



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB review; 30-day comment request

National Toxicology Program (NTP) Level of Concern Categories Study (NIEHS)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH) has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the Federal Register on August 19, 2015 (80 Fed. Reg. 50298) and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of Environmental Health Sciences (NIEHS), NIH may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

DIRECT COMMENTS TO OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget,

Office of Regulatory Affairs, OIRA_submission@omb.eop.gov or by fax to 202-395-6974, Attention: NIH Desk Officer.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project contact: Dr. Kristina Thayer, Director of the Office of Health Assessment and Translation, Division of National Toxicology Program, NIEHS, P.O. Box 12233, Mail Drop K2-04, Research Triangle Park, NC 27709, or call non-toll-free number (919) 541-5021, or E-mail your request, including your address, to: thayer@niehs.nih.gov. Formal requests for additional information must be requested in writing.

PROPOSED COLLECTION: National Toxicology Program (NTP) Level of Concern Categories, 0925-NEW, National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH).

Need and Use of Information Collection: The NTP has used a 5-point level of concern (LoC) framework to communicate NTP's assessment of the degree of concern regarding the potential human health effects of selected substances given what is known about their toxicity, level of human exposure, and pharmacokinetics. As part of its systematic review methodologies, the NTP is updating its LoC framework to enhance

transparency in what the LoC categories mean, describing the factors considered in reaching conclusions and identifying strategies for improving their use as a risk communication tool. This study will use expert solicitation from five NTP stakeholder sectors (academia, industry, non-government organizations, and federal and state agencies) to aid in determining the optimal number of LoC categories for an updated LoC framework. Information about this project was presented to the NTP Board of Scientific Counselors on June 16, 2015. Materials describing the project, including slides and summary minutes from the meeting, are available at <http://ntp.niehs.nih.gov/go/9741>.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 620.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondent	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden hour
Study Consent	Experts	200	1	6/60	20
LoC “Cards”	Experts	200	2	90/60	600
Total		200	600		620

Dated: January 28, 2016

Jane M. Lambert, CIP

Project Clearance Liaison, NIEHS, NIH

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