physicians practicing in rural and underserved urban areas. At least 11 members of the Council must be physicians as described in section 1861(r)(1) of the Act; that is, State-licensed doctors of medicine or osteopathy. The remaining 4 members may include dentists, podiatrists, optometrists and chiropractors. Members serve for overlapping 4-year terms; terms of more than 2 years are contingent upon the renewal of the Council by appropriate action before its termination.

Section 1868(a)(2) of the Act provides that the Council meet quarterly to discuss certain proposed changes in regulations and manual issuances that relate to physicians' services, identified by the Secretary. Section 1868(a)(3) of the Act provides for payment of expenses and per diem for Council members in the same manner as members of other advisory committees appointed by the Secretary. In addition to making these payments, the Department of Health and Human Services and CMS provide management and support services to the Council. The Secretary will appoint new members to the Council from among those candidates determined to have the expertise required to meet specific agency needs in a manner to ensure appropriate balance of the Council's membership.

The Council held its first meeting on May 11, 1992. The current members are: Anthony Senagore, M.D., Chairperson; Jose Azocar, M.D.; M. Leroy Sprang, M.D.; Karen S. Williams, M.D.; Peter Grimm, D.O.; Carlos R. Hamilton, M.D.; Dennis K. Iglar, M.D.; Joe Johnson, D.C.; Vincent J. Bufalino, M.D.; Tye J. Ouzounian, M.D.; Geraldine O'Shea, D.O.; Laura B. Powers, M.D.; Gregory J. Przybylski, M.D.; Jeffrey A. Ross, DPM, M.D.; and Robert L. Urata, M.D.

II. Meeting Format and Agenda

The meeting will commence with the Council's Executive Director providing a status report, and the CMS responses to the recommendations made by the Council at the December 4, 2006 meeting, as well as prior meeting recommendations. Additionally, an update will be provided on the Physician Regulatory Issues Team. In accordance with the Council charter, we are requesting assistance with the following agenda topics:

- National Provider Identification (NPI) Update
- Transparency Initiative
- Recovery Audit Contractors (RAC) Update
- Physician Quality and Cost Measures Update
- Hospital Conditions of Participation Update

For additional information and clarification on these topics, contact the DFO as provided in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Individual physicians or medical organizations that represent physicians wishing to make a 5-minute oral presentation on agenda issues must register with the DFO by the date listed in the **DATES** section of this notice. Testimony is limited to agenda topics only. The number of oral presentations may be limited by the time available. A written copy of the presenter's oral remarks must be submitted to the DFO for distribution to Council members for review before the meeting by the date listed in the **DATES** section of this notice. Physicians and medical organizations not scheduled to speak may also submit written comments to the DFO for distribution by the date listed in the **DATES** section of this notice.

III. Meeting Registration and Security Information

The meeting is open to the public, but attendance is limited to the space available. Persons wishing to attend this meeting must register by contacting the DFO at the address listed in the **ADDRESSES** section of this notice or by telephone at (410) 786–6132 by the date specified in the **DATES** section of this notice.

Since this meeting will be held in a Federal Government Building, the Hubert H. Humphrey Building, Federal security measures are applicable. As noted above, in planning your arrival time, we recommend allowing additional time to clear security. In order to gain access to the building, participants will be required to show a government-issued photo identification (for example, driver's license, or passport), and must be listed on an approved security list before persons are permitted entrance. Persons not registered in advance will not be permitted into the Hubert H. Humphrey Building and will not be permitted to attend the Council meeting.

All persons entering the building must pass through a metal detector. In addition, all items brought to the Hubert H. Humphrey Building, whether personal or for the purpose of presentation, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for the purpose of presentation.

Individuals requiring sign language interpretation or other special accommodation must contact the DFO via the contact information specified in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date listed in the **DATES** section of this notice.

Authority: (Section 1868 of the Social Security Act (42 U.S.C. 1395ee) and section 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, section 10(a)).)

Dated: January 18, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. E7–1112 Filed 1–25–07; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0018]

Agency Information Collection Activities; Proposed Collection; Comment Request; Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form Food and Drug Administration 3356; Eligibility Determination for Donors; and Current Good Tissue Practice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements for FDA regulations related to human cells, tissues, and cellular and tissue-based products (HCT/Ps) involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and current good tissue practice (CGTP).

DATES: Submit written or electronic comments on the collection of information by March 27, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets

Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Human Cells, Tissues, and Cellular and Tissue-Based Products: Establishment Registration and Listing; Form FDA 3356; Eligibility Determination for Donors; and Current Good Tissue Practice—21 CFR Part 1271 (OMB Control Number 0910–0543)—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 possessions or from foreign countries into the States. As derivatives of the human body, all HCT/Ps pose some risk of carrying pathogens that could potentially infect recipients or handlers. FDA has issued regulations related to HCT/Ps involving establishment registration and listing using Form FDA 3356; eligibility determination for donors; and CGTP.

