As with other elements, peer-reviewed literature may be referenced to substantiate claims of test performance.

E. *Clinical Validity.* SACGT proposes that information on the clinical validity of a test be provided to health professionals. SACGT defines clinical validity as the accuracy with which a laboratory measurement predicts the presence or absence of a clinical condition. For diagnostic, prenatal, and carrier tests, accuracy could be expressed as clinical sensitivity (the probability a person with the disease, or who will get the disease, will have a positive result), clinical specificity (the probability that a test will be negative in a person who does not have or will not get the disease), positive predictive value (the probability that a person with a positive result has, or will get, the disease), and negative predictive value (the probability that a person with a negative test result does not have, or will not get, the disease). For predictive tests, SACGT proposes to define accuracy as the prediction of expressivity (the range of phenotypes associated with positive and negative test results) and age-related penetrance (likelihood of disease at a given age in test-positive individuals). In addition, health professionals should be made aware of other factors, such as environment or lifestyle, that may influence the development or prognosis of a disease or condition in an individual with a positive test result, as they may assist in their clinical management approaches.

SACGT suggests that the testing laboratory should define clinical validity as relevant to the proposed uses of the test. Peer-reviewed literature as well as the laboratory's own data should be used to substantiate the claims of clinical validity of the test. Information about the clinical validity should include, as necessary, a statement about the limitations of the available data. For example, if a test has been evaluated in only high-risk families, the absence of population-based data should be noted. More detailed consideration of clinical validity through research studies and clinical experience may contribute to the development of practice standards over time by the professional, medical, and health policy communities.

F. *Clinical Utility.* SACGT proposes that information relating to the clinical utility of a test be provided to health professionals. SACGT defines clinical utility as the contribution of the test result to improved outcome in the person tested. Clinical utility usually reflects the efficacy of clinical interventions for persons with positive test results. However, even when no interventions are available to treat or prevent the disease or condition, there may be other benefits associated with the knowledge of positive or negative test results.

If a clinical intervention is available for individuals who test positive for the disease or condition, this information should be provided to health professionals, along with the level of evidence regarding its efficacy. Other potential benefits associated with the knowledge of test results should also be described.

SACGT has not identified a specific source that would be responsible for providing information related to clinical utility. References to peer-reviewed literature or contact information for professional or patient advocacy organizations in the relevant field could be listed. Health professionals should also be active in investigating possible clinical interventions or preventive strategies. In-depth consideration of clinical utility through research studies and clinical experience will contribute to the development of practice standards and guidelines over time by professional medical and health policy communities and patient and disease advocacy organizations.

G. *Cost of Test and Billing/ Reimbursement Information.* SACGT suggests that the testing laboratory provide information to health professionals on the cost of the test. At present, some genetic tests are very expensive, though, as technology advances and the use of these tests increases, it is expected that costs will decrease. If possible, the laboratory could also provide any information on billing and reimbursement policies for the test. For example, the laboratory may indicate which CPT codes should be used for billing purposes. In addition, since patients may wish to pay for the test directly due to concerns related to the confidentiality and privacy of test results, information on direct payments should be included. SACGT recognizes that laboratories may have limited information regarding reimbursement policies since these are variable and often decided over time by third-party payors. Many health insurers provide information on their reimbursement policies via their web-site or customer information services.

Questions on Which Comment Is Being Solicited

1. Do the proposed elements sufficiently address the relevant information that should be made available to health professionals about a genetic test? Are there other elements that should be added to the template? If so, please define the element and propose a specific source for the element.

2. Are the proposed sources of information appropriate for each element?

3. Who should provide information regarding the clinical utility of a genetic test?

4. Would this information template be useful to you? If so, how?

5. How would this information best be disseminated to health professionals?

6.If FDA becomes involved in the oversight of genetic tests, much of the content of the proposed fact sheets will be considered during FDA's review process. In the interim, what other review mechanisms should be considered to ensure the accuracy of the material provided in the information sheets?

Dated: December 6, 2000.

Sarah Carr,

Executive Secretary, Secretary's Advisory Committee on Genetic Testing.

[FR Doc. 00–31523 Filed 12–11–00; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1642]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishment Registration and Listing Requirements for Human Cells, Tissues, and Cellular and Tissue-Based Products

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 relating to FDA regulations for human tissue intended for transplantation.

DATES: Submit written or electronic comments on the collection of information by February 12, 2001.

ADDRESSES: Submit electronic comments on the collection of

information to http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm. Submit written comments on the collection of information to the Dockets Management Branch (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: JonnaLynn P. Capezzuto, Office of Information Resources Management (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 request 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: (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.

