Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2014–04939 Filed 3–5–14; 8:45 am]

BILLING CODE 4150–05–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS–OS–21524–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990–0278, which expires on June 30, 2014. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before May 5, 2014.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier HHS–OS–21524–60D for reference.

Information Collection Request Title: Federalwide Assurance Form—Extension OMB No. 0990–0278, Assistant Secretary for Health, Office for Human Research Protections.

OMB No.: 0990–0278

Abstract: The Office for Human Research Protections is requesting a three year extension of the Federalwide Assurance (FWA). The FWA is designed to provide a simplified procedure for institutions engaged in HHS-conducted or supported research to satisfy the assurance requirements of Section 491(a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR 46.103. The respondents are institutions engaged in human subjects research that is conducted or supported by HHS.

Need and Proposed Use of the Information: The information collected by OHRP through the FWA is the minimum necessary to satisfy the assurance requirements of the Public Health Service Act and the requirements of HHS regulations at 45 CFR 46.103.

Likely Respondents: Research institutions engaged in HHS-conducted or -supported research involving human subjects.

Burden Statement: The estimate of the hours per response assumes that virtually all respondents will complete the FWA form via the internet on an interactive page on the OHRP Web site. The time estimate includes an estimate of the time needed to (i) read and understand the instructions for completing the FWA; (ii) read and understand the FWA terms of assurance; and (iii) enter the information requested on the FWA form. 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	Average burden per response (in hours)	Total burden hours
Federalwide Assurance (FWA)	11,050	2	30/60	11,050
Total				11,050

OS 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.

Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2014–04933 Filed 3–5–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–20762–30D]

Agency Information Collection Activities; Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Assistant Secretary for Financial Resources, Office of Grants and Acquisition Policy and Accountability, Division of Acquisition, Department of Health and Human Services, has submitted an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB) for review and approval. The ICR is for a new collection. There were no comments received during the first public review of this ICR. OMB will accept further comments from the public on this ICR during the review and approval period.

DATES: Comments on the ICR must be received on or before April 7, 2014.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the Information Collection Request Title and document identifier HHS–OS–20762–30D for reference.

Information Collection Request Title: HHSAR 352.227–11 Patent Rights—Exceptional Circumstances and 352.227–14 Rights in Data—Exceptional Circumstances

Abstract: HHS found that systematically, over a period of several years, when Determinations of Exceptional Circumstances (DECs) were executed, additional legal protection for the patent and data rights of third parties beyond those covered by FAR were necessary. A decision was made to add two clauses—352.227–11 Patent Rights—Exceptional Circumstances and 352.227–14 Rights in Data—Exceptional Circumstances—to the HHS supplement to the FAR, the HHS Acquisition Regulation (HHSAR), to provide the additional legal protection required. These clauses would ensure that providers of proprietary material(s) to the government will retain all their preexisting rights to their material(s), and rights to any inventions made under a contract or subcontract (at all tiers), when a DEC has been executed. Rights in data regulations concern the rights of the Government, and organizations with which the Government contracts, to information developed under such contracts. The delineation of such rights is necessary in order to protect the contractor's rights to not disclose proprietary data and to insure that non-proprietary data developed with public funds is available to the public. As these HHSAR clauses would be used in lieu of the related FAR clauses, the clauses also address the patent and data rights currently covered in FAR clauses 52.227–11 and 52.227–14 prescribed under FAR part 27. It is the policy and objective of the Government to: (1) Use the patent system to promote the use of inventions arising from federally supported research or development; (2) Encourage maximum participation of industry in federally supported research and development efforts; (3) Ensure that these inventions are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; (4) Promote the commercialization and public availability of the inventions made in the United States by United States industry and labor; (5) Ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and (6) Minimize the costs of administering patent policies.

Need and Proposed Use of the Information: In order to accomplish the objectives described above through the clauses, it will be necessary to collect the information described below. All submissions are considered critical to the Government ensuring the patent and data rights of the Contractor, Government and third parties are protected appropriately.

Likely Respondents: It is anticipated that the respondents to the collection of information will be the prime contractor(s), subcontractor(s) and third party providers for contracts awarded that include the two clauses 352.227–11 Patent Rights—Exceptional Circumstances and 352.227–14 Rights in Data—Exceptional Circumstances.

