21 CFR part; guidance; or FDA form	Topic	OMB control No.
801 and 809	Labeling	0910–0485
''Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices''.	CLIA waiver	0910–0598
807, subparts A through D	Registration and listing	0910–0625
''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff''.	Q-submissions	0910–0756
''De Novo Classification Process (Evaluation of Automatic Class III Designation)''.	De Novo classification process	0910–0844

Dated: December 11, 2017.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2017–26987 Filed 12–14–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Rural Health Opioid Program Grant Performance Measures, OMB No. 0906–xxxx–New

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

ACTION: Notice

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this ICR should be received no later than February 13, 2018.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Rural Health Opioid Program Grant Performance Measures.

OMB No. 0906–xxxx–New.

Abstract: The Rural Health Opioid Program aims to promote rural health care services outreach by expanding the delivery of opioid related health care services to rural communities. The program will work to reduce the morbidity and mortality related to opioid overdoses in rural communities through the development of broad community consortiums to prepare individuals with opioid-use disorder to start treatment, implement care coordination practices to organize patient care activities, and support individuals in recovery through the enhancement of behavioral counselling and peer support activities.

Need and Proposed Use of the Information: For this program, performance measures were drafted to provide data to the program and to enable HRSA to provide aggregate program data required by Congress under the Government Performance and Results Act (GPRA) of 1993. These measures cover the principal topic areas of interest to the Federal Office of Rural Health Policy (FORHP), including: (a) Target population demographics; (b) referrals to substance abuse treatment; (c) substance abuse treatment process and outcomes; (d) education of health care providers and community members; and (e) rates of fatal and non-fatal opioid-related overdose. All measures will speak to FORHP's progress toward meeting the goals set.

Likely Respondents: The respondents would be recipients of the Rural Health Opioid Program grant funding.

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
Rural Health Opioid Program Grant Performance Measures	10	1	10	11	110
	10		10		110

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.

Amy McNulty,

Acting Director, Division of the Executive Secretariat.

[FR Doc. 2017–27013 Filed 12–14–17; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Determination Concerning a Petition To Add a Class of Employees to the Special Exposure Cohort

AGENCY: National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention, Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: HHS gives notice of a determination concerning a petition to add a class of employees from the Carborundum Company, in Niagara Falls, New York, to the Special Exposure Cohort (SEC) under the Energy Employees Occupational Illness Compensation Program Act of 2000 (EEOICPA).

FOR FURTHER INFORMATION CONTACT: Stuart L. Hinnefeld, Director, Division of Compensation Analysis and Support, National Institute for Occupational Safety and Health (NIOSH), 1090 Tusculum Avenue, MS C–46, Cincinnati, OH 45226–1938, Telephone 1–877–222–7570. Information requests can also be submitted by email to *DCAS@CDC.GOV.*

SUPPLEMENTARY INFORMATION:

Authority: [42 U.S.C.7384q].

On November 16, 2017, the Acting Secretary of HHS determined that the following class of employees does not meet the statutory criteria for addition to the SEC as authorized under EEOICPA:

All employees who worked in any area of the Carborundum Company facility on Buffalo Avenue, Niagara Falls, New York, from January 1, 1943, through December 31, 1976.

John Howard,

Director, National Institute for Occupational Safety and Health.

[FR Doc. 2017–27039 Filed 12–14–17; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Research Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Findings of research misconduct have been made on the part of Matthew Endo, former graduate student, Department of Chemistry, University of Illinois at Urbana-Champaign. The questioned research was supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM080436. The administrative actions, including three (3) years of supervision, which are implemented beginning on November 16, 2017, are detailed below.

FOR FURTHER INFORMATION CONTACT: Wanda K. Jones, Dr.P.H., Interim Director, Office of Research Integrity, 1101 Wootton Parkway, Suite 750, Rockville, MD 20852, (240) 453–8200.

SUPPLEMENTARY INFORMATION: Notice is hereby given that the Office of Research Integrity (ORI) has taken final action in the following case:

Matthew Endo, University of Illinois at Urbana-Champaign: Based on the Respondent's admission, an assessment conducted by University of Illinois at Urbana-Champaign (UIUC), and analysis conducted by ORI in its oversight review, ORI found that Mr. Matthew Endo, a former graduate student, Department of Chemistry, UIUC, engaged in research misconduct in research supported by National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH), grant R01 GM080436.

ORI found that Respondent engaged in research misconduct by intentionally, knowingly, or recklessly causing false data to be recorded, falsifying and/or fabricating data and related images by alteration and/or reuse and/or relabeling of experimental data, and reporting falsified and/or fabricated data in one (1) manuscript subsequently submitted for publication:

- ''Amphotericin primarily kills human cells by binding and extracting cholesterol.'' Submitted for publication to the *Proceedings of the National Academy of Sciences* [withdrawn prior to peer review] (hereafter referred to as ''Manuscript 1'')

Specifically, ORI found that:

- In Manuscript 1, Respondent caused falsified and/or fabricated results to be recorded by knowingly requesting biological testing of a mixture of compounds that he falsely claimed to be a single compound
- In Manuscript 1, Respondent falsified and/or fabricated the results on page S26 of the Supporting Information by modifying the HPLC trace through peak erasure to make the preparation of C35deOAmB appear more pure than in the actual results of experimentation
- In Manuscript 1, Respondent falsified and/or fabricated the results of Surface Plasmon Resonance data on page S7 of the Supporting Information to make the error bars smaller than the actual results of experimentation
- In Manuscript 1, Respondent falsified and/or fabricated the results of a WST08 Cell Proliferation Assay on page S32 of the Supporting Information by falsely claiming to run the reaction in triplicate when it was only performed in duplicate
- In correspondence with his advisor, Respondent falsified and/or fabricated the results of the preparation of putative C2deoAmB where Respondent modified and relabeled a HPLC trace and relabeled an NMR spectrum to falsely claim characterization, purity, and identification of sample that was sent for biological assay

Mr. Endo entered into a Voluntary Settlement Agreement and voluntarily agreed for a period of three (3) years, beginning on November 16, 2017:

(1) To have his research supervised; Respondent agreed to ensure that prior to the submission of an application for PHS support for a research project on which Respondent's participation is proposed and prior to Respondent's participation in any capacity on PHS-supported research, the institution employing him must submit a plan for supervision of Respondent's duties to ORI for approval; the plan for supervision must be designed to ensure the scientific integrity of Respondent's research contribution; Respondent agreed that he will not participate in any PHS-supported research until a plan for supervision is submitted and approved by ORI;

(2) that any institution employing him must submit in conjunction with each application for PHS funds, or report, manuscript, or abstract involving PHS supported research in which Respondent is involved, a certification to ORI that the data provided by Respondent are based on actual experiments or are otherwise legitimately derived and that the data, procedures, and methodology are