UNITED STATES FOOD & DRUG ADMINISTRATION

Planning for the Effects of High Absenteeism
to Ensure Availability of Medically Necessary Drug Products

OMB Control No. – 0910-0675

SUPPORTING STATEMENT – **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, the agency, us or we) regulations and related agency guidance. The document entitled, "*Guidance for Industry; Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products (MNPs)"* provides recommendations to manufacturers of drug and therapeutic biological products and manufacturers of raw materials and components used in those products for developing a written plan to maintain an adequate supply of MNPs during an emergency that results in high employee absenteeism. The guidance discusses issues such as: (1) identifying a person or position title (as well as two designated alternates) with the authority to activate and deactivate a plan (hereafter, "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 assist respondents to information collection requirements found in 21 CFR part 211 pertaining to CGMP and finished pharmaceuticals (currently approved under OMB control no. 0910-0139), specifically with regard to *personnel organization* in subpart B and *production and process controls* in subpart F.

We therefore request extension of OMB approval for the information collection as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The guidance recommends that manufacturers develop, maintain, and update a written plan (i.e., 1 Plan per manufacturer to include all manufacturing facilities, sites, and drug products). In addition, manufacturers are encouraged to include a procedure for notifying CDER when the plan is activated and when returning to normal operations. The guidance recommends that these notifications to occur within 1 day of activation and within 1 day of 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% of respondents will utilize electronic means to notify FDA.

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

We are unaware of undue burden on small entities.

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

The information collection recommendations in the guidance are consistent 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), we published a 60-day notice inviting public comment in the Federal Register of October 25, 2019 (84 FR 57448). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no questions of a sensitive nature associated with the information collection.

10. Assurance of Respondent Privacy and Confidentiality

No personally identifiable information (PII) or other data of a personal nature is being collected. Information is collected from manufacturers of (1) drug and therapeutic biological products and (2) raw materials and components used in those products and addresses the development of a written Emergency Plan for an adequate supply of medically necessary drug products (MNPs) and procedures in the Plan for notifying FDA. In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate handling of information collected. Confidentiality of the information submitted as recommended in the guidance is protected under 21 CFR 312.130 and 21 CFR part 20. 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 associated with the information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate:

Table 1.--Estimated Annual Reporting Burden

Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
Activate/deactivate Plan as recommended in the guidance	2	1	2	16	32

Table 2.--Estimated Annual Recordkeeping Burden

Activity	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Avg. Burden per Recordkeeper	Total Hours
Develop initial Plan as recommended in the guidance	70	1	70	250	17,500

12b. Annualized Cost Burden Estimate

We assume labor costs associated with preparing and maintaining the Emergency Plan and notifying FDA of the Plan activation and deactivation in the amount of $85 per hour (averaged from wages for upper management, middle management, and clerical support, plus overhead and personnel benefits), for a total annual cost of $1,447,720.

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

There are no capital, start-up, or operating or maintenance costs associated with the 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

Upon development of a plan for the effects of high absenteeism to ensure availability of MNPs, we believe fewer hours are necessary for maintaining the plan and making updates. Since establishing the information collection in 2011, we believe most respondents have developed a plan as recommended by the guidance. Accordingly, we have reduced burden we attribute to recordkeeping activities by half resulting in 17,500 fewer burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no publications or other schedules associated with the information collection.

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

Display of the OMB expiration date as required by 5 CFR 1320.5 is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.