

Ron A. Otten,

Director, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2013-12978 Filed 5-31-13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention

[CDC-2013-0007; NIOSH-233]

NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2014: Proposed Additions and Deletions to the NIOSH Hazardous Drug List

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

ACTION: Notice of Draft Document Available for Public Comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC) announces the availability of the following draft document for public comment entitled “NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2014: Proposed Additions and Deletions to the NIOSH Hazardous Drug List.” The document and instructions for submitting comments can be found at <http://www.regulations.gov>.

This guidance document does not have the force and effect of law.

Public Comment Period: Comments must be received by August 2, 2013.

ADDRESSES: You may submit comments, identified by CDC-2013-0007 and Docket Number NIOSH-233, by either of the two following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, Ohio 45226.

Instructions: All information received in response to this notice must include the agency name and the docket number (CDC-2003-0007; NIOSH-233). All relevant comments received will be posted without change to <http://www.regulations.gov>, including any personal information provided. All electronic comments should be

formatted as Microsoft Word. Please make reference to CDC-2013-0007 and Docket Number NIOSH-233.

SUPPLEMENTARY INFORMATION:

Background: The NIOSH Alert: Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings was published in September 2004 (<http://www.cdc.gov/niosh/docs/2004-165/>). This Alert contained Appendix A which was a list of drugs that were deemed to be hazardous and may require special handling. This list of hazardous drugs was updated in 2010 and 2012 and covered all new approved drugs and drugs with new warning up to December 2009. (<http://www.cdc.gov/niosh/docs/2010-167/>; <http://www.cdc.gov/niosh/docs/2012-150/>). Between January 2010 and December 2011, 48 new drugs received FDA approval and 276 drugs received special warnings (usually black box warnings) based on reported adverse effects in patients. From this list of 324 drugs, 42 drugs were identified by NIOSH as candidate hazardous drugs. Four of these drugs had safe handling recommendations from the manufacturer and NIOSH is following the recommendations of the manufacturers. Therefore, these four drugs will be listed as hazardous without requiring further review. A panel consisting of peer reviewers and stakeholders was asked to review and comment on the remaining 38 potentially hazardous drugs. In addition, the panel members were asked to comment on the addition of one drug requested by several stakeholders and the removal of one drug from the 2012 Hazardous Drug List. Reviewers were not asked to provide a consensus opinion and NIOSH made the final determination regarding additions and deletions to the 2014 hazardous drug list.

NIOSH reviewed the recommendations of the peer reviewers and stakeholders and determined that 24 drugs in addition to the 4 drugs with manufacturer’s warnings, were determined to have one or more characteristics of a hazardous drug and this list of 28 drugs is being published for comment in CDC-2013-0007 and NIOSH Docket Number 233. In addition, 1 drug from the 2012 Hazardous Drug List is being considered for removal. The complete list of these drugs can be found at: <http://www.regulations.gov> as a supporting document.

FOR FURTHER INFORMATION CONTACT: Barbara MacKenzie, NIOSH, Robert A. Taft Laboratories, 4676 Columbia Parkway, MS-C26, Cincinnati, Ohio

45226, telephone (513) 533-8132, Email hazardousdrugs@cdc.gov.

Dated: May 24, 2013.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health
Agency Information Collection Activities; Proposed Collection; Comment Request: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery, National Institute of Neurological Disorders and Stroke (NINDS)

SUMMARY: As part of a Federal Government-wide effort to streamline the process to seek feedback from the public on service delivery, the National Institute of Neurological Disorders (NINDS) has submitted a Generic Information Collection Request (Generic ICR): “Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery” to OMB for approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 et. seq.).

DATES: Comments must be submitted within 30 days after publication in the **Federal Register**.

ADDRESSES: Written comments may be submitted to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attn: NIH Desk Officer, by Email to OIRA_submission@omb.eop.gov, or by fax to 202-395-6974.

FOR FURTHER INFORMATION CONTACT: To request additional information, please contact: Paul Scott, Ph.D., Director, Office of Science Policy and Planning, NINDS, 31/8A03 Center Drive, Bethesda, MD 20892-2178, or Email your request, including your address to scottp@ninds.nih.gov.

