COST OF REGISTRATION—Continued

Affiliation	Before July 19, 2015	July 19–August 18, 2015	After August 18, 2015
Student Member	280	280	280
Student Nonmember*	310	310	310

* For this member type, online registration is not available and must be faxed in.

Please visit PDA's Web site: *www.pda.org/pdafda2015* to confirm the prevailing registration fees. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

If you need special accommodations due to a disability, please contact Wanda Neal (see *Contact*), at least 7 days in advance of the conference.

Registration Instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and email address, along with a check or money order payable to ''PDA.'' Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., Suite 150, Bethesda, MD 20814. To register via the Internet, go to PDA's Web site: *www.pda.org/pdafda2015.*

The registrar will also accept payment by major credit cards (VISA/American Express/MasterCard only). For more information on the meeting, or for questions on registration, contact PDA (see *Contact*).

Transcripts: As soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION: The PDA/FDA Joint Regulatory Conference offers the unique opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices, including:

- Product Quality
- Data Integrity
- Breakthrough Therapies
- Regulatory Challenges and Opportunities
- Lifecycle Management
- Clinically Relevant Specifications
- Food and Drug Administration Safety and Innovation Act
- Quality Metrics/Quality Culture
- Manufacturing of the Future With Submissions
- Continuous Verification and Validation
- Continuous Manufacturing
- ''Fishbowl'' Role Play
- Quality Systems
- Contract Manufacturing Organizations
- Maturity of Quality Systems
- Investigations
- Case Studies for Quality
- Quality Submissions
- Prescription Drug User Fee Act
- Risk-Based Control Strategies
- Supply Chain
- Quality Risk Management Systems
- Drug Shortages
- Customer Complaint Reviews and Trending
- Human Factors
- Office of Pharmaceutical Quality and Program Alignment Group
- Patient Perspective
- Compliance Update
- Center Initiatives—Regulatory Submission Update

To help ensure the quality of FDA-regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

Dated: March 4, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05513 Filed 3–11–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0253]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Drug Experience Reporting and Recordkeeping Biological Products

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 information collection provisions of FDA's postmarketing adverse drug experience reporting and recordkeeping requirements.

DATES: Submit either electronic or written comments on the collection of information by May 11, 2015.

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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@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.

Postmarketing Adverse Drug Experience Reporting (OMB Control Number 0910–0230)—(Extension)

Sections 201, 502, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 352, 355, and 371) require that marketed drugs be safe and effective. In order to know whether drugs that are not safe and effective are on the market, FDA must be promptly informed of adverse experiences associated with the use of marketed drugs. In order to help ensure this, FDA issued regulations at §§ 310.305 and 314.80 (21 CFR 310.305 and 314.80) to impose reporting and recordkeeping requirements on the drug industry that would enable FDA to take the action necessary to protect the public health from adverse drug experiences.

All applicants who have received marketing approval of drug products are required to report to FDA serious, unexpected adverse drug experiences (''15-day Alert reports''), as well as follow up reports (§ 314.80(c)(1)). This includes reports of all foreign or domestic adverse experiences as well as those based on information from applicable scientific literature and certain reports from postmarketing studies. Section 314.80(c)(1)(iii) pertains to such reports submitted by non-applicants.

Under § 314.80(c)(2), applicants must provide periodic reports of adverse drug experiences. A periodic report includes, for the reporting interval, reports of serious, expected adverse drug experiences and all nonserious adverse drug experiences and an index of these reports, a narrative summary and analysis of adverse drug experiences, an analysis of the 15-day Alert reports submitted during the reporting interval, and a history of actions taken because of adverse drug experiences. Under § 314.80(i), applicants must keep for 10 years records of all adverse drug experience reports known to the applicant.

For marketed prescription drug products without approved new drug applications or abbreviated new drug applications, manufacturers, packers, and distributors are required to report to FDA serious, unexpected adverse drug experiences as well as follow-up reports (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of follow-up reports to reports forwarded to the manufacturers, packers, and distributors by FDA. Under § 310.305(f), each manufacturer, packer, and distributor shall maintain for 10 years records of all adverse drug experiences required to be reported.

The primary purpose of FDA's adverse drug experience reporting system is to enable identification of signals for potentially serious safety problems with marketed drugs. Although premarket testing discloses a general safety profile of a new drug's comparatively common adverse effects, the larger and more diverse patient populations exposed to the marketed drug provide the opportunity to collect information on rare, latent, and long-term effects. Signals are obtained from a variety of sources, including reports from patients, treating physicians, foreign regulatory agencies, and clinical investigators. Information derived from the adverse drug experience reporting system contributes directly to increased public health protection because the information enables FDA to make important changes to the product's labeling (such as adding a new warning), decisions about risk evaluation and mitigation strategies or the need for postmarket studies or clinical trials, and when necessary, to initiate removal of a drug from the market.

Respondents to this collection of information are manufacturers, packers, distributors, and applicants. The following estimates are based on FDA's knowledge of adverse drug experience reporting, including the time needed to prepare the reports, and the number of reports submitted to the Agency.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1] [2]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
310.305(c)(5)	3	1	3	1	3
314.80(c)(1)(iii)	5	1	5	1	5
314.80(c)(2)	724	19.33	13,996	60	839,760
Total					839,768

[1] The reporting burden for § 310.305(c)(1), (c)(2), and (c)(3), and § 314.80(c)(1)(i) and (c)(1)(ii) is covered under OMB Control No. 0910–0291.
[2] The capital costs or operating and maintenance costs associated with this collection of information are approximately $25,000 annually.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1] [2]

21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
310.305(f)	25	1	25	16	400
314.80(i)	724	508	367,959	16	5,887,344
Total					5,887,744

[1] There are no capital costs or operating costs associated with this collection of information.
[2] There are maintenance costs of approximately $22,000 annually.

Dated: March 6, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–05591 Filed 3–11–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces a meeting for the initial review of applications in response to DP15–007, Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males.

Time and Date: 9:00 a.m.—6:00 p.m., April 7–9, 2015 (Closed).

Place: Teleconference.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92–463.

Matters for Discussion: The meeting will include the initial review, discussion, and evaluation of applications received in response to ''Effectiveness of Teen Pregnancy Prevention Programs Designed Specifically for Young Males'', DP15–007.

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway, NE., Mailstop F–80, Atlanta, Georgia 30341, Telephone: (770) 488–3585, *EEO6@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. 2015–05575 Filed 3–11–15; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

[Document Identifier: HHS–OS–0990—New–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, announces plans to submit a new Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the 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 11, 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 HHS–OS–0990—New–60D for reference.

Information Collection Request Title: HHS Entrepreneurs-in-Residence Program (EIR).

Abstract: The HHS IDEA Lab, in the Immediate Office of the Secretary, is requesting an approval by Office of Management and Budget (OMB) on a new information collection, which is critical to the success of the HHS EIR program, and identifies private sector entrepreneurs with unique skill sets not available in government to join HHS for a year to work on critical initiatives. The information collection for the HHS EIR custom form management system involves obtaining candidate resumes and responses to short essay questions specifically designed to determine whether entrepreneurs have the knowledge, skills and abilities to successfully complete HHS EIR projects in the government context and mentor existing government staff to acquire new, entrepreneurial skills.

Likely Respondents: The candidate pools, targeted for the HHS EIR program are serial private sector entrepreneurs with no prior federal government experience.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
HHS EIR Application	150	1	1	150
Total	150	1	1	150