

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0026]

Display Date MAY 26 2004
Publication Date MAY 27 2004
Certifier R LEDESMA

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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products; Establishment Registration and Listing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: JonnaLynn Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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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; Establishment Registration and Listing—(OMB Control Number 0910–0469)—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 from foreign countries into the States. As derivatives of the human body, all human cells, tissues, and cellular and tissue-based products (HCT/Ps) pose some risk of carrying pathogens that could potentially infect recipients or handlers. The regulations in part 1271 (21 CFR part 1271) require domestic and foreign establishments that recover, process, store, label, package, or distribute any HCT/P, or that perform screening or testing of the cell or tissue donor to register with FDA (§ 1271.10(b)(1)) and submit a list of each HCT/P manufactured (§ 1271.10(b)(2)). Section 1271.21(a) requires the initial establishment registration, and § 1271.25(a) and (b) identifies the required initial registration and HCT/P listing information. Section 1271.21(b) requires an annual update of the establishment registration. Section 1271.21(c)(ii) requires establishments to submit HCT/P listing updates when an HCT/P is changed as described in § 1271.25(c). Section 1271.25(c) identifies the required HCT/P listing update information. Section 1271.26 requires establishments to submit an amendment if ownership or location of the establishment changes.

FDA requires the use of a registration and listing form (Form FDA 3356; “Establishment Registration and Listing for Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps);” <http://forms.psc.gov/forms/FDA/fda.html>) (§§ 1271.22 and 1271.25) to submit the required information. To

further facilitate the ease and speed of submissions, electronic submission is accepted electronically at <http://www.fda.gov/cber/tissue/tisreg.htm>).

Sections 207.20, 207.26, 207.30 (approved under OMB control number 0910–0045), and 807.22(a) and (b) (approved under OMB control number 0910–0387) (21 CFR 207.20, 207.26, 207.30, and 807.22(a) and (b)) already require establishments that manufacture drugs or devices to submit to FDA initial establishment registration and product listing, as well as annual establishment registration, product listing updates, and location and ownership amendments. Sections 207.20(f) and 807.20(d) (21 CFR 807.20(d)) require that manufacturers of HCT/P drugs (subject to review under an application submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) or under a biological products license application under section 351 of the PHS Act (42 U.S.C. 262)) and devices (subject to premarket review or notification, or exempt from notification, under an application submitted under the device provisions of the act or under a biological product license application under section 351 of the PHS Act) submit this registration and listing information using Form FDA 3356 instead of the multiple forms identified under parts 207 and 807. Therefore these establishments (FDA estimates a total of 67 (1 + 66) respondents as shown in table 1 of this document) will incur only a one-time burden to transition from the use of several forms to the use of one form.

Respondents to this information collection are establishments that recover, process, store, label, package, or distribute any HCT/P, or perform donor screening or testing. In table 2 of this document, based on information from FDA's database system for the fiscal year (FY) 2003, there are 1,003 establishments that have registered and listed with FDA. This number includes

552 establishments manufacturing conventional or ocular HCT/Ps, which are currently required to register and list with FDA. The remaining 451 establishments are manufacturers of hematopoietic stem cells derived from peripheral or cord blood, and reproductive cells and tissue. Although these establishments currently are not required to register and list, some have registered voluntarily and are therefore included in the burden estimate. Based on information from FDA's database for FY 2002, there were 484 listing updates and 12 location/ownership amendments. When registration and listing requirements are implemented for all HCT/P establishments, i.e., when sections 207.20(f), 807.20(d), and 1271.3(d)(2) are effective, FDA estimates in table 1 of this document that approximately **367 (300 + 66 + 1)** HCT/P establishments would initially register and list in addition to the 1,003 currently registered establishments.

The burden estimates for the initial registration and listing and average hours per response are based on institutional experience with comparable reporting provisions for drugs, including biological products; devices; information from industry representatives and trade organizations; and data provided by the Eastern Research Group, a consulting firm hired by FDA to prepare an economic analysis of the potential economic impact on sperm banks and other reproductive tissue facilities.

In the **Federal Register** of January 29, 2004 (69 FR 4303), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

21 CFR Section	Form FDA 3356	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
207.20(f)	Change to form 3356	1	1	1	0.5	0.5
801.70(d)		66	1	66	0.5	33
1271.10(b)(1) and (b)(2), 1271.21(a), and 1271.25(a) and (b)	Initial registration and listing	300	1	300	0.75	225
Total						258.5

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

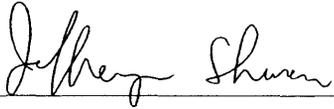
TABLE 2.—ESTIMATED INITIAL (ONE-TIME) REPORTING BURDEN¹

21 CFR Section	Form FDA 3356	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1271.10(b)(1) and 1271.21(b)	Annual registration	1,003	1	1,003	0.5	501.5
1271.10(b)(2), 1271.21(c)(ii), and 1271.25(c)	Listing update	484	1	484	0.5	242
1271.26	Registration amendment	12	1	12	0.25	3
Total						746.5

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 5.21.04

May 21, 2004.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

BILLING CODE 4160-01-S

