Respondents: Respondents will include grant recipient staff, evaluators, and community partners.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
SCWS web-based survey	60	1	0.5	30	10
SCWS focus group	30	1	1.5	45	15

Estimated Total Annual Burden Hours: 25.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: Statutory Authority Title II, Section 203(b)(4) of the Child Abuse Prevention and Treatment and Adoption Reform Act of 1978 (42 U.S.C. 5113(b)(4)).

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–11634 Filed 5–31–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0742]

Human Cells, Tissues, and Cellular and Tissue-Based Product Establishments That Are Improperly Registered in the Electronic Human Cell and Tissue Establishment Registration System Due to Lack of Annual Registration Update; Action Dates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of intent.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to begin inactivating the registration of establishments that manufacture human cells, tissues, or cellular or tissue-based products (HCT/Ps) that have not updated their registration during the annual update period, in accordance with FDA regulations, in the electronic human cell and tissue establishment registration system (eHCTERS). FDA regulations require establishments that manufacture certain HCT/Ps to update their establishment registration annually. These regulations also require establishments to amend their registration within 30 calendar days of certain changes.

DATES: This notice is applicable August 30, 2023.

FOR FURTHER INFORMATION CONTACT: Andrew C. Harvan, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

HCT/Ps are defined in § 1271.3(d) (21 CFR 1271.3(d)) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. FDA has a tiered, risk-based approach to the regulation of HCT/Ps. If all of the criteria in 21 CFR 1271.10(a) are met, and none of the exceptions in § 1271.15 (21 CFR 1271.15) apply, then the HCT/P is regulated solely under section 361 of the PHS Act (42 U.S.C. 264) and the regulations in part 1271 (21 CFR part 1271) (361 HCT/P), and FDA's premarket review and approval are not required.

Establishments that manufacture 361 HCT/Ps are required to register and list their HCT/Ps with FDA's Center for Biologics Evaluation and Research (CBER) using the electronic registration and listing system (§§ 1271.1(b), 1271.21, and 1271.22 (21 CFR 1271.1(b), 1271.21, and 1271.22)).[1] [2] Under § 1271.3(b), establishment ''means a place of business under one management, at one general physical location, that engages in the manufacture of [HCT/Ps].'' This includes ''any individual, partnership, corporation, association, or other legal entity engaged in the manufacture of [HCT/Ps] . . . [and includes] [f]acilities that engage in contract manufacturing services . . . .'' Under § 1271.3(e), ''manufacture means, but is not limited to, any or all steps in the recovery, processing, storage, labeling, packaging, or distribution of any human cell or tissue, and the screening or testing of the cell or tissue donor.''

Pursuant to § 1271.21, establishments that manufacture 361 HCT/Ps must register with FDA and submit a list of every HCT/P that they manufacture within 5 days after beginning operations. Establishments are required to update their registration annually each December. Establishments are also required to update their HCT/P list when changes occur. Such new information must be submitted at the time of change, or each June or December, whichever month occurs first. An establishment may accomplish its required annual registration update in conjunction with updating its HCT/P list.

In addition, under 21 CFR 1271.26, if the ownership or location of the

[1] An establishment that meets any of the exceptions in § 1271.15 is not required to register or comply with other requirements in part 1271.

[2] Manufacturers of HCT/Ps that are regulated as drugs, devices, and/or biological products under section 351 of the PHS Act (42 U.S.C. 262) and/or the Federal Food, Drug, and Cosmetic Act and applicable regulations, must register and list their products in accordance with part 207 or part 807 (21 CFR part 207 or part 807), as applicable (§ 1271.1(b)(2)). FDA does not require establishments that manufacture HCT/Ps regulated as drugs, devices, and/or biological products that are only for use in research under an investigational new drug application (IND) (21 CFR part 312) or an investigational device exemption (IDE) (21 CFR part 812) to register and list those HCT/Ps in accordance with part 207 or part 807 if they do not engage in other activities that would require them to register (21 CFR 207.13(e), 807.65(f), and 812.1).

establishment changes or if there is a change in the establishment's U.S. agent's name, address, telephone number, or email address, then establishments must also amend their registration within 30 calendar days. Of note, the regulations make clear that FDA's ''acceptance of an establishment registration and HCT/P listing form does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA'' (21 CFR 1271.27(b)).

