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 Administration, Office of Information Services, 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. E-mail 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: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: February 10, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–3099 Filed 2–12–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0043]

Agency Information Collection Activities; Proposed Collection; Comment Request; Irradiation in the Production, Processing, and Handling of Food

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 information collection provisions of FDA's requirements for food irradiation processors. This notice also notifies the public of and solicits comments on FDA's proposal to transfer the collection of information and associated burden hours from the Office of Management and Budget (OMB) control number 0910–0549 to the subject collection of information (OMB control number 0910–0186).

DATES: Submit written or electronic comments on the collection of information by April 14, 2009.

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: Jonna Capezzuto, Office of Information Management (HFA–710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–796–3794.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from 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.

Irradiation in the Production, Processing, and Handling of Food—21 CFR Part 179 (OMB Control Number 0910–0186)—Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum (or minimum and maximum) energy of radiation emitted by x-ray tube sources. Section 179.21(b)(2) requires that the label or accompanying labeling bear adequate directions for installation and use and a statement supplied by FDA that indicates maximum dose of radiation allowed. Section 179.26(c) requires that the label or accompanying labeling bear a logo and a radiation disclosure statement. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

In this request for extension of OMB approval, FDA proposes to include and consolidate into the subject collection of information (OMB control number 0910–0186) the collection of information and associated burden hours from OMB control number 0910–0549. This inclusion is reflected in the estimated burden reported in table 1 of this document, which has increased by the addition of one recordkeeper in the large processors line, increasing the number of estimated recordkeepers from two to three.

Description of Respondents: Respondents are businesses engaged in the irradiation of food.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
179.25(e), large processors	3	300	900	1	900
179.25(e), small processors	4	30	120	1	120
Total					1,020

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

FDA bases its estimate of burden for the recordkeeping provisions of § 179.25(e) on the agency's experience regulating the safe use of radiation as a direct food additive. The number of firms who process food using irradiation is extremely limited. FDA estimates that there are three irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. FDA estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on: Three facilities devoting 100 percent of their business to food irradiation (3 x 300 hours = 900 hours for recordkeeping annually); four facilities devoting 10 percent of their business to food irradiation (4 x 30 hours = 120 hours for recordkeeping annually).

No burden has been estimated for the labeling requirements in §§ 179.21(b)(1) and (b)(2) and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: February 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–3091 Filed 2–13–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0559]

Draft Guidance for Industry on Process Validation: General Principles and Practices; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until March 16, 2009, the comment period for the draft guidance entitled ''Process Validation: General Principles and Practices.'' FDA announced the availability of this draft guidance in the **Federal Register** of November 18, 2008 (73 FR 68431). The initial comment period closes on January 20, 2009. FDA