| | Number of respondents | Responses per respondent | Total responses | Average hours per respondent | Total hour burden |
|---|---|---|---|---|---|
| Healthy Start Grantee Web Survey | 102 | 1 | 102 | 4.0 | 408 |
| Total | 102 | 1 | 102 | 4.0 | 408 |

E-mail comments to *paperwork@hrsa.gov* or mail to the HRSA Reports Clearance Officer, Room 10–33, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: April 20, 2010.

**Sahira Rafiullah,**

*Director, Division of Policy and Information Coordination.*

[FR Doc. 2010–9974 Filed 4–28–10; 8:45 am]

**BILLING CODE 4165–15–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 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 5,660 for the purpose of establishing comparative norms. We will screen 52,800 households for members' age, gender and primary language to recruit the participants. The targeted population will be non-institutionalized U.S. residents, aged 3–85, with 66% English-speaking and 34% Spanish-speaking. *Frequency of Response:* Once to the screener, and 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:* 52,800 for the screener and 5,660 for the Toolbox measures; *Estimated Number of Responses per Respondent:* 1 screening and 1–2 for selected participants; *Average Burden Hours per Response:* For the screener, 0.1 and 2.49 for selected participants; and *Estimated Total Annual Burden Hours Requested:* 21,480. The annualized cost to respondents is estimated at: $393,250. 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 |
|---|---|---|---|---|
| **Screening** | | | | |
| Household member | 52,800 | 1 | .1 | 5,280 |
| **Adults** | | | | |
| Not affiliated with participating child, single assessment | 1710 | 1 | 3 | 5,130 |
| Not affiliated with participating child, two assessments | 350 | 2 | 3 | 2,100 |
| *Non-participating parent* of participating child, single assessment | 910 | 1 | 0.5 | 455 |
| *Non-participating parent* of participating child, two assessments | 350 | 2 | 0.5 | 350 |
| *Participating parent* of participating child, single assessment | 390 | 1 | 3.5 | 1,365 |
| *Participating parent* of participating child, two assessments | 150 | 2 | 3.5 | 1,050 |
| **Children** | | | | |
| Single assessment | 1300 | 1 | 2.5 | 3,250 |
| Two assessments | 500 | 2 | 2.5 | 2,500 |
| Totals | *54,600 | | | 21,480 |

*Includes one adult from each screened household plus selected child participants.

*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 Molly Wagster, Ph.D., 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: *wagsterm@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: April 23, 2010.

**Melissa Fraczkowski,**

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

[FR Doc. 2010–10015 Filed 4–28–10; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. Docket No. FDA–2009–N–0506]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Bar Code Label Requirement for Human Drug and Biological Products

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by June 1, 2010.

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0537. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–3792, *Elizabeth.Berbakos@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Bar Code Label Requirement for Human Drug and Biological Products—OMB Control Number 0910–0537—Extension

In the **Federal Register** of February 26, 2004 (69 FR 9120), we issued new regulations that required human drug product and biological product labels to have bar codes. The rule required bar codes on most human prescription drug products and on over-the-counter (OTC) drug products that are dispensed under an order and commonly used in health care facilities. The rule also required machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed under an order and commonly used in health care facilities, the bar code must contain the National Drug Code number for the product. For blood and blood components, the rule specifies the minimum contents of the machine-readable information in a format approved by the Director, Center for Biologics Evaluation and Research as blood centers have generally agreed upon the information to be encoded on the label. The rule is intended to help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Most of the information collection burden resulting from the final rule, as calculated in table 1 of the final rule (69 FR 9120 at 9149), was a one-time burden that does not occur after the rule's compliance date of April 26, 2006. In addition, some of the information collection burden estimated in the final rule is now covered in other OMB-approved information collection packages for FDA. However, parties may continue to seek an exemption from the bar code requirement under certain, limited circumstances. Section 201.25(d) (21 CFR 201.25(d)) requires submission of a written request for an exemption and describes the contents of such requests. Based on the number of exemption requests we have received, we estimate that approximately two exemption requests may be submitted annually, and that each exemption request will require 24 hours to complete. This would result in an annual reporting burden of 48 hours.

In the **Federal Register** of November 6, 2009 FR 74 57495, FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received on the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

| 21 CFR Section | Number of Respondents | Number of Responses per Respodent | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 201.25(d) | 2 | 1 | 2 | 24 | 48 |

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.