TABLE 2—FEES FOR ORIGINAL AND SUBSEQUENT EXPORT CERTIFICATES

Type of certificate	Fee (dollars)
Original certificates (may be multiple in number) [1]	175
All subsequent certificates issued for the same product(s) in response to the same request [1]	85

[1] As calculated under formula.

Under its formula for calculating applicable fees, CDRH has allowed multiple devices to be included in a single certificate rather than requiring that each device have a separate certificate for which a fee is charged. While CDRH will continue to allow multiple devices to be included in a single certificate, it is revising the formula by which the number of original device export certificates (at $175 per certificate) and subsequent certificates (at $85 per certificate) will be calculated. The number of original and subsequent device export certificates will be calculated using a revised formula that sets the maximum pages per certificate to 25 pages (the certificate page and a maximum of 24 pages for any attachments). Previously, the maximum number of pages was 50. If the request is more than 25 pages, then the total number of pages created by the request is divided by 25 and that number will be the number of original certificates that will be charged at $175 and the remaining number of subsequent certificates will be charged at $85 each. For example, if you request 15 certificates and each certificate has 12 attachment pages plus the certificate page that means each certificate is 13 pages, and your request will generate 195 pages in all. This number of pages is divided by 25 and that equals 7.8, which is rounded to 8. Therefore, you will be charged for 8 original certificates at $175 each and 7 subsequent certificates at $85 each. Please note the maximum number of attachment pages is 24 pages. If you have more than 24 pages you will need to split the request into two or more requests.

III. Request for Comments

Although the EREA does not require FDA to solicit comments on the assessment and collection of fees for export certificates, FDA is inviting comments from interested persons in order to have the benefit of additional views.

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. The Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in sections 801(e) and 802 of the FD&C Act have been approved under OMB control number 0910–0498.

Dated: August 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–20429 Filed 8–18–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request; Information Program on Clinical Trials: Maintaining a Registry and Results Databank (NLM)

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 June 10, 2015, page 32968 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 Library of Medicine (NLM), National Institutes of Health, 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 Contact: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: David Sharlip, Office of Administrative and Management Analysis Services, National Library of Medicine, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll-free number (301) 402–9680, or Email your request, including your address to: *sharlipd@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Information Program on Clinical Trials: Maintaining a Registry and Results Databank (NLM), 0925–0586, Expiration Date 08/31/2015, EXTENSION, National Library of Medicine (NLM), National Institutes of Health (NIH).

Need and Use of Information Collection: The National Institutes of Health operates ClinicalTrials.gov, which was established as a clinical trial registry under section 113 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) and was expanded to include a results data bank by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA). ClinicalTrials.gov collects registration and results information for clinical trials and other types of clinical studies (*e.g.,* observational studies and patient registries) with the objectives of enhancing patient enrollment and providing a mechanism for tracking subsequent progress of clinical studies, to the benefit of public health. It is widely used by patients, physicians, and medical researchers; in particular those involved in clinical research.

While many clinical studies are registered and submit results information voluntarily, FDAAA requires the registration of certain applicable clinical trials of drugs and devices and the submission of results information for completed applicable clinical trials of drugs and devices that are approved, licensed, or cleared by the Food and Drug Administration. Beginning in 2009, results information was required to include information about serious and frequent adverse events.

This extension request does not include any changes to the information submission requirements for ClinicalTrials.gov that were proposed in the Notice of Proposed Rulemaking on Clinical Trial Registration and Results Submission that was issued on November 21, 2014 and for which the public comment period closed on March 23, 2015 (79 FR 225, Nov. 21, 2014). The NIH is continuing to review submitted public comments as it prepares the final rule. The NIH will make any corresponding changes to the ClinicalTrials.gov information collection via separate procedure.

OMB approval is requested for 3 years. There are no costs to respondents other than there their time. The total estimated annualized burden hours are 682,535.

ESTIMATED ANNUALIZED BURDEN HOURS

Submission type	Number of respondents	Number of responses per respondent	Average time per response (in hours)	Total annual hour burden
PRS Account	5,700	1	15/60	1,425
Initial Registration	23,000	1	7	161,000
Updates	23,000	8	2	368,000
Initial Results	3,700	1	25	92,500
Updates	3,700	2	8	59,200
Certification to Delay Results	700	1	30/60	350
Extension Request	30	1	2	60

Dated: August 13, 2015.

David Sharlip,

Project Clearance Liaison, NLM, NIH.

[FR Doc. 2015–20473 Filed 8–18–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; National Toxicology Program (NTP) Level of Concern Categories Study (NIEHS)

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and 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 Email your request, including your address to: *thayer@niehs.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: National Toxicology Program 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 National Toxicology Program (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.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 300.