SUPPORTING STATEMENT

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

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 314.2 of the Federal Food, Drug and Cosmetic Act, this regulation also intends to establish an effective system for FDA's surveillance of marketed drugs. This information collection approval request is for a Food and Drug Administration (FDA) guidance for industry entitled "Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products." The guidance is intended to encourage manufacturers of medically necessary drug products (MNPs) and any components of those products to develop contingency production plans to use during emergencies that result in high absenteeism at production facilities. The guidance provides recommendations regarding considerations for the development and implementation of a contingency production plan, including specific elements to include in such a plan. The guidance also discusses the Center for Drug Evaluation and Research's (CDER's) intended approach to helping to avoid drug product shortages that could have a negative impact on the national public health during such emergencies. The guidance is intended for manufacturers of finished drug products as well as manufacturers of the raw materials necessary for manufacturing an MNP.

2. Purpose and Use of the Information Collection

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. The purpose of the guidance is 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. These considerations include, but are not limited to: General preparedness through employee education and immunization; prioritization of manufactured products based on medical necessity; developing training, manufacturing and laboratory contingencies for high absenteeism; and how to plan for returning to normal operations.

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 Emergency Plan recommended in the guidance, including the use of standard email technology to notify CDER at the email address given under section III.F of the guidance.

4. Efforts to Identify Duplication and Use of Similar Information

The information collection requested under the guidance does not duplicate any other information collection.

5. Impact on Small Businesses or Other Small Entities

The draft 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 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.

9. Explanation of Any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any payment or gift to respondents under this guidance.

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

Burden Hours -

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 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 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 CDER'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 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 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.

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

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

	Number of Respondents	Number of Responses per Respondent	Total 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 information collection.

Table 2.--Estimated Recordkeeping Burden[1]

	Number of Record-keepers	Number of Records per Recordkeeping	Total 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 information collection.

Costs –

There are labor costs associated with preparing and maintaining the Emergency Plan, and notifying FDA of the Plan activation and deactivation. Assuming a loaded wage rate of approximately $75 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 $2,627,400.

13. Estimates of Other Total Annual Cost Burden to Respondents and Recordkeepers

We do not anticipate any other costs, including capital costs or operating and maintenance costs, resulting from the information collection in the guidance.

14. Annualized Cost to the Federal Government

Because we only expect two responses as a result of the guidance, the additional application reviewer time would be negligible and would be covered by our general estimate of FDA reviewer time for all marketing application submissions under part 314 and approved by OMB under Control Number 0910-0001.

15. Explanation for Program Changes or Adjustments

This is a new collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no publications.

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

The agency is not seeking to display the expiration date for OMB approval of the information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in Item 19, "Certification for Paperwork Reduction Act Submission," of OMB Form 83-I.

PAPERWORK REDUCTION ACT SUBMISSION

Please read the instructions before completing this form. For additional forms or assistance in completing this form, contact your agency's Paperwork Clearance Officer. Send two copies of this form, the collection instrument to be reviewed, the supporting statement, and any additional documentation to: Office of Information and Regulatory Affairs, Office of Management and Budget, Docket Library, Room 10102, 725 17th Street NW, Washington, DC 20503.

1. Agency/Subagency originating request

DHHS/FDA

2. OMB control number b. [ ] None

a. 0910- ---------

3. Type of information collection (*check one*)

a. [X] New Collection

b. [ ] Revision of a currently approved collection

c. [ ] Extension of a currently approved collection

d. [ ] Reinstatement, without change, of a previously approved collection for which approval has expired

e. [ ] Reinstatement, with change, of a previously approved collection for which approval has expired

f. [ ] Existing collection in use without an OMB control number

For b-f, note Item A2 of Supporting Statement instructions

4. Type of review requested (*check one*)

a. [x] Regular submission

b. [ ] Emergency - Approval requested by at close of comment period

c. [ ] Delegated

5. Small entities

Will this information collection have a significant economic impact on a substantial number of small entities? [ ] Yes [x] No

6. Requested expiration date

a. [X] Three years from approval date b. [ ] Other Specify: /

7. Title: Guidance for Industry on Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products

8. Agency form number(s) (*if applicable*): NA

9. Keywords: drug products; manufacturing practices

10. Abstract:

This approval request is for a guidance for industry entitled “Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products.” The guidance is intended to encourage manufacturers of medically necessary drug products and any components of those products to develop contingency production plans to use during emergencies that result in high absenteeism at production facilities. The guidance provides recommendations regarding considerations for the development and implementation of a contingency production plan, including specific elements to include in such a plan.

11. Affected public (*Mark primary with "P" and all others that apply with "x"):*

a. ___ Individuals or households d. ___ Farms

b. _X_ Business or other for-profit e. ___ Federal Government

c. ___ Not-for-profit institutions f. ___ State, Local or Tribal Government

12. Obligation to respond (*check one*):

a. [X] Voluntary- (guidance document)

b. [ ] Required to obtain or retain benefits

c. [ ] Mandatory

13. Annual recordkeeping and reporting burden:

a. Number of respondents 70

b. Total records & responses 70 & 2

1. Percentage of these responses collected electronically: Undetermined because new program, but could be 100%.

c. Total hours requested 35,032

d. Current OMB inventory 0

e. Difference

f. Explanation of difference: This is a new collection

1. Program change

2. Adjustment

14. Annual reporting and recordkeeping cost burden *(in thousands of dollars)*

a. Total annualized capital/startup costs

b. Total annual costs (O&M)

c. Total annualized cost requested

d. Current OMB inventory

e. Difference

f. Explanation of difference

1. Program change

2. Adjustment

15. Purpose of information collection (*Mark primary with "P" and all others that apply with "X"*):

a. __ Application for benefits e. X Program planning or management

b. __ Program evaluation f.__ Research

c. __ General purpose statistics g. P Regulatory or compliance

d. __ Audit

16. Frequency of recordkeeping or reporting *(check all that apply):*

a. [X] Recordkeeping b. [ ] Third party disclosure

c. [X] Reporting

1. [x] On occasion 2. [ ] Weekly 3. [ ] Monthly

4. [ ] Quarterly 5. [ ] Semi-annually 6. [ ] Annually

7. [ ] Biennially 8. [ ] Other (describe)

17. Statistical methods

Does this information collection employ statistical methods

[ ] Yes [x] No

18. Agency Contact (person who can best answer questions regarding the content of this submission)

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