DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

[CDC–2013–0009; Docket Number NIOSH–264]

National Institute for Occupational Safety and Health (NIOSH) Traumatic Injury Research and Prevention Program and Strategic Goals; Draft Document Availability

AGENCY: The 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 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 a draft document entitled *National Institute for Occupational Safety and Health (NIOSH) Traumatic Injury Research and Prevention Program and Strategic Goals* now available for public comment. To view the notice and related materials, visit *http://www.regulations.gov* and enter CDC–2013–0009 in the search field and click ''Search.''

Public comment period: Comments must be received September 16, 2013 from publication of the **Federal Register** Notice.

ADDRESSES: You may submit comments, identified by CDC–2013–0009 and Docket Number NIOSH–264, 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 docket number (CDC–2013–0009; NIOSH–264). 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–2013–0009 and Docket Number NIOSH–264.

SUPPLEMENTARY INFORMATION: The purpose of this review is to receive public comments and input on a draft document entitled ''NIOSH Traumatic Injury Research and Prevention Program and Strategic Goals.'' This document includes revisions to program strategic goals last updated in 2009. The draft strategic goals are intended to guide NIOSH intramural and extramural research for the 5-year period, 2014–2019. NIOSH is seeking comments on: (1) The relevance of the draft strategic goals; (2) suggested areas where research is needed or no-longer needed; (3) the adequacy of the goals for addressing the changing workplace and emerging hazards that threaten the safety of workers; (4) the adequacy of proposed performance measures; (5) opportunities for collaboration between NIOSH scientists, extramural scientists, and state occupational public health programs; and (6) input on additional potential partners the NIOSH Traumatic Injury Program could work with to enhance future directions of the NIOSH Traumatic Injury Research and Prevention Program.

Background: The strategic goals in the Plan are largely based on fatal and nonfatal surveillance data, and address the following areas:

(1) Reduce Falls in the workplace

(2) Reduce Occupational Injuries and Deaths due to Motor-Vehicle Incidents and Crashes

(3) Reduce Occupational Injuries and Deaths due to Workplace Violence

(4) Reduce Occupational Injuries and Deaths due to Machines and Industrial Vehicles

(5) Reduce Occupational Injuries and Deaths among High Risk and Vulnerable Worker Groups, and

(6) Increase use of Surveillance Data to Guide Occupational Traumatic Injury Research and Prevention Efforts.

FOR FURTHER INFORMATION CONTACT: Dawn Castillo, NIOSH, Division of Safety Research, Mailstop H–1900, 1095 Willowdale Road, Morgantown, West Virginia 26505–2888. Ms. Castillo may be contacted at (304) 285–5894 or Email at *DCastillo@cdc.gov.*

Dated: June 7, 2013.

John Howard,

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

[FR Doc. 2013–14133 Filed 6–14–13; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Community Living

Agency Information Collection Activities: Submission for OMB Review; Comment Request; Alzheimer's Disease Supportive Services Program—Data Reporting Tool

AGENCY: Administration for Community Living, HHS.

ACTION: Notice.

SUMMARY: The Administration on Aging (AoA), Administration for Community Living (ACL) is announcing an opportunity to comment on the proposed collection of information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice collects comments on the information collection requirements relating to the continuation of an existing collection for the Alzheimer's Disease Supportive Services Program.

DATES: Submit written comments on the collection of information by August 16, 2013.

ADDRESSES: Submit written comments on the collection of information by email to *Jane.Tilly@acl.hhs.gov*

FOR FURTHER INFORMATION CONTACT: Jane Tilly 202.357.3438

SUPPLEMENTARY INFORMATION: The Alzheimer's Disease Supportive Services Program (ADSSP) is authorized through Sections 398, 399 and 399A of the Public Health Service (PHS) Act, as amended by Public Law 101–557 Home Health Care and Alzheimer's Disease Amendments of 1990. The ADSSP helps state efforts to expand the availability of community-level supportive services for persons with Alzheimer's disease and their caregivers, including underserved populations. In compliance with the PHS Act, ACL revised an ADSSP Data Reporting Tool (ADSSP–DRT) in 2010. The ADSSP–DRT collects information about the delivery of direct services by ADSSP state grantees, as well as basic demographic information about service recipients. This version includes some revisions to the approved 2010 version. The revised version would be in effect beginning 8/31/2013 and thereafter.

The proposed FY2013 ADSSP–DRT can be found on AoA's Web site at:

http://www.aoa.gov/AoARoot/AoA_Programs/HPW/Alz_Grants/docs/ADSSP_DataCollectionReportingForm_proposed.xls.

ACL estimates the burden of this collection of information as follows:

ANNUAL BURDEN ESTIMATES

Instrument	Type of respondent	Number of respondents	Responses per respondent	Burden hours per response	Total burden hours (annual)
ADSSP Data Reporting Tool	Local Program Site	60	2	5.8	696
ADSSP Data Reporting Tool	State Grantee	30	2	8	480

Estimated Total Annual Burden Hours: 1176.

Dated: June 11, 2013.

Kathy Greenlee,

Administrator & Assistant Secretary for Aging.

[FR Doc. 2013–14189 Filed 6–14–13; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0662]

Agency Information Collection Activities: Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug: Patent Submission and Listing Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements for submission and listing of patent information associated with a new drug application (NDA), an amendment, or a supplement.

DATES: Submit either electronic or written comments on the collection of information by August 16, 2013.

ADDRESSES: Submit electronic comments on the collection of information to *http://www.regulations.gov*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., P150–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA'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 respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Applications for FDA Approval To Market a New Drug: Patent Submission and Listing Requirements and Application of 30-Month Stays on Approval of Abbreviated New Drug Applications Certifying That a Patent Claiming a Drug Is Invalid or Will Not Be Infringed—(OMB Control Number 0910–0513)—Extension

Section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(b)(1)) requires all NDA applicants to file, as part of the NDA, ''the patent number and the expiration date of any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.'' Section 505(c)(2) of the FD&C Act (21 U.S.C. 355(c)(2)) imposes a similar patent submission obligation on holders of approved NDAs when the NDA holder could not have submitted the patent information with its application. Under section 505(b)(1) of the FD&C Act, we publish patent information after approval of an NDA in the list entitled ''Approved Drug Products With Therapeutic Equivalence Evaluations'' (the Orange Book). If patent information is submitted after NDA approval, section 505(c)(2) of the FD&C Act directs us to publish the information upon its submission.

FDA regulations at §§ 314.50(h) (21 CFR 314.50(h)) and 314.53 (21 CFR 314.53) clarify the types of patent information that must and must not be submitted to FDA as part of an NDA, an amendment, or a supplement, and require persons submitting an NDA, an amendment, or a supplement, or submitting information on a patent after NDA approval, to make a detailed patent declaration using Forms FDA 3542 and 3542a.

The reporting burden for submitting an NDA, an amendment, or a supplement in accordance with § 314.50