TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of response	Total Annual Responses	Hours per Response	Total Hours
316.10, 316.12, and 316.14	3	1	3	130	390
316.20, 316.21, and 316.26	138	2.0	276	130	35,880
316.22	22	1	22	2	44
316.27	5	1	5	4	20
316.30	500	1	500	2	1,000
316.36	.2	3	.6	15	9
Total					37,343

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

The information requested from respondents represents, for the most part, an accounting of information already in possession of the applicant. It is estimated, based on the frequency of requests over the past 13 years that 138 persons or organizations per year will request orphan drug designation and that no requests for recommendations on design of preclinical or clinical studies will be received. Based upon FDA experience over the last decade, FDA estimates that the effort required to prepare applications to receive consideration for sections 525 and 526 of the act (§§ 316.10, 316.12, 316.20, and 316.21) is generally similar and is estimated to require an average of 95 hours of professional staff time and 30 hours of support staff time per application. Estimates of annual activity and burden for foreign sponsor nomination of a resident, agent, change in ownership or designation, and inadequate supplies of drug in exclusivity, are based on total experience by FDA with such requests since 1983.

Dated: May 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12010 Filed 5–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0026]

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 June 28, 2004.

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.

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:

TABLE 1.—ESTIMATED INITIAL (ONE-TIME) REPORTING BURDEN[1]

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 BURDEN[1]

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: May 21, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–12011 Filed 5–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 84N–0102]

Cumulative List of Orphan Drug and Biological Designations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the cumulative list of orphan drug and biological designations as of December 31, 2003. FDA has announced the availability of previous lists, which are updated monthly, identifying the drugs and biologicals granted orphan designation under the Federal Food, Drug, and Cosmetic Act (the act).

ADDRESSES: Copies of the cumulative list of orphan drug and biological designations are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and the Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

FOR FURTHER INFORMATION CONTACT: Jeffrey Fritsch, Office of Orphan Products Development (HF–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3666.

SUPPLEMENTARY INFORMATION: FDA's Office of Orphan Products Development (OPD) reviews and takes final action on applications submitted by sponsors seeking orphan designation of their drug or biological under section 526 of the act (21 U.S.C. 360bb). In accordance with this section of the act which requires public notification of designations, FDA maintains a cumulative list of orphan drug and biological designations. This list includes the name of the drug or biological, the specific disease/condition for which the drug or biological is designated, and information about the sponsor such as the name, address, telephone, and contact.

At the end of each calendar year, the agency publishes a cumulative list of orphan drug and biological designations current through the calendar year. The list that is the subject of this notice is the cumulative list of orphan drug and biological designations through December 31, 2003, and, therefore, brings the April 15, 2003 (68 FR 18247) publication up to date. This list is available upon request from the Division of Dockets Management (see **ADDRESSES**). Those requesting a copy should specify Docket No. 84N–0102, which is the docket number for this document. In addition, the list is updated monthly and is available upon request from OPD or FDA's Division of Dockets Management (see **ADDRESSES**). The current list is also available on the Web site, *http://www.fda.gov/orphan*.

The orphan designation of a drug or biological applies only to the sponsor who requested the designation. Each sponsor interested in developing a drug or biological for an orphan indication must apply for orphan designation in order to obtain exclusive marketing rights. Any request for designation must be received by FDA before the submission of a marketing application for the proposed indication for which designation is requested (21 CFR 316.23). Copies of the orphan drug regulations (21 CFR part 316) (57 FR 62076, December 29, 1992) and explanatory background materials for use in preparing an application for orphan designation may be obtained from OPD (see **ADDRESSES**).

The names of the drugs and biologicals shown in the cumulative list of orphan designations may change upon marketing approval/licensing, reflecting the established, proper name approved by FDA. Because drugs and biologicals not approved/licensed for marketing are investigational, the appropriate established, proper name has not necessarily been assigned.

Dated: May 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–11948 Filed 5–26–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Members on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on certain device panels of the Medical Devices Advisory Committee, the National Mammography Quality Assurance Advisory Committee, the Device Good Manufacturing Practice Advisory Committee, and the Technical Electronic Products Radiation Safety Standards Committee in the Center for Devices and Radiological Health. Nominations will be accepted for current vacancies and those that will or may occur through August 31, 2005.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on advisory committees and, therefore, encourages nominations of qualified candidates from these groups.

DATES: Because scheduled vacancies occur on various dates throughout each year, no cutoff date is established for the receipt of nominations. However, when possible, nominations should be received at least 6 months before the date of scheduled vacancies for each year, as indicated in this document.

ADDRESSES: Send all nominations and curricula vitae to the following contact persons:

1. *For the device panels*: Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022, e-mail: *NJP@CDRH.FDA.GOV*.

2. *For the National Mammography Quality Assurance Advisory Committee, excluding consumer representatives*: Charles A. Finder, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, e-mail: *CAF@CDRH.FDA.GOV*.

3. *For health professionals, industry representatives and government representatives for the Device Good Manufacturing Practice Advisory Committee*: Sharon Kalokerinos, Center for Devices and Radiological Health (HFZ–300), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, e-mail: *SMK@CDRH.FDA.GOV*.

4. *For government representatives and industry representatives for the Technical Electronic Product Radiation Safety Standards Committee*: Richard V. Kaczmarek, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, *RVK@CDRH.FDA.GOV*.