UNITED STATES FOOD & DRUG ADMINISTRATION

OMB Control No. 0910-0543: PART 1271—HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS

Request for Emergency Processing to Reinstate OMB Approval for Collections of Information:

The Food and Drug Administration (FDA or we) is requesting emergency processing under 5 CFR 1320.13 to reinstate its approval for information collection provisions supporting implementation of regulatory requirements that govern certain human cells, tissues, and cellular and tissue-based products (HCT/Ps) found in 21 CFR part 1271. 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.

Although we have established internal procedures to ensure the timely renewal of our information collections, Departmental reorganization and unexpected staff reductions and departures over the past 18 months have caused a lag in publication of our Federal Register notice required under 5 CFR 1320.8(d)(1). The document published in the September 9, 2026, issue (91 FR 57347) under Docket ID **FDA-2026-N-9638**, but the delay prevented us from submitting our ICR before its expiration on August 31, 2026. Our ability to impose penalties is a critical mechanism in ensuring strict adherence to mandatory standards of safety and effectiveness applicable to HCT/Ps. Products regulated under 21 CFR part 1271 are used in implantation, transplantation, and infusion procedures and are subject to recordkeeping requirements for documenting, among other things, procedures and controls to prevent the introduction, transmission, or spread of communicable disease. Additionally, registration requirements include established time schedules and content requirements. Similarly, the regulations establish criteria for donor eligibility and mandate that screening and testing is undertaken by a "*responsible person*." Finally, the regulations compliment guidance documents intended to clarify regulatory requirements in the context of scientific developments and FDA's current thinking on a topic to timely communicate relevant information on issues such as considerations regarding emerging diseases and screening criteria. Any lapse in OMB approval of the information collections established in 21 CFR part 1271 compromises our authority to enforce the applicable requirements and necessarily undermines our ability to protect the public health.

Because of the public health safety provisions found in the regulations, we believe expiration of the ICR results in public harm, is the result of unanticipated consequences, and we are unable to utilize normal clearance procedures to prevent the disruption of the collections of information.

At the same time, we believe a180-day approval would allow us the time necessary to consider any public comment we receive in response to our 60-day notice on the information collection elements and subsequently publish a 30-day notice announcing our submission of the ICR to OMB and that we have requested emergency review.

PHILLIP R. KURS -S

Digitally signed by PHILLIP R. KURS -S
Date: 2026.09.16 15:47:58 -04'00'

Phillip Kurs
Acting Associate Director
for Policy
Center for Biologics Evaluation and Research (CBER)

Submitted: September 16, 2026