, and cellular and tissue-based products	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [3]
1271.155(a)	15	4.27	64	3	192
1271.350(a)(1) and (3)	13	14.46	188	1	188
1271.420(a)	200	2.8	560	0.25 (15 minutes)	140
Total					2,655

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part 1271; human cells, tissues, and cellular and tissue-based products	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [3]
New SOPs [2]	193	1	193	48	9,264
SOP Update [2]	2,736	1	2,736	24	65,664
1271.47(d)	1,368	1	1,368	1	1,368
1271.50(a)	2,736	39.846	109,019	5	545,095
1271.55(d)(1)	2,736	39.846	109,019	1	109,019
1271.55(d)(2)	2,736	1	2,736	1	2,736
1271.55(d)(4)	2,736	1	2,736	120	328,320
1271.60(d)(3) and (4) 1271.65(b)(3)(iii)	821	1	821	2	1,642
1271.155(f)	15	4.27	64	0.25 (15 minutes)	16
1271.160(b)(3) and (6)	2,109	12	25,308	1	25,308
1271.160(d)	2,109	12	25,308	1	25,308
1271.190(d)(2)	2,109	12	25,308	1	25,308
1271.195(d)	2,109	12	25,308	1	25,308
1271.200(e)	2,109	12	25,308	1	25,308
1271.210(d)	2,109	12	25,308	1	25,308
1271.230(a)	2,109	12	25,308	1	25,308
1271.230(c)	2,109	1	2,109	1	2,109
1271.260(d)	2,109	12	25,308	0.25 (15 minutes)	6,327
1271.260(e)	2,109	365	769,785	0.083 (5 minutes)	63,892
1271.265(c)(1)	2,109	1,163.781	2,454,415	0.083 (5 minutes)	203,716
1271.265(c)(3)	1,055	1	1,055	1	1,055
1271.265(e)	2,109	1,163.781	2,454,415	0.083 (5 minutes)	203,716
1271.270(a)	2,109	1,163.781	2,454,415	0.25 (15 minutes)	613,604
1271.270(e)	2,189	2	4,378	0.5 (30 minutes)	2,189
1271.290(d) and (e)	2,109	49.037	103,419	0.25 (15 minutes)	25,855
1271.320(b)	1,687	5	8,435	1	8,435
Total					2,371,178

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Sections 1271.47(a), 1271.85(b)(2), 1271.160(b)(2) and (d)(1), 1271.180(a), 1271.190(d)(1), 1271.200(b), 1271.200(c), 1271.230(a), 1271.250(a), and 1271.265(e).
[3] Rounded to the nearest whole number.

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

21 CFR part 1271; human cells, tissues, and cellular and tissue-based products	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1271.55(a)	1,632	1,589.715	2,594,415	0.5 (30 minutes)	1,297,208
1271.60(c) and (d)(2)	1,611	355.06	572,000	0.5 (30 minutes)	286,000
1271.290(c)	2,109	1,163.781	2,454,415	0.083 (5 minutes)	203,716
1271.290(f)	2,109	1	2,109	1	2,109
1271.370(b) and (c)	2,109	1,163.781	2,454,415	0.25 (15 minutes)	613,604
Total					2,402,637

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

Our estimated burden for the information collection reflects an overall increase of 628,585 hours (111 reporting burden hours; 305,118 recordkeeping hours; and 323,356 disclosure burden hours) and a corresponding increase of annual responses, annual records, and annual disclosures. We attribute this

adjustment to an increase in the number HCT/P establishments and an increase in the number HCT/Ps distributed over the past few years.

Dated: November 26, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–26234 Filed 12–4–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–1619]

Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

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 provisions of FDA's regulations regarding current good manufacturing practice (CGMP) for dietary supplements.

DATES: Submit either electronic or written comments on the collection of information by February 3, 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 February 3, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of February 3, 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–2013–N–1619 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling or Holding Operations for Dietary Supplements.'' 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.gpo.gov/fdsys/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