Identify type of respondents: It is anticipated that technical, legal, management and administrative personnel from the prime contractor(s), subcontractor(s) and providers of third party materials for contracts awarded that include the two clauses 352.227–11 Patent Rights—Exceptional Circumstances and 352.227–14 Rights in Data—Exceptional Circumstances will provide the responses to the information collection required.

Burden Statement: Clause 352.227–11 contains the following information collections.

(a) A request for a determination of whether the Contractor or the employer inventor is entitled to retain such greater rights must be submitted to the Agency Contracting Officer;

(b) The Contractor shall disclose in writing each Subject Invention to the Agency Contracting Office and to the Director, Division of Extramural Inventions and Technology Resources (DEITR);

(c) The Contractor agrees to execute or to have executed and promptly deliver to the Agency all instruments necessary to: 1. Establish or confirm the rights the Government has throughout the world in Subject Inventions . . . and 2. convey title to a Third party assignee . . . and enable the Third party assignee to obtain patent protection throughout the world in that Subject Invention;

(d) The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each Subject Invention made under contract;

(e) The Contractor agrees to provide a final invention statement and certification prior to the close-out of the contract listing all Subject Inventions or stating that there were none;

(f) The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under subparagraph b.3. has been granted by the Agency; and

(g) All invention disclosures and requests for greater rights shall be sent to the Agency Contracting officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications under this funding agreement at all tiers must be sent to . . . *http://www.iEdison.gov*. Clause 352.227–14 contains the following two collections of information.

(h) ''Accordingly, the Contractor will provide the Contracting Officer a copy of any proposed publication or other public disclosure relating to the proposed publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure.'' This information collection is being done to insure that the Contractor does not prematurely publish information concerning possible inventions made under this contract so that the ability to obtain patent protection on such inventions is adversely affected.

(i) ''The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings.'' This information collection is being done to preserve the Government's right to cancel or ignore the markings at any time after the stated period, making the data no longer subject to any disclosure prohibitions.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Information collection (see above list ''Burden statement'' for legend)	Number of Respondents	Number of responses per respondent	Average burden per response (hours)	Total burden hours
(a)	63	1	8	504
(b)	63	1	12	756
(c)	63	3	12	2268
(d)	63	3	14	2646
(e)	63	1	10	630
(f)	63	1	8	504
(g)	63	3	8	1512
(h)	63	3	3	567
(i)	63	3	8	1512
Total	63	19	83	10,899

Darius Taylor,

Deputy, Information Collection Clearance Officer.

[FR Doc. 2014–04931 Filed 3–5–14; 8:45 am]

BILLING CODE 4150–24–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee, Centers for Disease Control and Prevention: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Public Law 92–463) of October 6, 1972, that the Clinical Laboratory Improvement Advisory Committee, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), has been renewed for a 2-year period through February 19, 2016.

For information, contact Devery Howerton, Ph.D., Designated Federal Officer, Clinical Laboratory Improvement Advisory Committee, 1600 Clifton Road NE., Mailstop E–56, Atlanta, Georgia 30333, telephone 404–498–2602 or via email at *dxh7@cdc.gov*.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2014–04935 Filed 3–5–14; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0237]

Report to Congress; Report on the Food and Drug Administration's Policy To Be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices; Notice to Public of Web Site Location of Report to Congress

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is announcing the Web site location where the Agency has posted the report entitled ''Report to Congress; Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices.'' In addition, FDA has established a docket where stakeholders may provide comments.

DATES: Submit either electronic or written comments by June 4, 2014.

ADDRESSES: Submit electronic comments on this document to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Mike Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background

The Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) became law on July 9, 2012. FDASIA added section 510(n)(2) to the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360(n)(2)). This new provision requires, no later than 18 months after enactment of FDASIA, the Secretary of Health and Human Services to submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on when a premarket notification under section 510(k) of the FD&C Act (or a ''510(k)'') should be submitted for a modification to a legally marketed 510(k) device. This report fulfills that requirement.

This notice announces the Web site location of ''Report to Congress; Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices.'' FDA invites interested persons to submit comments on this report. FDA has established a docket where comments may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. To access ''Report to Congress; Report on FDA's Policy to be Proposed Regarding Premarket Notification Requirements for Modifications to Legally Marketed Devices,'' visit FDA's Web site *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm269873.htm*.

II. Request for Comments

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