4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0568]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance for Industry on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products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 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 [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 e-mailed to oira_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-NEW and title Draft Guidance for Industry on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products (MNPs). Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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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.

Draft Guidance for Industry on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products

The draft guidance recommends that manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those products develop a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 MNPs during an emergency that results in high employee absenteeism. The draft guidance discusses the issues that should be covered by the Plan, such as: (1) Identifying a person or position title (as well as two designated alternates) with the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 draft 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 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 draft guidance, we estimate that approximately 70 manufacturers will develop an Emergency Plan as recommended by the draft 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 draft guidance also encourages manufacturers to include a procedure in their Plan for notifying CDER when the Plan is activated and when returning to normal operations. The draft guidance recommends that these notifications occur within 1 day of a Plan's activation and within 1 day of a Plan's deactivation. The draft 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.

This draft guidance also refers to previously approved collections of information found in FDA regulations. Under the draft guidance, if a manufacturer obtains information after releasing a MNP under its Plan leading to suspicion that the product might be defective, CDER should be contacted immediately (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).

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 draft 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 draft guidance states: 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 January 8, 2010 (75 FR 1060), FDA announced the availability of the draft guidance. In that FEDERAL REGISTER notice, FDA provided the public with 60 days to comment on the proposed collection of information. FDA received the following comments that pertained to the information collection in the draft guidance.

Some comments stated that pharmaceutical companies already have business continuity plans that address shortages of medically necessary products and that these plans take into account high absenteeism and other factors that could affect production. FDA believes that a general business continuity plan is unlikely to take into account individual products or how execution of the plan would affect product quality.

Some comments stated that the recommendation that the Plan be maintained in the Quality System is burdensome and provides no value to ensuring protection of public health. FDA agrees with these comments and has revised the guidance to recommend that only the parts of the Plan that could have an effect on product quality be reviewed and approved by the Quality Unit before implementation of the Plan.

One comment stated that with adequate inventory on hand, an absenteeism-specific business plan might not be needed. FDA disagrees with the comment. As we discussed in the guidance, potential shortages could arise from emergencies not contemplated by inventory policy.

One comment stated that establishing provisions to use resources available at other sites will require significant effort. FDA recommends that these provisions be considered as part of the overall Plan for handling emergencies.

Some comments suggested different timeframes for notifying FDA of activation and deactivation of the Plan, stating that 1 day is too short a time. FDA did not change its recommendation for 1-day notification for Plan activation and deactivation because informing FDA of this activity in as close to real time as possible will assist the FDA in making critical decisions related to managing the causal event.

Some comments stated that testing the implementation of the Plan and producing test batches would be impractical and expensive. FDA agrees with these comments and has revised its recommendation to test the implementation of the Plan and removed its recommendation to produce test batches of the drug product.

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

Table 1.--Estimated Annual Reporting Burden[1]

	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Notify FDA of Plan activation and deactivation	2	1	2	16	32
Total					32

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

Table 2.--Estimated Recordkeeping Burden[1]					
	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Develop initial Plan	70	1	70	500	35,000
Total					35,000

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

Dated: October 12, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-26103 Filed 10/15/2010 at 8:45 am; Publication Date: 10/18/2010]