Food and Drug Administration
Guidance for Industry (GFI): Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products
OMB Control Number 0910-0675
Supporting Statement

A. Justification

1. Circumstances Making the Collection of Information Necessary

The information collection supports agency guidance entitled, "*Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products*." The guidance provides recommendations to manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those for developing a written Emergency Plan (the Plan) to maintain 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.

The guidance also encourages manufacturers to include a procedure in their Plan for notifying FDA's 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.

The guidance is intended to stimulate planning to avoid or mitigate disruptions in supply of MNPs during emergencies that result in high absenteeism at production facilities, and to provide to industry considerations for developing emergency plans, as well as to discuss CDER's intended approach to assist in avoiding shortages that may have a negative impact on the national public health during such emergencies.

2. Purpose and Use of the Information Collection

The guidance recommends that manufacturers develop, maintain, and update a Plan as specified in the guidance (i.e., 1 Plan per manufacturer to include all manufacturing facilities, sites, and

drug products). In addition, manufacturers are encouraged to include a procedure in their Plan for notifying 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.

3. Use of Improved Information Technology and Burden Reduction

Although not specifically addressed in the guidance, we assume that manufacturers will rely on their standard electronic information technology systems to develop and maintain the Plan recommended in the guidance, including the use of standard email technology to notify CDER at the email address given in the guidance. Therefore, we assume 100% electronic compliance.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The guidance applies to both large and small manufacturers of drug and therapeutic biologic products regulated by CDER, and any components of those products. Under the Regulatory Flexibility Act, FDA regularly analyzes regulatory options that would minimize any significant impact on small entities. FDA also assists small businesses in complying with regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

We believe that by following the recommendations in the guidance, including the reporting timeframes, manufacturers will help avoid or mitigate disruptions in supply of MNPs during emergencies that result in high absenteeism at production facilities.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This guidance contains no inconsistency with the guidelines in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of November 3, 2016 (81 FR 76618). We received no comments that pertained to the information collection analysis.

9. Explanation of Any Payment or Gift to Respondents

No payments or gifts are provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

Although we do not anticipate any confidentiality issues resulting from the information collection in the guidance, confidentiality of information submitted under marketing applications is protected under 21 CFR 314.430 and 21 CFR part 20. In addition, the unauthorized use or disclosure of trade secrets required in applications is specifically prohibited under section 310(j) of the FD&C Act.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Hours

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 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

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Activation/deactivation of Plan as recommended in GFI	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 Burden

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Develop Initial Plan as recommended in GFI	70	1	70	500	35,000

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

12b. Annualized Cost Burden Estimate

There are labor costs associated with preparing and maintaining the Emergency Plan, and notifying FDA of the Plan activation and deactivation. Assuming a wage rate of approximately $85 per hour (averaged from wages for upper management, middle management, and clerical support, plus overhead and personnel benefits), we estimate the costs to be approximately $2,977,720.

13. Estimates of Other Total Annual Cost Burden to Respondents and/or Recordkeepers/Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The information collection is covered by existing agency resource allocations.

15. Explanation for Program Changes or Adjustments

There are no changes from the currently approved burden estimate.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no such plans.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of the OMB expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.