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

OMB Control Number 0910–0675—Extension

This information collection supports recommendations found in Agency guidance. Specifically, we have developed guidance intended to encourage manufacturers of drug and therapeutic biological products, and any raw materials and components used in those products, to 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 entitled, ''Planning for the Effects of High Absenteeism to Ensure Availability of Medically Necessary Drug Products,'' discusses the elements that should be covered by such a Plan, and is available from our website at: *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/planning-effects-high-absenteeism-ensure-availability-medically-necessary-drug-products.*

In the **Federal Register** of October 25, 2019 (84 FR 57448), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Activate/deactivate Plan as recommended in the guidance	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 [1]

Activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeper	Total hours
Develop initial Plan as recommended in the guidance	70	1	70	250	17,500

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

As explained in the guidance, we provide recommendations for developing and implementing a written Plan, including: (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 also encourages manufacturers to include and document procedures in the Plan for notifying the FDA 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 identifies the information that should be included in these notifications, such as which drug products will be manufactured under altered procedures, which products' manufacturing will be temporarily delayed, and any anticipated or potential drug shortages. We assume two notifications (for purposes of this analysis, we consider an activation and a deactivation notification to equal one notification) will be submitted to CDER annually, and assume each notification requires 16 hours to prepare and submit.

Finally, 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 and the broader Plan to comprise one Plan for each manufacturer. Based on available data on the number of manufacturers that would be covered by the guidance, we previously estimated 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 would take approximately 500 hours to develop. Upon development of the plan, however, we believe fewer hours are necessary to maintain and update it as needed. As FDA issued the guidance in 2011, we now assume that most respondents have developed the recommended plan, and therefore we limit our current burden estimate to updates and maintenance. Accordingly, we have reduced our estimate by half, reasoning that, although it takes fewer hours for updates and maintenance, new respondents may choose to adopt recommendations found in the guidance.

Dated: January 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01992 Filed 1–31–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–1072]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Application for Participation in Food and Drug Administration Fellowship and Traineeship Programs

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 March 4, 2020.

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 *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0780. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Application for Participation in FDA Fellowship and Traineeship Programs; OMB Control Number 0910–0780—Revision

Sections 1104, 1302, 3301, 3304, 3320, 3361, 3393, and 3394 of Title 5 of the United States Code authorize Federal Agencies to rate applicants for Federal jobs. The proposed information collection involves brief online applications completed by applicants applying to FDA's Fellowship and Traineeship programs. These voluntary online applications will allow the Agency to easily and efficiently elicit and review information from students and healthcare professionals who are interested in becoming involved in FDA-wide activities. The process will reduce the time and cost of submitting written documentation to the Agency and lessen the likelihood of applications being misrouted within the Agency mail system. It will assist the Agency in promoting and protecting the public health by encouraging outside persons to share their expertise with FDA.

In the **Federal Register** of October 19, 2018 (83 FR 53065), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it wasn't responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Medical Device Fellowship Program	250	1	250	1	250
FDA Traineeship Program	1,000	1	1,000	1	1,000
Reagan-Udall Fellowship at FDA	50	1	50	1	50
Total					1,300

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

Because FDA is developing two new training programs, Trainee Program and Reagan-Udell Fellowship, our estimated burden for the information collection reflects an overall increase of 2 hours. FDA has removed the Commissioner Fellowship and Regulatory Science Internship Program from this information collection as the programs have been discontinued.

Dated: January 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–01989 Filed 1–31–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; The National Health Service Corps Loan Repayment Programs, OMB No. 0912–0127 Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this Notice has closed.

DATES: Comments on this Information Collection Request must be received no later than March 4, 2020.

ADDRESSES: Submit your comments, including the ICR Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The National Health Service Corps Loan Repayment Programs, OMB No. 0915–0127 Revision.

Abstract: The National Health Service Corps (NHSC) Loan Repayment Program (LRP) was established to assure an adequate supply of trained primary care health professionals to provide services in the neediest Health Professional Shortage Areas (HPSAs) of the United States. The NHSC Substance Use