distribution of materials, professional development and individualized technical assistance on health promotion programs and environmental approaches to Physical Activity, Nutrition and Tobacco (PANT).

The asthma management questionnaire includes questions about planning and improving projects; joint activities of the Local Education Agency and Local Health Agency (LHA); policies; asthma-related education; health promotion and environmental approaches to asthma management; provision of health services; collaboration with external partners; reducing disparities among populations of youth at disproportionate risk; and information about additional program activities. The sections on policies, asthma-related education, health services and health promotion and environmental approaches to asthma management include questions that address the development and distribution of materials, professional development, and individualized technical assistance.

Information gathered will: (1) Provide standardized information about how HIV prevention, CSHP, and asthma management funds are used by LEAs, SEAs, TEAs, and TGs; (2) assess the extent to which programmatic adjustments are indicated; (3) provide descriptive and process information about program activities; and (4) provide greater accountability for use of public funds.

Participation in the information collection is required for programs that receive funding through DASH. Each Web-based questionnaire will be completed annually by the program coordinator for the activity. There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hrs)	Total burden (in hrs)
Local Education Agency Officials	Indicators for School Health Programs: HIV Prevention (LEA).	16	1	7	112
	Indicators for School Health Programs: Asthma Management (LEA).	10	1	7	70
State and Territorial Education Agency and Tribal Government Officials.	Indicators for School Health Programs: HIV Prevention (SEA).	57	1	7	399
	Indicators for School Health Programs: Coordinated School Health Programs.	23	1	10	230
Total	.....	.....	.....	.....	811

Dated: January 5, 2011.

Carol E. Walker,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–328 Filed 1–10–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970–0159]

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Statewide Automated Child Welfare Information System (SACWIS) Assessment Review Guide.

Description: The Department of Health and Human Services is authorized under section 474 of the Social Security Act to provide funding to state title IV–E agencies for information systems that support the provision of services to the nation's foster care and adoption populations. The Act authorizes funding for the planning, design, development, or installation of statewide automated child welfare systems (SACWIS). The data from these systems allows the Department to report accurate, meaningful and reliable information to Congress about the extent of problems facing these children and the effectiveness of assistance provided to this population.

Currently, SACWIS enable State efforts to meet the following Federal reporting requirements: The Adoption and Foster Care Analysis and Reporting System (AFCARS) required by section 479(b)(2) of the Social Security Act; the National Child Abuse and Neglect Data System (NCANDS); Child Abuse Prevention and Treatment Act (CAPTA); and the Chafee Independent Living Program National Youth in Transition Database (NYTD). SACWIS systems also support States' efforts to provide the information to conduct the Child and Family Service Reviews. Currently, 40 States and the District of Columbia have developed, or are developing, a SACWIS with Federal financial participation.

The SACWIS Assessment Reviews validate that all aspects of the project, as described in the approved Advance Planning Document, have been adequately completed, and conform to applicable regulations and policies. States use the SACWIS Assessment Review Guide (SARG) to document system components and functioning; each State's submission is unique and State-specific. These reviews are usually initiated by the State; however, ACF reserves the right to initiate SACWIS Assessment Reviews, at any time in the system life cycle. Submission of the SACWIS SARG and other supporting documentation by States, completed at the point that they have completed system development and the system is operational statewide, initiates a SACWIS Assessment Review. The additional supporting documentation submitted as part of the review process should be readily available to States as a result of their routine good project management practices. The SARG and supporting documentation may be submitted electronically.

The information collected in the SACWIS Assessment Review Guide will allow State and Federal officials to determine if the State's SACWIS meets the requirements of title IV–E Federal Financial Participation (FFP) defined at 45 CFR 1355.50. Additionally, other States will be able to use the documentation provided as part of this

review process to inform their own system development efforts.

No small businesses will be involved in this data collection effort.

Respondents: Title IV–E Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
SACWIS Assessment Review Guide (SARG)	3	1	250	750

Estimated Total Annual Burden Hours: 750.

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. 2011–332 Filed 1–10–11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0637]

Trials to Verify and Describe Clinical Benefit of Midodrine Hydrochloride; Establishment of Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a public docket to provide a forum to facilitate communication regarding the conduct of clinical trials needed to verify and describe the clinical benefit of midodrine hydrochloride (HCl) when used to treat symptomatic orthostatic hypotension.

DATES: Submit either electronic or written comments by July 11, 2011.

ADDRESSES: Submit electronic comments 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. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Wei Lu, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6196, Silver Spring, MD 20993–0002, *e-mail: Wei.Lu@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: FDA approved PROAMATINE (midodrine HCl) for marketing under its accelerated approval regulations, 21 CFR part 314, subpart H, on September 6, 1996, to treat patients with symptomatic orthostatic hypotension. Since that time, FDA has approved five generic versions of this product. Orthostatic hypotension is a condition in which patients are unable to maintain blood pressure in the upright position and become dizzy or faint upon standing. Subpart H allows approval of drugs to treat serious or life-threatening illnesses based on adequate and well-controlled clinical trials establishing that the drug has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or based on a clinical endpoint other than survival or irreversible morbidity. Approval of PROAMATINE was based on trials demonstrating that PROAMATINE increased 1-minute standing systolic blood pressure, a surrogate marker considered likely to correspond to a clinical benefit, principally relief of symptoms of orthostatic hypotension and improved ability to perform life activities.

The subpart H regulations specify that approvals based upon surrogate endpoints are "subject to the requirement that the applicant study the drug further to verify and describe its clinical benefit" in postmarketing studies. The postmarketing study requirement for midodrine HCl was described in the new drug application (NDA) submission seeking its approval and referenced in the Agency's 1996 approval letter. In the time since PROAMATINE was approved, the NDA holder has sponsored clinical trials and information regarding the drug's efficacy has been published, but data submitted to the Agency have not verified the drug's clinical benefit to FDA's satisfaction. Accordingly, on August 16, 2010, FDA issued a notice of opportunity for a hearing (NOOH) on a proposal to withdraw approval of the NDA for midodrine HCl.

Although the NOOH process is proceeding on a separate track, FDA recognizes that existing and potential sponsors may wish to conduct the clinical trials needed to support continued marketing authorization of midodrine HCl. To assist sponsors in planning and designing such trials, we are placing in the docket a brief description of a recommended clinical trial design. We are also inviting interested parties to submit information to the docket such as any existing controlled studies that verify the clinical benefit of midodrine HCl when used to treat orthostatic hypotension. Physicians who treat orthostatic hypotension and patient organizations that would like to work with any