

In addition, in September 2009, FDA convened an internal 510(k) Working Group to conduct a comprehensive assessment of the 510(k) process. The 510(k) Working Group evaluated the 510(k) program with the goal of strengthening the program and improving the consistency in the Agency's decisionmaking process. In August 2010, the Center for Devices and Radiological Health (CDRH) published two documents in consideration of the comments made at the public meeting and the Agency's preliminary assessment of the program. These documents are titled "CDRH Preliminary Internal Evaluations—Volume I: 510(k) Working Group Preliminary Report and Recommendations" and "CDRH Preliminary Internal Evaluations—Volume II: Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations" (<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm>). In January 2011, CDRH published the "Plan of Action for Implementation of 510(k) and Science Recommendations" (<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239450.pdf>). One of the action items identified in the Plan of Action included publication of an update to the 1997 Device Modifications Guidance.

The recommendations in this draft guidance document are consistent with longstanding FDA policy for when a modification to a device does and does not require the submission of a 510(k). The guidance has been updated, however, to address issues associated with software and other rapidly changing technologies, and to provide greater clarity about changes that do not trigger the need for a new premarket submission. This guidance uses examples of modifications to devices involving such technologies to illustrate changes that require a new 510(k), and changes that may simply be documented in accordance with a manufacturer's existing Quality System without prompting the need for a new 510(k) submission. FDA believes increased certainty about the regulatory consequences of device modifications is critical to facilitating advancements in device technology. FDA is specifically interested in seeking comments on the changes described, types of changes that are not covered by this document but should be, and illustrative examples of types of changes.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on when a new 510(k) should be submitted for a change or modification to a legally marketed device. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>. To receive the draft guidance entitled "510(k) Device Modifications: Deciding When To Submit a 510(k) for a Change to an Existing Device," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1793 to identify the guidance you are requesting.

## IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 56.115 have been approved under OMB control number 0910-0130; the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910-0437; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910-0078; and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910-0073.

## V. Comments

Interested persons may submit to the Division of Dockets Management (see

ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 21, 2011.

**Nancy K. Stade,**

*Deputy Director for Policy, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Advisory Committee on Organ Transplantation; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

*Name:* Advisory Committee on Organ Transplantation (ACOT).

*Date and Times:* August 23, 2011, 1 p.m. to 5 p.m.; August 24, 2011, 8:30 a.m. to 5 p.m.

*Place:* Georgetown University Hotel and Conference Center, 3800 Reservoir Road, NW., Washington, DC 20057.

*Status:* The meeting will be open to the public.

*Purpose:* Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, and 42 CFR 121.12 (2000), ACOT was established to assist the Secretary in enhancing organ donation, ensuring that the system of organ transplantation is grounded in the best available medical science, and assuring the public that the system is as effective and equitable as possible, and, thereby, increasing public confidence in the integrity and effectiveness of the transplantation system. ACOT is composed of up to 25 members, including the Chair. Members are serving as Special Government Employees and have diverse backgrounds in fields such as organ donation, health care public policy, transplantation medicine and surgery, critical care medicine and other medical specialties involved in the identification and referral of donors, non-physician transplant professions, nursing, epidemiology, immunology, law and bioethics, behavioral sciences, economics and statistics, as well as representatives of transplant candidates, transplant recipients, organ donors, and family members.

*Agenda:* The Committee meeting will convene at 1 p.m. The Committee will hear reports from two ACOT Work Groups: Declining Rates of Donation/Geographical

and Other Variations in Organ Distribution and the Alignment of the Centers for Medicare and Medicaid Services' Regulatory Requirements with the Organ Procurement and Transplantation Network and the Health Resources and Services Administration. ACOT presentations will include an update on the Kidney Allocation Policy; financial challenges of kidney paired donation; circulatory determination of death criteria; organ donation and transplantation alliance; vascularized composite allografts; and disease transmission and informed consent. Agenda items are subject to change as priorities indicate.

After the presentations and Committee discussions, members of the public will have an opportunity to provide comments. Because of the Committee's full agenda and the timeframe in which to cover the agenda topics, public comment will be limited. All public comments will be included in the record of the ACOT meeting. Meeting summary notes will be made available on the Department's donation Web site at <http://www.organdonor.gov/legislation.asp>. The draft meeting agenda will be available on the Department's donation Web site at <http://www.organdonor.gov/legislation.asp> and at <http://www.team-psa.com/dot/spring2011/ACOT>.