Establishment Registration and Listing; Form FDA 3356

The regulations in part 1271 (21 CFR part 1271) require domestic and foreign establishments that recover, process, store, label, package, or distribute any HCT/Ps, 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 to submit the required information (§§ 1271.10, 1271.21, 1271.25, and 1271.26)). To further facilitate the ease and speed of submissions, electronic submission is accepted (*http://www.fda.gov/cber/tissue/tisreg.htm*).

Eligibility Determination for Donors

FDA requires HCT/P establishments described in § 1271.1(b) to screen and test the donors of cells and tissue used in those products for risk factors for and clinical evidence of relevant communicable diseases agents and diseases. The documented determination of a donor's eligibility is made by a responsible person and is based on the results of required donor screening, which includes a donor medical history interview (defined in § 1271.3(n)), and testing (§ 1271.50(a)). HCT/P establishments are permitted to ship an HCT/P only if it is accompanied by documentation of the donor-eligibility determination (§ 1271.55(a)). This requirement applies to an HCT/P from a donor determined to be eligible as well as to a product from a donor who is determined to be ineligible and made available for use under certain provisions. The accompanying documentation must contain a summary of records used to determine donor eligibility, and a statement whether, based on the results of the screening and testing of the donor, that the donor is determined to be eligible or ineligible.

Records used in determining the eligibility of a donor, i.e., results and interpretations of screening and testing, the donor eligibility determination, the name and address of the testing laboratory or laboratories, and the name of the responsible person who made the determination and the date, must be maintained (§ 1271.55(d)(1)). If any information on the donor is not in English, the HCT/P establishment must retain the original record and the statement of authenticity from the translator (§ 1271.55(d)(2)). HCT/P establishments must retain the records pertaining to HCT/Ps at least 10 years after the date of administration, distribution, disposition, or expiration, whichever is latest (§ 1271.55(d)(4)).

When a product is shipped in quarantine, before completion of screening and testing, the HCT/P establishment must provide the donor identification, a statement that the donor-eligibility determination is not completed and that the product is not to be used until eligibility determination is completed (§ 1271.60(c)). With the use of a product from an incompletely tested donor, the results of any completed donor screening and testing, and a list of any required screening and testing not yet completed must accompany the HCT/P (§ 1271.60(d)(2)). When using an HCT/P from an ineligible donor, documentation by the HCT/P establishment is required showing that the recipient's physician received notification of the screening and testing results (§ § 1271.60(d)(3) and 1271.65(b)(3)).

An HCT/P establishment is also required to establish and maintain procedures for all steps that are performed in determining eligibility (§ 1271.47(a)), including the use of a product from a donor testing positive for cytomegalovirus (§ 1271.85(b)(2)). The HCT/P establishment must record any departure from the procedures (§ 1271.47(d)).

Current Good Tissue Practice

FDA requires certain HCT/P establishments to follow CGTPs. Section 1271.155(a) permits the submission of a request for FDA approval of an exemption or an alternative from any requirement in subpart C or D of part

1271. Section 1271.290(c) requires the establishment to affix a distinct identification code to each HCT/P relating the HCT/P to the donor and all records pertaining to the HCT/P. Whenever an establishment initially distributes an HCT/P to a consignee, § 1271.290(f) requires the establishment to inform the consignee, in writing, of the product tracking requirements and the methods the establishment uses to fulfill the requirements. Non-reproductive HCT/P establishments described in § 1271.10 are required under § 1271.350(a)(1) and (b)(1) to report to FDA adverse reactions (defined in § 1271.3(y)) and HCT/P deviations (defined in § 1271.3(dd)). Section 1271.370(b) and (c) requires establishments to include specific information either on the HCT/P label or in the package insert.

The standard operating procedures (SOP) provisions under part 1271 include the following: (1) Section 1271.160(b)(2) (receiving, investigation, evaluating, and documenting information relating to core CGTP requirements received from other sources and for sharing information with consignees and other establishments); (2) section 1271.180(a) (to meet core CGTP requirements for all steps performed in the manufacture of HCT/Ps); (3) section 1271.190(d)(1) (facility cleaning and sanitization); (4) section 1271.200(b) (cleaning, sanitizing, and maintenance of equipment); (5) section 1271.200(c) (calibration of equipment); (6) section 1271.230(a) (verification or validation of changes to a process); (7) section 1271.250(a) (controls for labeling HCT/Ps); (8) section 1271.265(e) (receipt, pre-distribution shipment, availability for distribution, and packaging and shipping of HCT/Ps); (9) section 1271.265(f) (suitable for return to inventory); (10) section 1271.270(b) (records management system); (11) section 1271.290(b)(1) (system of HCT/P tracking); and (12) section 1271.320(a) (review, evaluation, and documentation of all complaints).