Establishment Registration and Listing of Requirements for Human Cellular and Tissue-Based Products—21 CFR Part 1270 (OMB Control Number 0910–0372)—Extension

Under section 361 of the Public Health Service Act (the PHS Act) (42 U.S.C. 264), FDA issued regulations to prevent the transmission of human immunodeficiency virus (HIV), hepatitis B, hepatitis C, and other organisms causing infectious disease through the use of human tissue for transplantation. The regulations in part 1271 (21 CFR part 1271) require establishments that recover, process, store, label, package, or distribute any human cell, tissue, and cellular and tissue-based product (HCT/P), or that perform donor screening or testing, to submit an initial establishment registration and HCT/P list to FDA. Subsequently, establishments must submit an annual update to their establishment registration. In addition, establishments are required to submit HCT/P list updates, if any, and amendments whenever an establishment changes ownership or locations. FDA provides a registration and listing form (Form FDA 3356) to facilitate the ease and speed of submissions.

Sections 1271.10(b) and 1271.21(a) and (b) require the initial establishment registration and HCT/P listing information. Sections 1271.10(b) and 1271.21(b) require the annual establishment registration by domestic and foreign HCT/P establishments that are solely regulated under section 361 of the PHS Act and this part. Sections 1271.10(b), 1271.21(c)(ii), and 1271.25(c) require domestic and foreign HCT/P establishments to submit HCT/P listing updates only when an HCT/P is changed, added, or discontinued, and when there has been a material change to information submitted previously to the agency. If no change has occurred since the previous submission, an update is not required. Sections 1271.10(b) and 1271.26 require domestic and foreign HCT/P establishments to submit an amendment, but only when the establishment makes a change in location or ownership.

Sections 207.20, 207.26, 207.30, 807.20, 807.26, and 807.30 (21 CFR 207.20, 207.26, 207.30, 807.20, 807.26, and 807.30) already require establishments that manufacture drug or device products to submit 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) require that manufacturers of HCT/P drugs and devices submit this registration and listing information using Form FDA 3356 instead of the multiple forms identified under parts 207 and 807 (21 CFR parts 207 and 807). Therefore, these establishments 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 human cells, tissue, and cellular and tissue-based product. Based on information provided to FDA by industry representatives, trade organizations, and professional societies, the estimated number of establishments 1,225 (i.e., approximately 110 conventional tissue, 114 eye tissue banks, 400 peripheral blood stem cells, 25 stem cell products from cord blood, 400 reproductive tissue, 110 sperm banks, and 66 licensed biological products and approved devices). Our burden estimates for the annual frequency per response and average hours per response are based on institutional experience with comparable reporting provisions for drugs, including biological products, and 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.

Table 1 of this document provides the initial, one-time estimated burden for HCT/P establishment registration and HCT/P listing. This information may be submitted simultaneously on the same form, Form FDA 3356. We estimate that 0.75 hour of staff time will be needed for each initial submission.

In table 1 of this document we also include the one-time burden for HCT/P drug and device manufacturers regulated under parts 207 and 807. Parts 207 and 807 require that drug and device manufacturers submit initial establishment registration and product listing, annual establishment registration, product listing updates, and location/ownership amendments. Sections 207.20(f) and 807.20(d) change only the reporting format and require use of only one form, new Form FDA 3356, in place of the multiple forms currently required, i.e., Forms FDA–2656 and FDA–2657 for drug manufacturers, and Forms FDA–2891, FDA–2891(a), and FDA–2892 for device manufacturers. Therefore, the one-time reporting burden estimate for §§ 207.20(f) and 807.20(d) in table 1 of this document reflects only the time necessary to transition from the use of current multiple forms to the use of Form FDA 3356.

Table 2 of this document provides the estimate of the ongoing annual reporting burden for establishment registration. In

addition, table 2 of this document sets out estimated reporting burdens for HCT/P listing updates and establishment location or ownership amendments that would occur during any given year. If there is no change to an HCT/P listing, establishment location or ownership, a submission is not required. It is estimated that ongoing annual registration, updates and amendments require 0.50 hour, while the initial submission requires on average 0.75 hour. In addition, table 2 of this document shows that the average hours per response is 0.25 hour for the HCT/P listing updates and location/ownership amendments, which are required only when a change is made. In table 2 of this document, we also estimate that approximately 5 percent of the 1,159 establishments, or 58 establishments, will make changes to HCT/P's, location, or ownership in any one year after the initial registration and listing.

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)		1	1	1	0.5	0.5
807.20(f)		65	1	65	0.5	32.5
1271.10(b) and 1271.25(a) and (b)	Inital registration and listing	1,159	1	1,159	0.75	869.25
Total						902.25

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

TABLE 2.—ESTIMATED ANNUAL 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) and 1271.21(b)	Annual registration	1,159	1	1,159	0.5	579.5
1271.10(b), 1271.21(c), and 1271.25(c)	Listing update	58	1	58	0.5	29
1271.10(b) and 1271.26	Location/ownership amendment	58	1	58	0.25	14.5
Total						623

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

Dated: December 5, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31592 Filed 12–11–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N–1353]

Agency Information Collection Activities; Announcement of OMB Approval; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 6, 2000 (65 FR 41674), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0116. The approval expires on November 30, 2003. A copy of the supporting statement for this information collection is available on the Internet at http://www.fda.gov/ohrms/dockets.

Dated: December 5, 2000.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 00–31588 Filed 12–11–00; 8:45 am]

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