security measures are applicable. In planning your arrival to the CMS facility, we recommend allowing additional time to clear security. Attendees should arrive between 8:15 a.m. and 8:30 a.m., in order to be prompt for the 9:00 a.m. meeting. Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 8:15 a.m. (45 minutes before the convening of the meeting).

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel. Persons without proper identification may be denied access to the building.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: May 22, 2012.

Marilyn Tavenner,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–12982 Filed 5–25–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0274]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

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 June 28, 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 0910–0428. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, 301–796–5733, *domini.bean@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.

Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act—21 U.S.C. 379aa–1(b)(1) (OMB Control Number 0910–0635)—Extension

The Dietary Supplement and Nonprescription Drug Consumer Protection Act (DSNDCPA) (Pub. L. 109–462, 120 Stat. 3469) amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act) with respect to serious adverse event reporting and recordkeeping for dietary supplements and nonprescription drugs marketed without an approved application. Section 761(b)(1) of the FD&C Act (21 U.S.C. 379aa–1(b)(1)) requires the manufacturer, packer, or distributor whose name (under section 403(e)(1) of the FD&C Act (21 U.S.C. 343(e)(1))) appears on the label of a dietary supplement marketed in the United States to submit to FDA all serious adverse event reports associated with the use of a dietary supplement, accompanied by a copy of the product label. The manufacturer, packer, or distributor of a dietary supplement is required by the DSNDCPA to use the MedWatch form (FDA 3500A) when submitting a serious adverse event report to FDA. In addition, under section 761(c)(2) of the FD&C Act, the submitter of the serious adverse event report (referred to in the statute as the ''responsible person'') is required to submit to FDA a followup report of any related new medical information the responsible person receives within 1 year of the initial report.

Section 761(e)(1) of the FD&C Act (21 U.S.C. 379aa–1(e)(1)) requires that responsible persons maintain records related to the dietary supplement adverse event reports they receive, whether or not the adverse event is serious. Under the statute, the records must be retained for a period of 6 years.

As required by section 3(d)(3) of the DSNDCPA, FDA issued guidance to describe the minimum data elements for serious adverse event reports for dietary supplements. In the **Federal Register** of July 14, 2009 (74 FR 34024), FDA announced the availability of guidance entitled ''Guidance for Industry: Questions and Answers Regarding Adverse Event Reporting and Recordkeeping for Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act.'' The guidance discusses how, when, and where to submit serious adverse event reports for dietary supplements and followup reports. The guidance also provides FDA's recommendation on records maintenance and access for serious and non-serious adverse event reports and related documents.

The guidance recommends that the responsible person document the attempts to obtain the minimum data elements for a serious adverse event report. Along with these records, the guidance recommends that the responsible person keep the following other records: (1) Communications between the responsible person and the initial reporter of the adverse event and

between the responsible person and any other person(s) who provided information about the adverse event, (2) the responsible person's serious adverse event report to FDA with attachments, (3) any new information about the adverse event received by the responsible person, and (4) any reports to FDA of new information related to the serious adverse event report.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 U.S.C. Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
21 U.S.C. 379aa–1(b)(1)—Serious adverse event reports for dietary supplements	480	17	8,160	2	16,320
21 U.S.C. 379aa–1(c)(2)—Followup reports of new medical information	120	17	2,040	1	2,040
Total					18,360

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

This estimate is based on FDA's experience with similar adverse event reporting programs and the number of serious adverse event reports and followup reports received in the past 2 years. All dietary supplement manufacturers, packers, or distributors are subject to serious adverse event mandatory reporting. In 2007, we estimated in the final rule entitled ''Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements'' (72 FR 34752, June 25, 2007) that there were 1,460 such firms. FDA estimates that, in 2012, there are approximately 1,600 such firms, based on the estimate of 1,460 provided in the rule, with a 2 to 3 percent annual rate of growth applied.

FDA received 830 initial serious adverse event reports in FY 2010. The number of reports more than doubled to 1,777 in FY 2011. We expect this trend to continue and, in fact, increase due to continued industry compliance with mandatory reporting rules. Based on this, FDA expects to receive over the next 3 years an increasing number of reports per year: We estimate that we will receive 3,500 in 2012; 7,000 in 2013; and 14,000 in 2014; for an annual average of 8,166.66 per year, rounded to 8,160. Based on the Agency's records, the average number of initial reports per year on a per firm basis during 2010 and 2011 was 17. Thus, FDA estimates that, on average over the next 3 years, 480 firms will file 17 initial dietary supplement serious adverse event reports, for a total of 8,160 total annual responses.

FDA estimates that it will take respondents an average of 2 hours per report to collect information about a serious adverse event associated with a dietary supplement and report the information to FDA on Form FDA 3500A. Thus, the estimated total annual hour burden of initial dietary supplement serious adverse event reports is 16,320 hours (8,160 responses $\times$ 2 hours) as shown in row 1 of table 1 in this document.

If a respondent that has submitted a serious adverse event report receives new information related to the serious adverse event within 1 year of submitting the initial report, the respondent must provide the new information to FDA in a followup report. FDA estimates that 25 percent of serious adverse event reports related to dietary supplements will have a followup report submitted, resulting in approximately 2,040 followup reports submitted annually ($8,160 \times 0.25 = 2,040$). Assuming that 25 percent of submitters of initial reports will submit followup reports ($480 \times 0.25 = 120$) and the average number of followup reports per year per firm to be 17, FDA estimates that, on average over the next 3 years, 120 firms will file 17 followup reports, for a total of 2,040 total annual responses. We estimate that each followup report will require an hour to assemble and submit, including the time needed to copy and attach the initial serious adverse event report as recommended in the guidance. The estimated total annual hour burden for followup reports of new information is 2,040 hours (2,040 responses $\times$ 1 hour) as shown in row 2 of table 1.