Section 1271.155(f) requires an establishment operating under the terms of an exemption or alternative to maintain documentation of the terms and date of FDA approval. Section 1271.160(b)(3) requires documentation of corrective actions taken as a result of an audit of the quality program. Section 1271.160(b)(6) requires documentation of HCT/P deviations. Section 1271.160(d) requires documentation of computer validation or verification activities and results when computers are used to comply with the core CGTP requirements for its intended use. Section 1271.190(d)(2) requires documentation of all significant facility cleaning and sanitation. Section 1271.195(d) requires documentation of environmental control and monitoring activities. Section 1271.200(e) requires documentation of all equipment maintenance, cleaning, sanitizing, calibration, and other activities. Section 1271.210(d) requires documentation of the receipt, verification, and use of each supply or reagent. Section 1271.230(a) requires documentation of validation activities when the results of a process cannot be fully verified by subsequent inspection and tests. Section 1271.230(c) requires documentation of the review and evaluation of a process and revalidation of the process, if necessary, when any changes to a validated process occur. Section 1271.260(d) and (e) requires documentation of the storage temperature of HCT/Ps and any corrective action taken when acceptable storage conditions are not met. Section 1271.265(c)(1) requires documentation that all release criteria are met before distribution of an HCT/P. Section 1271.265(c)(3) requires documentation of any departure from a procedure at the time of occurrence. Section 1271.265(e) requires documentation of the receipt, pre-distribution shipment, distribution, and packaging and shipping of HCT/Ps. Section 1271.270(a) requires documentation of each step in manufacturing required in part 1271, subparts C and D. Section 1271.270(e) requires documentation of the name and address, and a list of responsibilities of any establishment that performs a manufacturing step for you. Section 1271.290(d) and (e) requires documentation of the disposition of each non-reproductive HCT/P as part of its tracking method. Section 1271.320(b) requires an establishment to maintain a record of each complaint that it receives, including a review and evaluation.

Respondents to this information collection are establishments that recover, process, store, label, package or distribute any HCT/P, or perform donor screening or testing. The estimates provided below are based on information from FDA's database system and trade organizations for 2006. The hours per response and hours per record are based on data provided by the Eastern Research Group, or FDA experience with similar recordkeeping or reporting requirements.

There are an estimated 2,017 HCT/P (conventional tissue, eye tissue, peripheral blood stem cell, stem cell products from cord blood, reproductive tissue, and sperm banks) establishments, including 481 manufacturers of HCT/P products regulated under the Federal Food, Drug, and Cosmetics Act and section 351 of the PHS Act, that have registered and listed with FDA. In addition, we estimate that 241 new establishments have registered with FDA (§§ 1271.10(b)(1) and (b)(2) and 1271.25(a) and (b)). There are an estimated 3,289 listing updates (§§ 1271.10(b)(2), 1271.21(c)(2)(ii) and 1271.25(c)) and 500 location/ownership amendments (§ 1271.26).

Under § 1271.55(a), an estimated 1,677,105 HCT/Ps (approximately 1,500,000 conventional tissues, 44,186 eye tissues, 7,919 hematopoetic stem cells/progenitor cells (total of 1,552,105 non-reproductive cells and tissues), and 125,000 reproductive cells and tissues) are distributed per year by an estimated 1,536 establishments (2,017 - 481 establishments with approved applications).

Under § 1271.60(c), FDA estimates that 1,200 establishments shipped an estimated 250,000 HCT/P under quarantine, and that an estimated 8 establishments requested an exemption from or alternative to any requirement under part 1271, subpart C or D, specifically under § 1271.155(a).

Under §§ 1271.290(c) and 1271.370(b) and (c), the estimated 1,449 non-reproductive HCT/P establishments label each of their 1,552,105 HCT/Ps with certain information. These establishments are also required to inform their consignees in writing of the requirements for tracking and of their established tracking system under § 1271.290(f).

FDA estimates 42 HCT/P establishments submitted 67 adverse reaction reports involving communicable disease (§ 1271.350(a)(1)), and 81 establishments submitted 144 deviation reports relating to the core CGTP requirements (§ 1271.350(b)(1)).

FDA estimates that 241 new establishments will create SOPs, and that 2,017 establishments will review and revise existing SOPs annually.

FDA estimates that 1,009 HCT/P establishments (2,017x50%=1,009) and 725 non-reproductive HCT/P establishments (1,449x50%=725) record and justify a departure from the procedures (§ 1271.47(d) and § 1271.265(c)(3)).

