DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Family Violence Prevention and Services: Grants to State; Native American Tribes and Alaskan Native Villages, and State Domestic Violence Coalitions.

OMB No.: 0970–0280.

Description: The Family Violence Prevention and Services Act (FVPSA), 42 U.S.C. 10401 *et seq.,* authorizes the Department of Health and Human Services to award grants to States, Tribes—and Tribal Organizations, and State Domestic Violence Coalitions for family violence prevention and intervention activities. The proposed information collection activities will be used to make grant award decisions and to monitor grant performance.

Respondents

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State Grant Application	53	1	10	530
Tribal Grant Application	200	1	5	1,000
State Domestic Violence Coalition Application	56	1	10	560
State FVPSA Grant Performance Progress Report	53	1	10	530
Tribal FVPSA Grant Performance Progress Report	200	1	10	2,000

Estimated Total Annual Burden Hours: 4,620

In compliance with the requirements of Section 3506(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.

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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–5181 Filed 3–7–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0457]

Guidance for Industry and Food and Drug Administration Staff; Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence." This guidance document describes FDA's recommendations for clinical investigations of medical devices indicated for the treatment of urinary incontinence.

DATES: Submit either electronic or written 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 entitled "Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence " to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. *See* the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: John Baxley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G210, Silver Spring, MD 20993–0002, 301–796–6549.

SUPPLEMENTARY INFORMATION:

I. Background

Urinary incontinence is defined as the involuntary loss of urine. This guidance is intended to assist device manufacturers who plan to conduct clinical investigations of devices intended to treat urinary incontinence in support of premarket approval (PMA) applications or premarket notification (510(k)) submissions. The guidance describes FDA's recommendations for human clinical trials that involve the use of any type of urinary incontinence

device, including, but not limited to, implanted electrical urinary continence devices; implanted mechanical/hydraulic urinary continence devices; urological clamp for males; nonimplanted, peripheral and other electrical continence devices; protective garment for incontinence; surgical mesh; electrosurgical cutting and coagulation device and accessories; perineometer; gynecologic laparoscope and accessories; and vaginal pessary.

In the **Federal Register** of September 19, 2008 (73 FR 54406), FDA announced the availability of the draft guidance. Comments on the draft guidance were due by December 18, 2008. Two comments were received with each comment making multiple recommendations on changes to the content of the guidance document.

The comments included recommended changes to or removals of primary, secondary, and composite endpoints and changes to the recommended clinical study design. In response to these comments, FDA has clarified the appropriate context for recommended endpoints and a sponsor's options with respect to use of a given endpoint. FDA also revised the recommended requirements for use of voiding diaries and clarified the recommendation regarding the randomization of subjects.

Comments also involved recommendations on the categorization of adverse events. In response to these comments, FDA clarified the recommendation for categorization of adverse events as either device- or procedure-related.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on clinical investigations of devices intended to treat urinary incontinence. 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 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 "Clinical Investigations of Devices Indicated for the Treatment of Urinary Incontinence," you may either send an e-mail request to *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 1636 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This 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 part 812 have been approved under OMB control number 0910–0078; 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 814 have been approved under OMB control number 0910–0231; and the collections of information in 21 CFR parts 50.23 and 56.115 have been approved under OMB control number 0910–0130.

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: March 2, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5148 Filed 3–7–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0097]

Medical Device Reporting; Malfunction Reporting Frequency

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is clarifying that device manufacturers and importers of all devices, including class I and those class II devices that are not permanently implantable, life supporting, or life sustaining, must continue to submit malfunction reports in full compliance with FDA's Medical Device Reporting regulation, pending future FDA notice under the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

DATES: Submit either electronic or written comments by May 9, 2011.

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

FOR FURTHER INFORMATION CONTACT: Victoria Schmid, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 3236, Silver Spring, MD 20993–0002, 301–796–6108.

I. Background

Title II, section 227 of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110–85), amended section 519(a) of the FD&C Act (21 U.S.C. 360i(a)), relating to the reporting of malfunctions to FDA under part 803 (21 CFR part 803). The malfunction reporting requirements for class III devices and those class II devices that are permanently implantable, life supporting, or life sustaining were not altered by FDAAA. Under the amended section 519(a), device manufacturers and importers are to continue to submit malfunction reports in accordance with part 803 for all class III devices and for those class II devices that are permanently implantable, life supporting, or life sustaining, unless the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) grants an exemption, variance from, or an alternative to, a requirement under such regulations under § 803.19 (section 519(a)(1)(B)(i) of the FD&C Act).

However, FDAAA changed malfunction reporting requirements for class I devices and those class II devices that are not permanently implantable, life supporting, or life sustaining. Under section 519(a) of the FD&C Act, as amended by FDAAA, the Secretary (and, by delegation, FDA) is required to publish a notice in the **Federal Register** or send a letter to the person who is the manufacturer or importer of a class I device or a class II device that is not permanently implantable, life