Survey of Drug Product Manufacturing, Processing, and Packing Facilities—21 CFR parts 210 and 211

OMB Control Number 0910–NEW

FDA has the responsibility to regulate the safety, as well as the efficacy and quality, of drugs in the United States. Under the Food and Drug Administration Safety and Innovation Act, enacted in 2012, the term current good manufacturing practice (CGMP) includes the implementation of oversight and controls over the manufacturing, processing, and packing of drugs to ensure quality, including managing the risk of, and establishing the safety of, raw materials used in the manufacture of drugs. The safety and availability of drugs can be affected by raw material suppliers, the material supply chain, and the facility's controls over raw material quality. Risk management enables manufacturers to make proper choices and ensure the continued suitability of these materials and supply chains. The Agency needs to better understand how manufacturers, processors, and packers of drug products approach managing risks related to components, containers, and closures as well as the supply and distribution chains between the producers of raw materials and drug product manufacturers, processors, and packers. Such information will allow FDA to examine the potential economic impact of changes to regulations that govern the manufacturing, processing, and packing of drugs.

In the **Federal Register** of September 18, 2020 (85 FR 58370), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited and therefore will not be discussed in this document.

This is a one-time information collection, the primary purpose of which is to collect industry-wide data on how facilities that manufacture, process, and pack drug products for use in humans and/or animals ensure the quality of their operations, including their current risk management approaches and practices for ensuring the quality and suitability of the drug components, containers, and closures that they use. FDA intends to use this information to inform its economic analyses of potential updates to CGMPs for human and animal drug product manufacturing, processing, and packing facilities under 21 CFR parts 210 and 211. Survey respondents will be contacted by email or, if necessary, by regular mail. Respondents will be able to take the survey online or, if requested, they can return a hard copy by mail. FDA estimates the maximum burden of this collection of information as follows:

TABLE 1.—ESTIMATED BURDEN HOURS FOR ONE-TIME DATA COLLECTION[1]

Type of respondent/facility	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Group 1: Facilities in United States engaged in drug manufacturing (in addition to other possible activities).	394	1	394	1.1	433
Group 2: Facilities in United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.).	333	1	333	0.75 (45 minutes)	250
Group 3: Facilities outside United States engaged in drug manufacturing (in addition to other possible activities).	407	1	407	2.20	895
Group 4: Facilities outside United States *not* engaged in manufacturing but engaged in other forms of drug processing or packing (e.g., labeling, repacking, etc.).	261	1	261	1.5	392
Total	1,395		1,395		1,970

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

Burden hours are based on pretests of the survey and interviews with industry representatives and reflect the time required by each type of respondent to read the survey invitation and instructions and complete the survey questions. The total estimated one-time burden hours are 1,970.

Dated: January 11, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Faculty Loan Repayment Program; OMB No. 0915–0150—Revision

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

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 ICR should be received no later than February 16, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain*. Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

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: When submitting comments or requesting information, please include the ICR title for reference.

Information Collection Request Title: Faculty Loan Repayment Program

OMB No.: 0915–0150—Revision.

Abstract: HRSA's Bureau of Health Workforce administers the Faculty Loan Repayment Program (FLRP). FLRP provides degree-trained health professionals from disadvantaged backgrounds based on environmental and/or economic factors the opportunity to enter into a contract with the HHS in exchange for the repayment of qualifying educational loans for a minimum of 2 years of service as a full-time or part-time faculty member at eligible health professions schools.

A 60-day notice published in the **Federal Register** on October 6, 2020, vol. 85, No. 194; pp. 63120–21. There were no public comments.

Need and Proposed Use of the Information: The information collected will be used to evaluate applicants' eligibility to participate in FLRP and to monitor FLRP related activities. The FLRP intends to include a Disadvantaged Background (DB) form in the FLRP application. FLRP applicants are required to provide certification from a health professions school previously attended that identifies the individual as coming from an economically or environmentally disadvantaged background. In the past, applicants provided this information in varying formats. The DB form is not requesting new information from FLRP applicants. The form will allow an easier method for applicants to compete and convey their DB status and will standardize the collection of information. The information collected will be used to evaluate applicants' rank and tier in the FLRP award process.

Likely Respondents: FLRP applicants and institutions providing employment to the applicants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

Total Estimated Annualized burden hours:

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Eligible Applications	186	1	186	1	186
Institution/Loan Repayment Employment Form	*186	1	186	1	186
Authorization to Release Information Form	186	1	186	.25	46.5
Disadvantaged Background Form	186	1	186	.20	37.2
Total	744		744		455.70

*Respondent for this form is the institution for the applicant.

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–00808 Filed 1–14–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–0990–0263]

Agency Information Collection Request. 60-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before March 16, 2021.

ADDRESSES: Submit your comments to *Sherrette.Funn@hhs.gov* or by calling (202) 795–7714.

FOR FURTHER INFORMATION CONTACT: When submitting comments or requesting information, please include the document identifier 0990–0263–60D, and project title for reference, to Sherrette Funn, the Reports Clearance Officer, *Sherrette.funn@hhs.gov,* or call 202–795–7714.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collection: Incident Report Form—the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form.

Type of Collection: OMB No. 0990–0263 Office of the Assistant Secretary for Health, Office for Human Research Protections.

Abstract: The Office of the Assistant Secretary for Health, Office for Human Research Protections is requesting is requesting a three-year extension of the Protection of Human Subjects: Assurance Identification/IRB Certification/Declaration of Exemption Form, OMB No. 0990–0263.

This form will facilitate prompt reporting of specific human subject