The total reporting hour burden is 18,360 hours, which equals the burden for the mandatory reports (16,320) plus the burden for the followup new information (2,040).

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 U.S.C. Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
(21 U.S.C. 379aa–1(e)(1))—Dietary supplement adverse event records	1,600	74	118,400	[2] 0.5	59,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 30 minutes.

All 1,600 dietary supplement manufacturers, packers, or distributors, are subject to serious adverse event mandatory recordkeeping, thus FDA estimates that there are a total of 1,600 recordkeepers. FDA further estimates that each recordkeeper will keep approximately 74 records per year, for a total of 118,400 records. The Agency estimates that assembling and filing these records, including any necessary photocopying, will take approximately 30 minutes, or 0.5 hours, per record. Therefore, 118,400 records $\times$ 0.50 hours = 59,200 total hours. FDA bases its estimates on its experience with similar adverse event reporting programs.

Once the documents pertaining to an adverse event report have been assembled and filed under the Safety Reporting Portal, FDA expects the

records retention burden to be minimal, as the Agency believes most establishments would normally keep this kind of record for at least several years after receiving the report, as a matter of usual and customary business practice.

Dated: May 22, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–12878 Filed 5–25–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Commission on Childhood Vaccines; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given of the following meeting:

Name: Advisory Commission on Childhood Vaccines (ACCV).

Date and Time: June 14, 2012, 8:30 a.m. to 11:45 a.m. EDT.

Place: Parklawn Building (and via audio conference call), Conference Room 10–65, 5600 Fishers Lane, Rockville, MD 20857.

The ACCV will meet on Thursday, June 14 from 8:30 a.m. to 11:45 a.m. (EDT). The public can join the meeting via audio conference call by dialing 1–800–369–3104 on June 14 and providing the following information:

Leader's Name: Dr. Geoffrey Evans.

Password: ACCV.

Agenda: The agenda items for the June meeting will include, but are not limited to: updates from the Division of Vaccine Injury Compensation (DVIC), Department of Justice (DOJ), National Vaccine Program Office (NVPO), Immunization Safety Office (Centers for Disease Control and Prevention), National Institute of Allergy and Infectious Diseases (National Institutes of Health) and Center for Biologics, Evaluation and Research (Food and Drug Administration). A draft agenda and additional meeting materials will be posted on the ACCV Web site (*http://www.hrsa.gov/vaccinecompensation/accv.htm*) prior to the meeting. Agenda items are subject to change as priorities dictate.

Public Comment: Persons interested in attending the meeting in person or providing an oral presentation should submit a written request, along with a copy of their presentation to: Annie Herzog, DVIC, Healthcare Systems Bureau (HSB), Health Resources and Services Administration (HRSA), Room 11C–26, 5600 Fishers Lane, Rockville, Maryland 20857 or email: *aherzog@hrsa.gov.* Requests should contain the name, address, telephone number, email address, and any business or professional affiliation of the person desiring to make an oral presentation. Groups having similar interests are requested to combine their comments and present them through a single representative. The allocation of time may be adjusted to accommodate the level of expressed interest. DVIC will notify each presenter of their assigned presentation time by email, mail, or telephone. Persons who do not file an advance request for a presentation, but desire to make an oral statement, may announce it at the time of the public comment period. Public participation and ability to comment will be limited to space and time as it permits.

For Further Information Contact: Anyone requiring information regarding the ACCV should contact: Annie Herzog, DVIC, HSB, HRSA, Room 11C–26, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–6593; email: *aherzog@hrsa.gov.*

Dated: May 22, 2012.

Reva Harris,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2012–12849 Filed 5–25–12; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel; 2012–10 K and R13 Review Teleconference.

Date: June 25, 2012.

Time: 9:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Rm. 951, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, 6707 Democracy Boulevard, Democracy Two Building, Suite 957, Bethesda, MD 20892, 301–496–4773, *zhour@mail.nih.gov.*

Dated: May 21, 2012.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2012–12866 Filed 5–25–12; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Recombinant DNA Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: Recombinant DNA Advisory Committee.

Date: June 19, 2012.

Time: 9:00 a.m. to 3:30 p.m.

Agenda: The NIH Recombinant DNA Advisory Committee (RAC) will discuss selected human gene transfer protocols. Please view the meeting agenda at *http://oba.od.nih.gov/rdna_rac/rac_meetings.html* for more information.

Place: National Institutes of Health, Building 31C, 9000 Rockville Pike, 6th Floor Conference Room, Rockville, MD 20892.

Contact Person: Chezelle George, Office of Biotechnology Activities, Office of Science Policy/OD, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892, 301–496–9838, *georgec@od.nih.gov.*

OBA will again offer those members of the public viewing the meeting via webcast (see OBA Meetings Page available at *http://oba.od.nih.gov/rdna_rac/rac_meetings.html*) the opportunity to submit comments during the public comment periods. Individuals wishing to submit comments should use the comment form, which will accommodate comments up to 1500 characters, and will be available on the OBA Web site during the meeting (see OBA Meetings Page). Please limit your comments to a statement that can be read in one to two minutes. Please include your name and affiliation with your comment. Only comments submitted through the OBA Web site will be read.

OBA will read comments into the record during the public comment periods as stated on the agenda. It is not unusual for the meeting to run ahead or behind schedule due to changes in the time needed to review a protocol. It is advisable to monitor the webcast to determine when public comments will be read. Each public comment period follows a specific discussion item. OBA will