Web sites provide some labeling, FDA believes that most do not provide the label and package insert for all of their home-use devices listed with FDA.

II. CDRH Home Use Device Labeling Pilot

CDRH is developing an electronic submissions database, accessible to the public through FDA's Web site, of labels and package inserts for listed home-use devices. This database would fill an important gap in the information available to patients, caregivers, and the healthcare community concerning home-use devices. The database would allow both broad searches to identify legally marketed home-use devices that may fill a particular need and focused searches to obtain information concerning the use of a specific home-use device.

This electronic submissions database will be evaluated for usability through the CDRH Home Use Device Labeling Pilot Project. This pilot project will proceed for 6 months. Participation in the pilot is open to applicants who label their device(s) for home use. Participants will be asked to navigate through the electronic submissions system and practice submitting labels and package inserts. The pilot project is intended to provide industry and CDRH staff the opportunity to evaluate the submissions process and system and to receive comments from industry participants. Comments received during the pilot project will be used to evaluate the usability of the database. FDA will not review the content of any labeling submitted to the pilot database for a regulatory purpose. The submitted labeling and the database will only be available to pilot participants.

A. Participation

Volunteers interested in participating in the pilot project should contact pilot staff by email at *Mary.Brady@fda.hhs.gov.* The following information should be included in the request: Contact name, contact phone number, and contact email address. FDA will contact interested applicants to discuss the pilot project. FDA is seeking a limited number of participants (no more than nine) to participate in this pilot project.

B. Procedures

By following a series of prompts and instructions, pilot participants will submit a PDF version of their device labeling to the pilot database. The content of the submissions will not be reviewed by FDA for any regulatory purpose, nor will the pilot database be available to the public during this pilot project. During the pilot, CDRH staff will be available to answer any questions or concerns that may arise. Pilot project participants will be asked to comment on and discuss their experiences with the pilot submissions process. Their comments and discussions will assist CDRH in its development of this electronic submissions database.

III. Duration of the Home Use Device Labeling Pilot

FDA intends to accept requests for participation in the Home Use Device Labeling Pilot from May 1, 2015, through May 31, 2015. The pilot will proceed for 6 months, from July 1, 2015, through December 31, 2015. This pilot program may be extended as resources and needs allow.

IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in FDA regulations. 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 21 CFR parts 801 and 809 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit electronic comments regarding the Home Use Device Labeling Pilot to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. 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.*

Dated: April 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08957 Filed 4–17–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990–0392–30–D]

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

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), 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 renewal of the approved information collection assigned OMB control number 0990–0392, scheduled to expire on May 31, 2015. Comments submitted during the first public review of this ICR will be provided to OMB. 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 May 20, 2015.

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 OMB control number 0990–0392 and document identifier HHS–OS0990–0392–30D for reference.

Information Collection Request Title: Office of Adolescent Health and Administration for Children, Youth and Families Teen Pregnancy Prevention Performance Measure Collection.

Abstract: The Office of Adolescent Health (OAH), U.S. Department of Health and Human Services (HHS) is requesting an extension without change of a currently approved information collection request by OMB. The purpose of the extension is to complete the ongoing data collection for the Office of Adolescent Health and Administration for Children, Youth and Families Teen Pregnancy Prevention Performance Measures.

Need and Proposed Use of the Information: To collect performance measure data on the OAH Teen

Pregnancy Prevention (TPP) Program and the ACF/FYSB Personal Responsibility Education Program Innovative Strategies (PREIS). These data will allow OAH and FYSB to monitor the progress of program grantees, and to report to Congress on the performance of the programs.

Likely Respondents: The 106 TPP and PREIS grantees and approximately 2000 PREIS youth participants.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information.

The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Forms (if necessary)	Type of respondent	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Measures for all grantees	Grantee program staff—all	106	1	7	742
Participant-level measures	Grantee program staff—Tier 1 C/D, Tier 2, and PREIS.	45	1	1	45
Perceived impact questions	Youth participants—PREIS	2,000	1	5/60	167
Perceived impact measures	Grantee program staff—PREIS	11	1	3	33
Total					987

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2015–08960 Filed 4–17–15; 8:45 am]

BILLING CODE 4168–11–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS–0990–0260–30D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant 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 0990–0260, which expires on April 30, 2015. 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 20, 2015.

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 0990–0260 for reference.

Information Collection Request Title: Protection of Human Subjects: Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/ Informed Consent/Consent Documentation—Extension OMB No. 0990–0260, Assistant Secretary for Health, Office for Human Research Protections.

OMB No.: 0990–0260.

Abstract: The information collected through the Protection of Human Subjects: Assurance. *Identification/IRB Certification/ Declaration of Exemption Form Protection of Human Subjects:* Assurance of Compliance with Federal Policy/IRB Review/IRB Recordkeeping/ Informed Consent/Consent Documentation collection requirement is the minimum necessary to satisfy the assurance, certification, reporting, disclosure, documentation and recordkeeping requirements of Section 491(a) of the Public Health Service Act and HHS Regulations for the protection of human subjects at 45 CFR part 46.

Likely Respondents: Research institutions engaged in HHS-conducted or -supported research involving human subjects. Institutional use of the form is also relied upon by other federal departments and agencies that have codified or follow the Federal Policy for the Protection of Human Subjects (Common Rule).

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Title	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
.103(b)(4), .109(d)IRB Actions, .116 and .117 Informed Consent	6,000	39.33	1	235,980
.115(a) IRB Recordkeeping	6,000	15	10	900,000
.103(b)(5) Incident Reporting, .113 Suspension or Termination Reporting	6,000	0.5	45/60	2,250
Total				1,138,230