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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-N-1168]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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, Agency, or we) 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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: 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: 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--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.

In the *Federal Register* of April 19, 2023 (88 FR 24193), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment in response to the notice. The comment was outside the scope of the four collection of information topics on which the notice solicited comments.

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.

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

Table 1.--Estimated Annual Reporting Burden[1]

21 CFR Section; Reporting Activities	No. of Respondents	No. 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)(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	No. of Recordkeepers	No. 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 Subparts C & 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	No. of Respondents	No. 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: July 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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