

Dated: February 7, 2012.

Nicole Lurie,

Assistant Secretary for Preparedness and Response.

[FR Doc. 2012-6608 Filed 3-19-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director, Centers for Disease Control and Prevention: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the Advisory Committee to the Director, Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS), has been renewed for a 2-year period through February 1, 2014.

For information, contact Carmen Villar, M.S.W., Designated Federal Officer, Advisory Committee to the Director, CDC, HHS, 1600 Clifton Road, NE., Mailstop D-14, Atlanta, Georgia 30333, telephone 404/639-7000 or fax 404/639-7111.

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.

Dated: March 13, 2012.

Elaine L. Baker,

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

[FR Doc. 2012-6637 Filed 3-19-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee on Breast Cancer in Young Women (ACBCYW)

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 the following meeting of the aforementioned committee:

DATES: Times and Dates:
12 p.m.–5 p.m., April 18, 2012,
9 a.m.–5 p.m., April 19, 2012,

8 a.m.–12 p.m., April 20, 2012.

Place: Atlanta Marriott Perimeter Center, 246 Perimeter Center Parkway NE., Atlanta, Georgia 30346.

Status: Open to the public, limited only by the space available.

Purpose: The committee provides advice and guidance to the Secretary, HHS; the Assistant Secretary for Health; and the Director, CDC, regarding the formative research, development, implementation and evaluation of evidence-based activities designed to prevent breast cancer (particularly among those at heightened risk) and promote the early detection and support of young women who develop the disease. The advice provided by the Committee will assist in ensuring scientific quality, timeliness, utility, and dissemination of credible appropriate messages and resource materials.

Matters To Be Discussed: The agenda will include discussions on approaches to increase awareness of clinicians/practitioners regarding topics such as breast health, symptoms, diagnosis, and treatment of breast cancer in young women; and information needs and delivery mechanisms for women at higher risks for developing breast cancer.

Agenda items are subject to change as priorities dictate.

Online Registration Required: All ACBCYW attendees must register for the meeting online in advance at http://www.cdc.gov/cancer/breast/what_cdc_is_doing/meetings.htm. Please complete all the required fields before submitting your registration and submit no later than April 3, 2012.

CONTACT PERSON FOR MORE INFORMATION:

Temeika L. Fairley, Ph.D., Designated Federal Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 5770 Buford Hwy, NE., Mailstop K52, Atlanta, Georgia 30341, Telephone (770) 488-4518, Fax (770) 488-4760, Email: acbcyw@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 Agency for Toxic Substances and Disease Registry.

Dated: March 13, 2012.

Elaine L. Baker,

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

[FR Doc. 2012-6641 Filed 3-19-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): A Pilot Surveillance for High Impact/Low Prevalence Congenital and Inherited Conditions, FOA DD12-002, 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 the aforementioned meeting:

Time and Date: 11 a.m.–5 p.m., April 17, 2012 (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 to be Discussed: The meeting will include the initial review, discussion, and evaluation of applications received in response to "A Pilot Surveillance for High Impact/Low Prevalence Congenital and Inherited Conditions, FOA DD12-002, initial review."

Contact Person for More Information: M. Chris Langub, Ph.D., Scientific Review Officer, CDC, 4770 Buford Highway, NE., Mailstop F-46, Atlanta, Georgia 30341, Telephone: (770) 488-3585.

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.

Dated: March 13, 2012.

Elaine L. Baker,

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

[FR Doc. 2012-6640 Filed 3-19-12; 8:45 am]

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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

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 postmarketing adverse drug experience reporting and recordkeeping requirements.

DATES: Submit either written or electronic comments on the collection of information by May 21, 2012.

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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, Juanmanuel.Vilela@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: (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—21 CFR 310.305 and 314.80 (OMB Control Number 09109-0230)—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 occasioned by 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, as well as followup reports when needed (§ 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 nonapplicants. 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, 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 followup reports when needed (§ 310.305(c)). Section 310.305(c)(5) pertains to the submission of followup reports to reports forwarded 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 provide a signal 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. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

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)	665	22.85	15,195	60	911,700
Total					911,708

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 reported under OMB control number 0910-0291. 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

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)	665	601.5	399,998	16	6,399,968
Total					6,400,368

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

These 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.

Dated: March 15, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012-6692 Filed 3-19-12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0883]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by April 19, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written

comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0572. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-7651, *Juanmanuel.Vilela@FDA.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products—(OMB Control Number 0910-0572)—(Extension)

FDA’s final rule entitled “Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products” (the final rule), which published on January 24, 2006 (71 FR 3922), and was effective on June 30, 2006, amended FDA’s regulations governing the format and content of labeling for human prescription drug and biological products to require that the labeling of new and recently approved products contain highlights of prescribing information, a table of contents for prescribing information, reordering of

certain sections, minor content changes, and minimum graphical requirements. These revisions were intended to make it easier for health care practitioners to access, read, and use information in prescription drug labeling; to enhance the safe and effective use of prescription drug products; and to reduce the number of adverse reactions resulting from medication errors due to misunderstood or incorrectly applied drug information.

A. Summary of Prescription Drug Labeling Content and Format Requirements That Contain Collections of Information

Section 201.56 (21 CFR 201.56) requires that prescription drug labeling contain certain information in the format specified in either § 201.57 (21 CFR 201.57) or § 201.80 (21 CFR 201.80), depending on when the drug was approved for marketing. Section 201.56(a) sets forth general labeling requirements applicable to all prescription drugs. Section 201.56(b) specifies the categories of new and more recently approved prescription drugs subject to the revised content and format requirements in §§ 201.56(d) and 201.57. Section 201.56(c) sets forth the schedule for implementing these revised content and format requirements. Section 201.56(e) specifies the sections and subsections, required and optional, for the labeling of older prescription drugs not subject to the revised format and content requirements.

Section 201.57(a) requires that prescription drug labeling for new and more recently approved prescription drug products include “Highlights of