Registration is performed using CBER's eHCTERS. Establishments electronically submit required registration and HCT/P listing information, as well as updates to such information, through their eHCTERS account.[3] The public can access eHCTERS to search and review tissue establishment registration information (registered, inactive, and pre-registered establishments) through the eHCTERS Public Query Application.

Complete, accurate, and up-to-date establishment registration and HCT/P listing information is essential to FDA's mission. If registration and listing information is outdated or otherwise unreliable, the integrity of the HCT/P registration and listing database is compromised. Registration information assists FDA in identifying industry participants and the scope of HCT/Ps manufactured. This assists FDA in more efficiently monitoring industry and providing new information including guidances, policies, and requirements. Establishment registration information also assists FDA in reacting swiftly to newly discovered or understood risks by enabling FDA to quickly alert industry of our concerns and, when appropriate, to conduct establishment inspections. Without this information, FDA would not be able to effectively monitor compliance under FDA's risk-based surveillance inspection program.

Establishment registration and HCT/P listing information is also widely used outside of FDA for various purposes. The public uses the Public Query Application of eHCTERS to search for and locate HCT/P establishments. For example, certain voluntary healthcare accreditation organizations require hospitals or surgical centers to annually confirm that their tissue suppliers are registered with FDA. Therefore, inclusion of inaccurate or outdated information in eHCTERS can negatively affect public health.

II. Circumstances Under Which HCT/P Registration and Listing Information Becomes Inaccurate or Outdated

Establishments that manufacture HCT/Ps are required to update their registration annually in December, even if there are no changes or updates to their information (§ 1271.21). Every year, many HCT/P establishments fail to update their registration information during the annual update period. In recent years, 390 of 2671, 379 of 2361, and 319 of 2431 registered domestic and foreign establishments failed to submit their annual registration for 2019, 2020, and 2021, respectively. Some of the establishments have not submitted their annual update for more than 2 years.

After the annual registration period ends, CBER generates a list of establishments that have failed to submit their annual registration update. From this list, FDA attempts to follow up with each of these establishments to rectify their registration status. However, for a variety of reasons, such as outdated contact information, FDA is not able to contact some of these establishments. The follow-up process, including sending a reminder email and contact by phone, requires considerable additional time and FDA staff resources.

When establishments fail to update their registration information in eHCTERS, they are improperly registered in eHCTERS and improperly displayed in the Public Query Application as ''Registered''. Not only does this inaccurate and outdated information compromise the integrity of eHCTERS, it also hinders the public's ability to rely on establishment registration information.

III. FDA's Intended Response

To address the above registration and listing problems, FDA is encouraging establishments that are required to register under part 1271 to review their current registration to ensure its accuracy. Any registrations that are outdated should be updated as soon as possible. Establishments are required to annually update their registration pursuant to FDA regulations. Establishments who do not submit their annual registration are in violation of the regulations at part 1271.

Ninety days after publication of this notice, and every January thereafter, FDA will inactivate an HCT/P establishment's registration when the establishment fails to submit their annual registration update during the previous annual update period between November 15 to December 31. FDA will no longer attempt to follow up with establishments to rectify their registration status. The eHCTERS Public Query Application will display the establishment registration status as ''inactive'' and include the last annual registration year. Email notification of the inactivation will be sent to the reporting official of the establishment, and the reporting official may access the establishment's account in eHCTERS to change or update its registration. If the email notifying the establishment of the change in registration status to ''inactive'' is undeliverable, FDA will call the phone number of the establishment to provide notification.

If an establishment changes or updates its registration in eHCTERS after its registration has been inactivated due to failure to annually update registration information, the eHCTERS Public Query Application will display the establishment's status as ''Registered'' and the last annual registration year will be updated to the current year.

IV. Resources Available To Assist With Updating Registration and HCT/P Listings

Access to part 1271 is available at: *https://www.ecfr.gov/current/title-21/chapter-I/subchapter-L/part-1271?toc=1.* The instructions for using eHCTERS to complete HCT/P establishment registration and HCT/P listing and submitting the annual registration updates, as well as information on the eHCTERS Public Query Application, are available at: *https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/tissue-establishment-registration.* Questions concerning registration can be emailed to *tissuereg@fda.hhs.gov.*

Dated: May 18, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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[3] Electronic submission of HCT/P establishment and product listing information may be waived in certain circumstances as described in 21 CFR 1271.23. Submission of a request for a waiver does not excuse timely compliance with registration and listing requirements.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Early Hearing Detection and Intervention (EHDI) Program

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice of a HRSA-initiated competitive supplement for the EHDI Program.