Under § 1271.50(a), HCT/P establishments are required to have a documented medical history interview about the donor's medical history and relevant social behavior as part of the donor's relevant medical records for each of the estimated 77,944 donors

(approximately 23,295 conventional tissue donors, 42,649 eye tissue donors, 7,000 peripheral and cord blood stem cell donors (72,944 non-reproductive cells and tissue donors), and 5,000 reproductive cell and tissue donors).

FDA estimates that 605 HCT/P establishments (2,017x30%=605) document an urgent medical need of the product to notify the physician using the HCT/P (§§ 1271.60(d)(3) and 1271.65(b)(3)).

FDA also estimates that 1614 HCT/P establishments (2,017x80%=1,614) have to maintain records for an average of 2 contract establishments to perform their manufacturing process (§ 1271.270(e)) and 1,009 HCT/P establishments maintain an average of 5 complaint records annually (§ 1271.320(b)).

In some cases, the estimated burden may appear to be lower or higher than the burden experienced by individual establishments. The estimated burden in these charts is an estimated average burden, taking into account the range of impact each regulation may have.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1271.10(b)(1) and 1271.21(b)[2]	2,017	1	2,017	0.5	1,008.5
1271.10(b)(1) and (b)(2), 1271.21(a), and 1271.25(a) and (b)[2]	241	1	241	0.75	180.75
1271.10(b)(2), 1271.21(c)(2)(ii) and 1271.25(c)[2]	3,289	1	3,289	0.5	1,644.50
1271.26[2]	500	1	500	0.25	125
1271.55(a)	1,536	1,091.87	1,677,105	0.5	838,552.50
1271.60(c) and (d)(2)	1,200	208.33	250,000	0.5	125,000
1271.155(a)	8	1	8	3	24
1271.290(c)	1,449	1,071.16	1,552,105	0.08	124,168.4
1271.290(f)	1,449	1	1,449	1	1,449
1271.350(a)(1)	42	1.60	67	1	67
1271.350(b)(1)	81	1.78	144	1	144
1271.370(b) and (c)	1,449	1,071.16	1,552,105	0.25	388,026.25
Total					1,480,389.80

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Using Form FDA 3356.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
New SOPs[2]	241	1	241	48	11,568
SOP Update[2]	2,017	1	2,017	24	48,408
1271.47(d)	1,009	1	1,009	1	1,009
1271.50(a)	2,017	38.64	77,944	5	389,720
1271.55(d)(1)	2,017	38.64	77,944	1	77,944
1271.55(d)(2)	2,017	1	2,017	1	2,017
1271.55(d)(4)	2,017	1	2,017	120	242,040
1271.60(d)(3) and 1271.65(b)(3)	605	1	605	2	1,210
1271.155(f)	8	1	8	0.25	2
1271.160(b)	1,449	12	17,388	1	17,388
1271.160(d)	1,449	12	17,388	1	17,388
1271.190(d)(2)	1,449	12	17,388	1	17,388

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]—Continued

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
1271.195(d)	1,449	12	17,388	1	17,388
1271.200(e)	1,449	12	17,388	1	17,388
1271.210(d)	1,449	12	17,388	1	17,388
1271.230(a)	1,449	12	17,388	1	17,388
1271.230(c)	1,449	1	1,449	1	1,449
1271.260(d)	1,449	12	17,388	0.25	4,347
1271.260(e)	1,449	365	528,885	0.08	42,310.8
1271.265(c)(1)	1,449	1,071.16	1,552,105	0.08	124,168.4
1271.265(c)(3)	725	1	725	1	725
1271.265(e)	1,449	1,071.16	1,552,105	0.08	124,168.4
1271.270(a)	1,449	1,071.16	1,552,105	0.25	388,026.25
1271.270(e)	1614	2	3228	0.5	1,614
1271.290(d) and (e)	1,449	50.34	72,944	0.25	18,236
1271.320(b)	1,009	5	5,045	1	5,045
Total					1,605,723.85

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.
[2]Sections 1271.47(a), 1271.85(b)(2), 1271.160(b)(2), 1271.180(a), 1271.190(d)(1), 1271.20c(b) and (c), 1271.230(a), 1271.250(a), and 1271.265(e).

Dated: January 19, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–1196 Filed 1–25–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0015]

Agency Information Collection Activities; Proposed Collection; Comment Request; Adoption of the Food and Drug Administration Food Code by Local, State, and Tribal Governments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on FDA's collection of information from local, State, and tribal governmental agencies concerning their adoption of, or plans to adopt, all or portions of the FDA Food Code or its equivalent by regulation, law, or ordinance.

DATES: Submit written or electronic comments on the collection of information by March 27, 2007.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and