DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on April 6, 2011, between approximately 9 a.m. and 4 p.m. and on April 7, 2011, between approximately 8:30 a.m. and 3:30 p.m.

Location: Hilton Hotel, Washington DC North/Gaithersburg, 620 Perry Pkwy., Gaithersburg, MD 20877.

Contact Person: Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0314, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On the morning of April 6, 2011, the committee will meet in open session to hear updates of the research programs in the Laboratory of Bacterial Polysaccharides, Division of Bacterial, Parasitic, and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA. In the afternoon of April 6, 2011, the committee will meet in open session and will be briefed on the use of immunological markers for demonstration of effectiveness of meningococcal serogroups A, C, Y, and W–135 conjugate vaccines administered to children less than 2 years of age. On April 7, 2011, the committee will meet in open session to review and discuss approaches to licensure of meningococcal serogroup B vaccines.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee link.

Procedure: On April 6, 2011, from approximately 9 a.m to 10:50 a.m. and from approximately 12:30 p.m to 4 p.m., the meeting is open to the public. On April 7, 2011, the entire meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 30, 2011. Oral presentations from the public will be scheduled between approximately 10:20 a.m. and 10:50 a.m. and between approximately 2:30 p.m. and 3 p.m. on April 6, 2011, and between approximately 1:30 p.m. and 2 p.m. on April 7, 2011. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before March 22, 2011. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by March 23, 2011.

Closed Committee Deliberations: On April 6, 2011, between approximately 10:50 a.m. and 11:30 a.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: March 4, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5727 Filed 3–11–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Statement of Delegation of Authority

Notice is hereby given that I have delegated to the Administrator, Health Resources and Services Administration (HRSA), authority vested in the Secretary under Title XX, Section 2008(b) of the Social Security Act (42 U.S.C. 1397g(b)), as added by Section 5507(a) of the Affordable Care Act, as it pertains to the functions assigned to HRSA. This authority may be redelegated.

HRSA will consult with the Assistant Secretary for Planning and Evaluation, as appropriate, in implementing this authority.

This delegation excludes the authority to issue regulations, to establish advisory councils and committees and appoint their members, and to submit reports to Congress, and shall be exercised in accordance with the Department's applicable policies, procedures, and guidelines. In addition, I hereby affirm and ratify any actions taken by the Administrator, HRSA, or other HRSA officials, which involved

the exercise of this authority prior to the effective date of this delegation.

This delegation is effective upon date of signature.

Dated: March 4, 2011.

Kathleen Sebelius,

Secretary.

[FR Doc. 2011–5808 Filed 3–11–11; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request—Interactive Diet and Activity Tracking in AARP (iDATA): Biomarker Based Validation Study

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute (NCI), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection: Title: Interactive Diet and Activity Tracking in AARP (iDATA): Biomarker Based Validation Study.

Type of Information Collection Request: New.

Need and Use of Information Collection: The AARP-based study is one component of a multi-center biomarker validation study project involving two other large cohorts in the United States. The iDATA study involves large cohorts and provides the necessary sample size to evaluate the measurement error structure of the diet and physical activity assessment instruments and the heterogeneity of the measurement error structure across multiple and diverse study populations. The iDATA study will include 1,500 participants from the NIH–AARP Diet and Health Study and current AARP membership. The data collection instruments adhere to The Public Health Service Act, which provides authority to the Risk Factor Monitoring and Methods Branch in the Division of Cancer Control and Population Sciences and the Division of Cancer Epidemiology and Genetics. Both divisions work to reduce cancer in the U.S. population by establishing and supporting programs for the detection, diagnosis, prevention and treatment of cancer; and by collecting, identifying, analyzing and disseminating information on cancer research, diagnosis, prevention and treatment. Dietary and physical activity data will be gathered using the instruments as detailed below. In addition, biospecimen and clinic data will be also gathered.

Frequency of Response: Monthly.

Affected Public: Individuals.

Type of Respondents: U.S. adults (persons aged 50–74).

The annual reporting burden is provided for each study component as shown in the table below. There are no Capital Costs, Operating Costs, and/or Maintenance Costs to report.

TABLE 1 ESTIMATES OF ANNUAL BURDEN HOURS

[Type of respondents for all instruments: Adult participants, 50–74 years of age]

Study component	Instrument	Number of respondents	Frequency of response	Average time per response (minutes/hour)	Annual burden hours
Screening	Pre-Screening Telephone Interview (Attachment 1)	1,334	1	15/60 (.25)	334
	Clinic Eligibility Screening Interview (Attachment 3)	742	1	10/60 (.167)	124
Clinical Components	NHANES III Anthropometry (Attachment 13)	742	3	10/60 (.167)	371
	Resting Metabolic Rate—Main (Attachment 7)	742	1	30/60 (.50)	371
	Resting Metabolic Rate—Subsample (Attachment 7)	34	1	30/60 (.50)	17
	Fasting Blood Protocol and Form (Attachment 5)	742	2	10/60 (.167)	247
	Fitness test Protocol and Form (Attachment 10)	742	1	15/60 (.25)	186
	Physical Activity Readiness Questionnaires—PAR–Q or PARmed-X (Attachments 11A–11B).	742	1	5/60 (.083)	62
	Doubly Labelled Water—Main (Attachment 6)	742	1	40/60 (.667)	495
	Doubly Labelled Water—Subsample (Attachment 6)	34	1	40/60 (.667)	23
Dietary Questionnaires	Automated Self-Administered 24-hour Dietary Recall (ASA24) (Attachment 32).	742	6	30/60 (.50)	2,227
	4-Day Food Record (Attachment 17)	742	2	60/60 (1.0)	1,485
	Diet History Questionnaire (DHQ*Web-II) (Attachment 33).	742	2	45/60 (.75)	1,114
	7-Day Food Checklist (Attachment 16)	742	2	60/60 (1.0)	1,485
Physical Activity Questionnaires.	Activities Completed over Time in 24 Hours (ACT24) (Attachment 34).	742	6	30/60 (.50)	2,227
	Community Healthy Activities Model Program for Seniors (CHAMPS) (Attachment 19).	742	2	15/60 (.25)	371
	Harvard Lifestyle Validation Study Physical Activity Questionnaire (Attachment 18).	742	2	10/60 (.167)	247
	Sedentary Behaviors Questionnaire (Attachment 21)	742	2	20/60 (.33)	495
	Stanford physical activity Survey (Attachment 22)	742	2	8/60 (.133)	198
	NIH–AARP physical activity questions (Attachment 20).	742	2	10/60 (.167)	247
Home Collections	24 Hour Urine Collection Log (Attachment 14)	742	2	60/60 (1.0)	1,485
	Saliva Protocol and Form (Attachment 15)	742	3	10/60 (.167)	371
	Heart Rate Monitor Log (Attachment 8)	34	1	35/60 (.583)	20
	Physical Activity Monitor Log (Accelerometer/Inclinometer) (Attachment 12).	742	2	35/60 (.583)	866
Total					15,060