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]

BILLING CODE 4184–01–P

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

sponsors of new clinical trials are invited to submit correspondence to the docket identifying themselves. We anticipate that any sponsor planning to conduct new clinical studies may contact interested physicians and organizations to solicit information and suitable volunteer test subjects.

The public docket is available for public review in the Division of Dockets Management (*see* **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 6, 2011.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2011–355 Filed 1–10–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; NIH Toolbox for Assessment of Neurological and Behavioral Function

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute on Aging (NIA), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: NIH Toolbox for Assessment of Neurological and Behavioral Function. *Type of Information Collection Request:* New. *Need and Use of Information Collection:* The overall goal of the NIH Toolbox project is to develop unified, integrated methods and measures of four domains of neurological and behavioral functioning (cognitive, emotional, motor and sensory) for use in large longitudinal or epidemiological studies where functioning is monitored over time. The current phase ("Norming"), will involve a large sample of 12,900 for the purpose of establishing comparative norms. Existing recruitment databases will be randomly sampled and screened for household members' age, gender, race/ethnicity, education and primary language. The targeted population will be non-institutionalized U.S. residents, aged 3–85, with 70% English-speaking and 30% Spanish-speaking. *Frequency of Response:* Once or twice (depending on subsample). *Affected Public:* Individuals. *Type of Respondents:* U.S. residents (persons aged 3–85 years). The annual reporting burden is as follows: *Estimated Number of Respondents:* 12,900; *Estimated Number of Responses per Respondent:* 1–2; *Average Burden Hours per Response:* 1.96; and *Estimated Total Annual Burden Hours Requested:* 29,700. The annualized cost to respondents is estimated at: $414,375. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

Type of respondents	Estimated number of respondents	Estimated number of responses per respondent	Average burden hours per response	Estimated total annual burden hours requested
Adults *				
Adult study participants, single assessment	3,150	1	3	9,450
Adult study participants, two assessments	750	2	3	4,500
Parent proxies for child participants, single assessment	3,750	1	0.5	1,875
Parent proxies for child participants, two assessments	750	2	0.5	750
Children				
Single assessment	3,750	1	2.5	9,375
Two assessments	750	2	2.5	3,750
Totals	* 12,900			29,700

* Some adults may participate both as a study participant and as a parent proxy if their child is also a study participant.

Request for Comments: Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Eddie Billingslea, PhD, Division of Neuroscience, National Institute on Aging, NIH, DHHS, 7201 Wisconsin Avenue, Suite 350, Bethesda, Maryland 20892–9205 or call non-toll-free number 301–496–9350 or e-mail your request, including your address to: *billingsleae@nia.nih.gov.*

Comments Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: January 4, 2011.

Melissa Fraczkowski,

National Institute on Aging, Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2011–379 Filed 1–10–11; 8:45 am]

BILLING CODE 4140–01–P