TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of record-keepers	Number of records per record-keeper	Total annual records	Average burden per record-keeping	Total hours
1140.32 (Format and content requirements for labeling and advertising)	1	1	1	1	1
Total					1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
1140.32	1	1	1	1	1

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden hour estimates for this collection of information were based on industry-prepared data and information regarding pharmaceutical advertising and cigarette and smokeless tobacco product advertising expenditures. The burden collection does not include reporting burdens associated with providing established names on labels and statements of intended use because section 102 of the Tobacco Control Act required that these provisions be struck from the reissued final rule (previously included in 897.24 and 897.32(c)).

Section 1140.30 (previously 897.30) requires manufacturers, distributors, and retailers to observe certain format and content requirements for labeling and advertising, and requires manufacturers, distributors, and retailers to notify FDA if they intend to use an advertising medium that is not listed in the regulations. The concept of permitted advertising in 1140.30 is sufficiently broad to encompass most forms of advertising. FDA estimates that approximately 300 respondents will submit an annual notice of alternative advertising, and the Agency has estimated it should take 1 hour to provide such notice.

For the recordkeeping and disclosure requirements, 1140.32 (previously 897.32) requires competent and reliable survey evidence to establish whether a newspaper, magazine, periodical, or other publication qualifies as an ''adult'' publication. Section 1140.32 also requires the use of a black text on a white background for labeling and advertising. The respondent and hourly burden for recordkeeping and disclosure under this section (2 burden hours total) reflect placeholders for the number of manufacturers who would keep records under this section.

During the next 3 years, FDA does not intend to enforce the recordkeeping and disclosure requirements of 1140.32 and has revised the burden to act as a placeholder in the event FDA exercises its authority to enforce the requirements of this section in the future.

FDA estimates that the total time required for this collection of information is 302 hours.

Dated: September 21, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–23833 Filed 9–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Gastrointestinal Drugs Advisory Committee; Notice of Postponement of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is postponing the Gastrointestinal Drugs Advisory Committee Meeting scheduled for October 15, 2012. This meeting was announced in the **Federal Register** of August 16, 2012 (77 FR 49446). The postponement is due to scheduling issues.

FOR FURTHER INFORMATION CONTACT: Cindy Hong, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, Fax: 301–847–8533, email: *GIDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), or visit our Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: September 25, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2012–23885 Filed 9–27–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; CareerTrac

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Fogarty International Center (FIC), National Institute of General Medical Science (NIGMS), National Cancer Institute (NCI), and National Library of Medicine (NLM) of the National Institutes of Health (NIH), in conjunction with the National Institute of Environmental Health Sciences (NIEHS), including the Intramural Research and Training Award (IRTA) and Superfund Research Program (SRP) within NIEHS, has submitted to the Office of Management and Budget (OMB) for review and approval. This proposed information collection was previously published in the **Federal Register**, Vol. 77, No. 106, on June 1, 2012, pages 32648–32649 and allowed 60 days for public comment. One public comment was received from the Association for Research in Vision and Ophthalmology (ARVO). The

purpose of this notice is to allow an additional 30 days for public comment. NIH 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.

Proposed Collection: Title: CareerTrac. *Type of Information Collection Request:* REVISION (OMB NO.: 0925–0568). *Need and Use of Information Collection:* This data collection system is being developed to track, evaluate and report short and long-term outputs, outcomes, and impacts of international trainees involved in health research training programs—specifically tracking this for at least ten years following training by having Principal Investigators enter data after trainees have completed the program. The data collection system provides a streamlined, web-based application permitting Principal Investigators to record career achievement progress by trainee on a voluntary basis. FIC, NIEHS, NCI, NLM and NIGMS management will use this data to monitor, evaluate, and adjust grants to ensure desired outcomes are achieved, comply with OMB Part requirements, respond to congressional inquiries, and guide future strategic and management decisions regarding the grant program.

Frequency of Response: Annual and periodic. *Affected Public:* None. *Type of Respondents:* Principal Investigators and/or their administrators funded by FIC, NIEHS, NCI, NIGMS, and NLM. The annual reporting burden hours are as follows:

Type of respondents	Number of respondents	Response frequency	Average time per response (in hrs)	Total annual hour burden
Principal Investigators	385	30	30/60	5,775
Total	385	30	30/60	5,775

There are no capital, operating, or maintenance costs.

Request for Comments: 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.

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: Desk Officer for NIH. To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact Dr. Rachel Sturke, Evaluation Officer, Division of Science Policy, Planning, and Evaluation, FIC, NIH, 16 Center Drive, Bethesda, MD 20892, or call non-toll-free number (301) 480–6025 or email your request, including your address to: *rachel.sturke@nih.gov*.

Comments 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.

Dated: September 14, 2012.

Dexter Collins,

Executive Officer, FIC, National Institutes of Health.

[FR Doc. 2012–23970 Filed 9–27–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

NIH Evidence-Based Methodology Workshop on Polycystic Ovary; Syndrome

Notice

Notice is hereby given of the National Institutes of Health (NIH) Evidence-based Methodology Workshop on Polycystic Ovary Syndrome, to be held December 3–5, 2012. The workshop's opening session will be on December 3, from 6:30 p.m. to 9:00 p.m. at the Bethesda Marriott Hotel, 5151 Pooks Hill Road, Bethesda, Maryland 20814. The workshop will continue December 4–5 at the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892; beginning at 8:00 a.m. on December 4 and at 8:30 a.m. on December 5. The workshop will be open to the public.

Polycystic ovary syndrome (PCOS) is a common hormone disorder that affects approximately 5 million reproductive-aged women in the United States. Women with PCOS have difficulty becoming pregnant (i.e., are infertile) due to hormone imbalances that cause or result from altered development of ovarian follicles. One such imbalance is high blood levels of androgens, which can come from both the ovaries and adrenal gland. Other organ systems that are affected by PCOS include the pancreas, liver, muscle, blood vasculature, and fat.

In addition to fertility impairment, other common symptoms of PCOS include:

- Irregular or no menstrual periods (for women of reproductive age)
- Acne
- Weight gain
- Excess hair growth on the face and body
- Thinning scalp hair
- Ovarian cysts.

Women with PCOS are often resistant to the biological effects of insulin and, as a consequence, may have high insulin levels. As such, women with PCOS are at risk for type 2 diabetes, high cholesterol, and high blood pressure. Obesity also appears to worsen the condition. Costs to the U.S. health care system to identify and manage PCOS are approximately $4 billion annually; however, this estimate does not include treatment of the serious conditions associated with PCOS.

For most of the 20th century, PCOS was a poorly understood condition. In 1990, the NIH held a conference on PCOS to create both a working definition of the disorder and diagnostic criteria. The outcome of this conference, the *NIH Criteria,* served as a standard for researchers and clinicians for more than a decade. In 2003, a consensus