

Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACE Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 19, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E8-5951 Filed 3-24-08; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Temporary Assistance for Needy Families (TANF) State Plan; Guidance.

OMB No.: 0970-0145.

Description: The State plan is a mandatory statement submitted to the Secretary of the Department of Health and Human Services by the State. It consists of an outline of how the State's TANF program will be administered and operated and certain required certifications by the State's Chief Executive Officer. Its submittal triggers the State's family assistance grant funding and it is used to provide the public with information about the program. If a State makes changes in its program, it must submit a State plan amendment.

Respondents: The 50 States, the District of Columbia, Guam, Puerto Rico and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	No. of respondents	No. of responses per respondent	Average burden hours per response	Total burden hours
Temporary Assistance for Needy Families (TANF) State Plan Guidance	54	0.5	33	891

Estimated Total Annual Burden Hours: 891.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: infocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0149] (formerly Docket No. 2007D-0031)

Global Harmonization Task Force, Study Group 4; Final Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a final document that has been prepared by Study Group 4 of the Global Harmonization Task Force (GHTF). This document represents a harmonized proposal and recommendation from Study Group 4 of the GHTF that may be used by governments developing and updating their regulatory requirements for medical devices. This document is

intended to provide information only and does not describe current regulatory requirements; elements of this document may not be consistent with current U.S. regulatory requirements.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written comments concerning this document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jan Welch, GHTF, Study Group 4, Office of Compliance, Center for Devices and Radiological Health (HFZ-320), Food

and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 240-276-0115.

SUPPLEMENTARY INFORMATION:

I. Background

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as the Global Harmonization Task Force (GHTF) to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using their own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of a document that has been developed by one of the Study Groups (4).

Study Group 4 was initially tasked with the responsibility of developing guidance documents on quality systems auditing practices. As a result of its efforts, this group has developed document SG4/N33R16:2007. The final document (SG4/N33R16:2007) entitled "Guidelines for Regulatory Auditing of Quality Management Systems of Medical Device Manufacturers—Part 3: Regulatory Audit Reports" provides a structure for audit reports used in multiple jurisdictions, promoting consistency and uniformity and should assist the auditor in preparing a report

for use by multiple regulators and/or auditing organizations. Having reports that are consistent in content should facilitate the review and exchange of audit reports. Acceptance of audit reports by multiple regulators should eventually reduce the number of audits for manufacturers. This document was announced as available for comment on February 6, 2007 (72 FR 5443). GHTF received several comments on the document proposed on February 6, 2007. In response to the comments, GHTF made changes to clarify the document.

II. Significance of Guidance

This document represents recommendations from the GHTF study groups and does not describe regulatory requirements. FDA is making this document available so that industry and other members of the public may express their views and opinions.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. The Center for Devices and Radiological Health (CDRH) maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. Information on the GHTF may be accessed at <http://www.ghtf.org>. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>.

IV. Paperwork Reduction Act of 1995

For this final document, FDA concludes that there are no collection of information requirements under the Paperwork Reduction Act of 1995.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: March 14, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8-5927 Filed 3-24-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Child Health and Human Development; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Child Health and Human Development Special Emphasis Panel; Down Syndrome.

Date: April 18, 2008.

Time: 1 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, 5B01, Rockville, MD 20852 (Telephone Conference Call).

Contact Person: Norman Chang, Ph.D., Scientific Review Administrator, Division of Scientific Review, National Institute of Child Health and Human Development, NIH, 6100 Executive Blvd., Room 5B01 Bethesda, MD 20892, (301) 496-1485, changnmail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)