

**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](mailto: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.*  
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**BILLING CODE 4184-01-P**

**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