Registration can be completed by e-mailing or faxing a confirmation of participation to Brittany Carey, with the HRM/Professional and Scientific Associates (PSA), the logistical support contractor for the meeting. Ms. Carey's e-mail address is [b\\_carey@team-psa.com](mailto:b_carey@team-psa.com) and her fax number is (703) 234-1701. Individuals without access to the Internet who wish to register may call Brittany Carey with HRM/PSA at (703) 889-9033.

*For Further Information Contact:* Patricia Stroup, Executive Secretary, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 12C-06, Rockville, Maryland 20857; telephone (301) 443-1127.

Dated: July 21, 2011.

**Reva Harris,**

*Acting Director, Division of Policy and Information Coordination.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Request for Comments Under the Paperwork Reduction Act, Section 3506

**SUMMARY:** The National Institute of Health (NIH), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the

Paperwork Reduction Act of 1995, Section 3506.

*Proposed Collection: Title:* The Genetic Testing Registry; *Type of Information Collection Request:* New collection; *Need and Use of Information Collection:* Laboratory tests for more than 2,000 genetic conditions are available; however, there is no centralized public resource that provides information about the availability and scientific basis of these tests. Recognizing the importance of making this information easily accessible to health care providers, patients, consumers, and others, NIH is developing a voluntary registry of genetic tests. The Genetic Testing Registry (GTR) will provide a centralized, online location for test developers, manufacturers, and researchers to submit detailed information about genetic tests. The overarching goal of the GTR is to advance the public health and research in the genetic basis of health and disease.

As such, the Registry will have several key functions, including (1) encouraging providers of genetic tests to enhance transparency by publicly sharing information about the availability and utility of their tests; (2) providing an information resource for the public, including health care providers, patients, and researchers, to locate laboratories that offer particular tests; and (3) facilitating genetic and genomic data-sharing for research and new scientific discoveries.

*Frequency of Response:* The information will be submitted voluntarily on a non-repeating, continual basis, which means submitters will register a test once and can add new tests on a continual basis. Submitters will be requested to update their test information at least once every 12 months.

*Description of Respondents:* Submitters to the GTR are expected to include clinical laboratories, test manufacturers, researchers, and entities that report and interpret tests performed elsewhere. The GTR is not limited to U.S. respondents; it will also include submissions from outside the United States. Information will be collected and managed using an online submission system.

*Estimate of Burden:* Data from the GeneTests Laboratory Directory, which is currently the most comprehensive listing available for laboratories that provide genetic tests, was used to estimate both the number of participating laboratories as well as the number of genetic tests which might be submitted to the GTR. Analysis of the

database showed that there are 593 laboratories and approximately 7,800 genetic tests listed in GeneTests. Approximately half of the laboratories in GeneTests (291, or 49 percent) list 12 or fewer tests, while approximately 40 percent (239) list between 13 and 100 tests, and the remaining 10 percent (63) list 100 or more tests. To account for genetic test providers that are not listed in GeneTests, the number of laboratories was multiplied by 1.2, bringing the estimated number of potential participants in GTR to 770. A multiplier of 1.2 was used to account for tests that are not in GeneTests but that might be submitted to the GTR, including test categories not covered by GeneTests (e.g., pharmacogenomic tests), as well as tests that meet the criteria for GeneTests but that have not been submitted to the database. Applying the 1.2 multiplier yields an estimated 9,360 tests for which information could be submitted to GTR.

Although participation in the GTR is voluntary, in order to participate, the submitter must provide information for a certain subset of data fields, identified as the "minimal fields." GTR includes 31 minimal fields and 85 optional fields. Separate estimates of hour burden are provided for minimal, optional, and all fields (Table 1). The calculations include the time and effort necessary for the test provider to gather information for the data elements and to enter the information into the GTR online submission form.

Based on simulated trials of entering test information into GTR, it will take submitters an average of 0.5 hours per test to provide information for the minimal fields. With an average of 12.2 tests per respondent, the estimated annual hour burden for a respondent to complete the minimal fields is 6.1 hours. An estimated additional 2.5 hours per test was projected for the optional fields for an annual burden of 30.5 hours per respondent. The annual hour burden for a respondent to complete all fields is 36.6 hours.

The calculations for annual burden reflect the average time for submitters who are familiar with their tests and know where to find information about the tests. For those submitters who are not familiar with information about their tests, it may take longer than the estimated 2.5 hours to provide the optional fields information. However, submitters should become more efficient in data entry as they gain experience with GTR, and significant time savings can be achieved by laboratories with large numbers of tests who use the bulk upload feature. In addition, those test providers whose