



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0719]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; 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 or we) 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 (PRA).

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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 emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0675. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, PRAStaff@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.

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., one 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.

In the Federal Register of November 3, 2016 (81 FR 76618), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received in response to the notice.

We estimate the burden of this information collection as follows:

Table 1.--Estimated Annual Reporting Burden¹

| Absenteeism Guidance | No. of Respondents | No. 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 Annual Recordkeeping Burden¹

| Absenteeism Guidance | No. of Record-keepers | No. 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: March 9, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017-05100 Filed: 3/14/2017 8:45 am; Publication Date: 3/15/2017]