TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Type of respondent	Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Parent of Youth Baseline Survey Participants.	Outcome Evaluation Parent Baseline Questionnaire.	12,940	1	12,940	0.17 (10 min.) ...	2,200
Youth aged 13–18 in the United States.	Screener	40,000	1	40,000	0.03 (2 min.)	1,200
	1st Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 min.)	2,000
	Screener	40,000	.....	40,000	0.03 (2 min.)	1,200
	2nd Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 min.)	2,000
	Screener	40,000	1	40,000	0.03 (2 min.)	1,200
	3rd Media Tracking Questionnaire.	4,000	1	4,000	0.5 (30 min.)	2,000
Total	.....	238,833	.....	.....	.....	35,523

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

Dated: June 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14809 Filed 6–20–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0719]

Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products

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 in the guidance on planning for the effects of high absenteeism to ensure availability of medically necessary drug products.

DATES: Submit either electronic or written comments on the collection of information by August 20, 2013.

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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.mizrachi@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.

Guidance for Industry on Planning for the Effects of High Absenteeism To Ensure Availability of Medically Necessary Drug Products—(OMB Control Number 0910–0675)—Extension

The guidance recommends that manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those products develop a written Emergency Plan (Plan) for maintaining an adequate supply of medically necessary drug products (MNPs) during an emergency that results in high employee absenteeism. The guidance discusses the issues that should be covered by the Plan, such as: (1) Identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate the Plan and make decisions during the emergency; (2) prioritizing the manufacturer's drug products based on medical necessity; (3) identifying actions that should be taken prior to an anticipated period of high absenteeism; (4) identifying criteria for activating the Plan; (5) performing quality risk assessments to determine which manufacturing activities may be reduced to enable the company to meet

a demand for MNPs; (6) returning to normal operations and conducting a post-execution assessment of the execution outcomes; and (7) testing the Plan. The guidance recommends developing a Plan for each individual manufacturing facility as well as a broader Plan that addresses multiple sites within the organization. For purposes of this information collection analysis, we consider the Plan for an individual manufacturing facility as well as the broader Plan to comprise one Plan for each manufacturer. Based on FDA's data on the number of manufacturers that would be covered by the guidance, we estimate that approximately 70 manufacturers will develop a Plan as recommended by the guidance (i.e., 1 Plan per manufacturer to include all manufacturing facilities, sites, and drug products), and that each Plan will take approximately 500 hours to develop, maintain, and update.

The guidance also encourages manufacturers to include a procedure in their Plan for notifying the Center for Drug Evaluation and Research (CDER) when the Plan is activated and when returning to normal operations. The guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The guidance specifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products will have manufacturing temporarily delayed, and any anticipated or potential drug shortages. We expect that approximately two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be sent to CDER by approximately two manufacturers each year, and that each notification will take approximately 16 hours to prepare and submit.

The guidance also refers to previously approved collections of information found in FDA regulations. Under the guidance, if a manufacturer obtains information after releasing an MNP under its Plan leading to suspicion that the product might be defective, CDER should be contacted immediately at *drugshortages@fda.hhs.gov* in adherence to existing recall reporting regulations (21 CFR 7.40; OMB control number 0910–0249), or defect reporting requirements for drug application products (21 CFR 314.81(b)(1)) and therapeutic biological products regulated by CDER (21 CFR 600.14) (OMB control numbers 0910–0001 and 0910–0458, respectively).

In addition, the following collections of information found in FDA current good manufacturing practice (CGMP) regulations in part 211 (21 CFR part 211) are approved under OMB control number 0190–0139. The guidance encourages manufacturers to maintain records, in accordance with the CGMP requirements (see, e.g., § 211.180) that support decisions to carry out changes to approved procedures for manufacturing and release of products under the Plan. The guidance states that a Plan should be developed, written, reviewed, and approved within the site's change control quality system in accordance with the requirements in §§ 211.100(a) and 211.160(a); execution of the Plan should be documented in accordance with the requirements described in § 211.100(b); and standard operating procedures should be reviewed and revised or supplementary procedures developed and approved to enable execution of the Plan.

FDA estimates the burden of this information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Absenteeism guidance	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notify FDA of Plan Activation and Deactivation	2	1	2	16	32

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

TABLE 2—ESTIMATED RECORDKEEPING BURDEN [1]

Absenteeism guidance	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Develop Initial Plan	70	1	70	500	35,000

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

Dated: June 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0010]

Cooperative Agreement To Support the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single-source application for the award of a cooperative agreement in fiscal year 2013 (FY13) to the North Carolina State University, Prestage Department of Poultry Science and the Piedmont Research Station Poultry Unit located in Salisbury, NC. Egg-associated illness due to *Salmonella* is a major public health concern, with table eggs being the primary source of *Salmonella* Enteritidis. Therefore, an FDA priority is to implement preventative measures to reduce the vertical and horizontal transmission of *Salmonella* Enteritidis and other *Salmonella* serovars to table eggs and poultry products. The goal of