that consists of three criteria, weighted equally and combined to result in the total score. The three criteria are: (1) Frequency of occurrence at NPL sites; (2) toxicity; and (3) potential for human exposure. The site-specific information used to develop the priority list has been collected from ATSDR public health assessments and from site-file data packages used to develop the public health assessments. Since the development of the 2007 substance priority list, additional site specific information has been collected. The new information may include more recent NPL frequency-of-occurrence data, additional concentration data, and more information on exposure to substances at NPL sites. Using these additional data, seven substances have been replaced on the list of 275 substances since the 2007 publication; the replacement substances were previously under consideration. Changes in the order of substances appearing on the Priority List of Hazardous Substances will be reflected in program activities that rely on the list for future direction. Using the current algorithm, a total of 847 candidate substances have been analyzed and ranked. Of these candidates, the 275 substances on the priority list may in the future become the subject of toxicological profiles.

In two years ATSDR intends to publish the next revised list of hazardous substances, with an informal review and revision performed in one year. These revisions will reflect changes and improvements in data collection and availability. Additional information on the existing methodology used in the development of the Priority List of Hazardous Substances can be found in the Support Document and in the above-referenced **Federal Register** notices.

In addition to the revised priority list, ATSDR is also releasing a revised Completed Exposure Pathway Site Count Report. A completed exposure pathway (CEP) links a contaminant source to a receptor population. The CEP ranking is similar to a subcomponent of the substance priority list algorithm's potential-for-human-exposure component. The CEP ranking is based on a site frequency count and thus lists the number of sites at which a substance has been found in a CEP. This information is derived from ATSDR public health assessments and from health consultations. The CEP report therefore focuses on documented exposure, and lists hazardous substances according to exposure frequency.

The substances in the CEP report are similar to those in the Priority List of Hazardous Substances. However, some substances in the CEP report have a very low toxicity (*e.g.,* sodium) and as a result are not included in the substance priority list. Since the substance priority list uses toxicity, frequency of occurrence, and potential for human exposure to determine its priority substances, other low-toxicity substances will not appear on the list and, consequently, will not become subjects of toxicological profiles.

In addition, because CERCLA mandates the preparation of the Priority List of Hazardous Substances, that list only incorporates data from CERCLA NPL sites. The CEP report, on the other hand, uses data from all ATSDR-activity sites at which a CEP has been detected.

Dated: October 28, 2011.

Ken Rose,

Director, Office of Policy Planning and Evaluation, National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

[FR Doc. 2011–28477 Filed 11–2–11; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: State High Performance Bonus System (HPBS) Transmission File Layouts for HPBS Work Measures.

OMB No.: 0970–0230.

Description: There is no longer a High Performance Bonus associated with this information collection. The Deficit Reduction Act of 2005 (Pub. L. 109–171) eliminated the funding for the High Performance Bonus (HPB), but we are still requesting that States continue to submit data necessary to calculate the work measures previously reported under the HPB.

Specifically, The TANF program was reauthorized under the Deficit Reduction Act of 2005. The statute eliminated the funding for the HPB under section 403(a)(4). Nevertheless the Department is required under section 413(d) to annually rank State performance in moving TANF recipients into private sector employment. We are, therefore, requesting that States continue to transmit monthly files of adult TANF recipients necessary to calculate the work measures performance data. To the extent States do not provide the requested information, we will extract the matching information from the TANF Data Report. This may result in calculation of the work performance measures based on sample data, which would provide us less precise information on States' performance.

The Transmission File Layouts form provides the format that States will continue to use for the quarterly electronic transmission of monthly data on TANF adult recipients. States that have separate TANF–MOE files on these programs are also requested to transmit similar files. We are not requesting any changes to the Transmission File Layouts form.

Respondents: Respondents may include any of the 50 States, the District of Columbia, Guam, Puerto Rico, and the Virgin Islands.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
State High Performance Bonus System (HPBS) Transmission File Layouts for HPBS Work Measures	42	2	12	1,008

Estimated Total Annual Burden Hours: 1,008

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington,

DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov*.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, *Fax:* (202) 395–7285, *Email: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–28510 Filed 11–2–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0755]

Agency Information Collection Activities; Proposed Collection; Comment Request; Implementation of the Food and Drug Administration Amendments Act of 2007

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the requirement established by Title II of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Pub. L. 110–85) that device establishments must submit registration and listing information by electronic means, using FDA Form 3673, unless the Secretary of the Department of Health and Human Services (the Secretary) grants them a waiver from the electronic submission requirement.

DATES: Submit either written or electronic comments on the collection of information by January 3, 2012.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information 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: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, (301) 796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Implementation of Sections 222, 223, and 224 of the Food and Drug Administration Amendments Act of 2007 (OMB Control Number 0910–0625)—Extension

Sections 222, 223, and 224 of FDAAA, which were in effect on October 1, 2007, require that device establishment registrations and listings under section 510 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360), including the submission of updated information, be submitted to the Secretary by electronic means, unless the Secretary grants a request for waiver of the requirement because the use of electronic means is not reasonable for the person requesting the waiver. There are approximately 24,000 establishments that are electronically registered as of September 2011.

Section 222 of FDAAA amends sections 510(b) of the FD&C Act to require domestic establishments to register annually during the period beginning October 1 and ending December 31 of each year. Section 222 of FDAAA also amends section 510(i)(1) of the FD&C Act to require foreign establishments to register immediately upon first engaging in one of the covered device activities described under the statute, and in addition, they must also register annually during the time period beginning October 1 and ending December 31 of each year. Further, section 223 of FDAAA amends section 510(j)(2) of the FD&C Act to require establishments to list their devices with FDA annually, during the time period beginning October 1 and ending December 31 of each year.

Under FDAAA, device establishment owners and operators are required to keep their registration and device listing information up-to-date using the Agency's new electronic system. Owners and operators of new device establishments must use the electronic system to create new accounts, new registration records, and new device listings. Section 224 of FDAAA amends section 510(p) of the FD&C Act by allowing an affected person to request a waiver from the requirement to register electronically when the ''use of electronic means'' is not reasonable for the person.

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