

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Title	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
.103(b)(4), .109(d) IRB Actions, .116 and .117 Informed Consent	6,000	39.33	1	235,980
.115(a) IRB Recordkeeping	6,000	15	10	900,000
.103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting ..	6,000	0.5	45/60	2,250
Total				1,138,230

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency Information Collection Request, 30-Day Public Comment Request, Grants.Gov; 30-Day Notice

AGENCY: Office of the Secretary, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed

information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, e-mail your request, including your address, phone number, OMB number, and OS document identifier, to Sherette.funncoleman@hhs.gov, or call the Reports Clearance Office on (202) 690-5683. Send written comments and recommendations for the proposed information collections within 30 days of this notice directly to the OS OMB Desk Officer; faxed to OMB at 202-395-6974.

Proposed Project: SF-424 Individual—Revision—OMB No. 4040-0005—Grants.gov.

Abstract: This is a request for a revision of a previously approved collection. It is a simplified, alternative government-wide data set and application cover page for use by Federal grant-making agencies that award grants to individuals. The form is being revised with changes to the data field that collects the Social Security Number (SSN). The SSN field is an optional field. The current collection pre-fills the first five digits with "xxx-xx" and only collects the last four digits of the SSN. At OMB's request, we reviewed the usefulness of collection of a portion of the SSN, by polling the Agencies that used the SF-424 Individual form; however, it was determined that the partial SSN is not useful for processing the SF-424 Individual form by the Agencies. Therefore, no portion of the SSN will be collected as part of the electronic grant application process. Frequency of data collection varies by Federal agency.

ESTIMATED ANNUALIZED BURDEN TABLE

Agency	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
NEA	1,150	1	10/60	192
NEH	2,593	1	30/60	1,297
USDA	4,069	1	30/60	2,035
HHS	600	1	30/60	300
Total				3,824

Seleda Perryman,

Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Notice of Meeting; National Commission on Children and Disasters

AGENCY: Administration for Children and Families, Department of Health and Human Services.

ACTION: Notice, FACA Committee Meeting Announcement.

SUMMARY: Pursuant to Public Law 92-463, the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the First Meeting of the National Commission on Children and Disasters, Department of Health and Human Services. The meeting will be held from approximately 8:30 a.m. to 5 p.m. on Tuesday, October 14, 2008, at the

Administration for Children and Families, 370 L'Enfant Promenade, SW., Washington, DC. The meeting will be open to the public; however, seating is limited and pre-registration is encouraged (see below).

FOR FURTHER INFORMATION CONTACT: Roberta Lavin, Office of Human Services Emergency Preparedness and Response, e-mail roberta.lavin@acf.hhs.gov or (202) 401-9306.

SUPPLEMENTARY INFORMATION: The National Commission on Children and Disasters (henceforth "the Commission") is a commission that shall independently conduct a comprehensive study to examine and assess the needs of children as they relate to preparation for, response to, and recovery from all hazards, building upon the evaluations of other entities and avoiding unnecessary duplication by reviewing the findings, conclusions, and recommendations of these entities. The Commission shall then submit a report to the President, the Secretary of Health and Human Services, and the Congress on the Commission's independent and specific findings, conclusions, and recommendations to address the needs of children as they relate to preparation for, response to, and recovery from all hazards, including major disasters and emergencies. The Commission implements the intent of Congress as expressed in The Consolidated Appropriations Act, 2008 (Pub. L. 110-161), Division G, Title VI, (henceforth "the Act") signed into law on December 26, 2007, authorizing funds for a body performing the functions here assigned to the Commission.

The Commission will hear presentations on and discuss: (1) The Department of Health and Human Services' efforts to support the needs of children in disaster situations; (2) the Federal Emergency Management Administration's efforts to support the needs of children in disaster situations; (3) White House perspectives on the Administration's efforts to support the needs of children in disaster situations; and (4) plans for future work of the Commission.

The meeting will be open to the public; however, seating is limited and pre-registration is encouraged. To pre-register, please e-mail carol.apelt@acf.hhs.gov with "Meeting Registration" in the subject line, or call Carol Apelt at (202) 205-4618 by 5 p.m. EST, October 9, 2008. Registration must include your name, affiliation, phone number. If you require a sign language interpreter or other special assistance, please call Carol Apelt at (202) 205-

4618 as soon as possible and no later than October 6, 2008.

Dated: September 24, 2008.

Charles Keckler,

Deputy Assistant Secretary for Policy for Children and Families.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-N-0270] (formerly Docket No. 2007N-0357)

Medical Device User Fee and Modernization Act; Notice to Public of Web Location of 2009 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Web location where the agency will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development in fiscal year (FY) 2009. In addition, FDA has established a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

DATES: Submit written or electronic comments at any time.

ADDRESSES: Submit written comments 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: Deborah A. Wolf, Center for Devices and Radiological Health (HFZ-215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-2350.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These

commitments include annually posting a list of guidance documents that CDRH is considering for development and providing stakeholders an opportunity to provide comments and/or draft language for those topics, or suggestions for new or different guidances. This notice announces the Web location of the list of guidances (see § 10.115(c)(1) (21 CFR 10.115(c)(1))) on which CDRH is intending to work over the next FY. We note that the agency is not required to issue every guidance on the list, nor is it precluded from issuing guidance documents that are not on the list. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued level 1 drafts that may be finalized following review of public comments. We will consider stakeholder comments as we prioritize our guidance efforts.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. We also note that CDRH's experience over the years has shown that there are many reasons CDRH staff does not complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the Center is required each year to issue a number of guidances that it cannot anticipate at the time the annual list is generated. These may involve newly identified public health issues as well as special control guidance documents for de novo classifications of devices. It will be helpful, therefore, to receive comments that indicate the relative priority of different guidance topics to interested stakeholders.

Through feedback from stakeholders, including draft language for guidance documents, CDRH expects to be able to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. This will be the second annual list CDRH has posted. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the list. FDA has established a specific docket (see docket number found in brackets in the heading of this document) where comments about the FY 2009 list, draft language for guidance documents on those topics, and suggestions for new or different guidances may be submitted. FDA believes this docket is an