SUPPLEMENTARY INFORMATION:

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

Abstract: The information collection activity will garner qualitative customer and stakeholder feedback in an efficient, timely manner, in accordance with the Administration’s commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on perceptions and opinions,

but are not statistical surveys that yield quantitative results that can be generalized to the population of study. This feedback will provide insights into customer or stakeholder perceptions, experiences and expectations, provide an early warning of issues with service, or focus attention on areas where communication, training or changes in operations might improve delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between the Agency and its customers and stakeholders. It will also allow feedback to contribute directly to the improvement of program management.

Feedback collected under this generic clearance will provide useful information, but it will not yield data that can be generalized to the overall population. This type of generic clearance for qualitative information will not be used for quantitative information collections that are designed to yield reliably actionable results, such as monitoring trends over time or documenting program performance. Such data uses require more rigorous designs that address: the target population to which generalizations will be made, the sampling frame, the sample design (including stratification and clustering), the precision requirements or power calculations that justify the proposed sample size, the expected response rate, methods for assessing potential non-response bias, the protocols for data collection, and any testing procedures that were or will be undertaken prior fielding the study. Depending on the degree of influence the results are likely to have, such collections may still be eligible for submission for other generic mechanisms that are designed to yield quantitative results.

No comments were received in response to the 60-day notice published in the **Federal Register** of December 22, 2010 (75 FR 80542).

Below we provide NINDS's projected average estimates for the next three years:

Current Actions: New collection of information.

Type of Review: New Collection.

Affected Public: Individuals and Households, Businesses and Organizations, State, Local or Tribal Government.

Average Expected Annual Number of activities: 6.

Respondents: 14,700.

Annual responses: 24,700.

Frequency of Response: Once per request for 5 activities, twice per request for 1 activity.

Average minutes per response: 57.

Burden hours: 5750.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid Office of Management and Budget control number.

Dated: May 24, 2013.

Story Landis,

Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting hosted by the NIH Scientific Management Review Board (SMRB). Presentations and discussions will address optimal approach to assessing the value of biomedical research supported by NIH.

The NIH Reform Act of 2006 (Pub.L. 109-482) provides organizational authorities to HHS and NIH officials to: (1) Establish or abolish national research institutes; (2) reorganize the offices within the Office of the Director, NIH including adding, removing, or transferring the functions of such offices or establishing or terminating such offices; and (3) reorganize, divisions, centers, or other administrative units within an NIH national research institute or national center including adding, removing, or transferring the functions of such units, or establishing or terminating such units. The purpose of the SMRB is to advise appropriate HHS and NIH officials on the use of these organizational authorities and identify the reasons underlying the recommendations.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Scientific Management Review Board (SMRB).

Date: June 4, 2013.

Time: 8:00 a.m. to 6:30 p.m.

Agenda: The meeting topics will include: 1) an update from the SMRB's Value of Biomedical Research Working Group, and 2)

presentations that explore approaches to studying the value of biomedical research. Time will be allotted on the agenda for public comment. Sign up for public comments will begin approximately at 7:30 a.m. on June 4, 2013, and will be restricted to one sign-in per person. In the event that time does not allow for all those interested to present oral comments, any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Place: National Institutes of Health, Building 1, 3rd Floor, Wilson Hall, 1 Center Drive, Bethesda, MD 20892.

Contact Person: Juanita Marnier, Office of Science Policy, Office of the Director, NIH, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20892. smrb@mail.nih.gov, (301) 435-1770.

This notice is being published less than 15 days prior to the meeting due to scheduling conflicts with the presenters.

The meeting will also be webcast. The draft meeting agenda and other information about the SMRB, including information about access to the webcast, will be available at <http://smrb.od.nih.gov>.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals From Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: May 30, 2013.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Co-Exclusive Licenses: Multi-Focal Structured Illumination Microscopy Systems and Methods

AGENCY: National Institutes of Health, HHS.