AI/AN/NA American Indian/Alaska Native/Native American

ANA Administration for Native Americans

BIA Bureau of Indian Affairs

Division Staff Division and/or Operating Division

EO Executive Order

FACA Federal Advisory Committee Act

FR **Federal Register**

HHS U.S. Department of Health and Human Services

NAAAC Native American Affairs Advisory Council

OPDIV Operating Divisions of HHS

SPOC Single Point of Contact

TFWG Tribal/Federal Workgroup

U.S. United States

U.S.C. United States Code

15. Policy Review

ACF shall review and, if necessary, revise its Tribal Consultation Policy no less than every 2 years. Should ACF determine that the policy requires revision, the TFWG will be convened to develop the revisions.

16. Retention of Executive Branch Authorities

Nothing in this policy waives the Government's deliberative process privilege, including when the Department is specifically requested by Members of Congress to respond to or report on proposed legislation. The development of such responses and related policy documents is a part of the deliberative process by the Executive Branch and should remain confidential.

Nothing in the Policy creates a right of action against the Department for failure to comply with this Policy nor creates any right, substantive or procedural, enforceable at law by a party against the United States, its agencies, or any individual.

17. Effective Date

This policy is effective on the date of signature by the Assistant Secretary for Children and Families and shall apply to all ACF program offices.

Dated: August 18, 2011.

George H. Sheldon,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2011–22825 Filed 9–7–11; 8:45 am]

BILLING CODE 4184–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0002]

Endocrinologic and Metabolic Drugs 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). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs 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 November 2, 2011, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel telephone number is 301–589–5200.

Contact Person: Paul Tran, 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, *e-mail: EMDAC@fda.hhs.gov,* 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 November 2, 2011, the committee will discuss supplemental new drug applications 21–687 and 21–445, VYTORIN (ezetimibe/simvastatin) and ZETIA (ezetimibe) tablets, respectively, MSP (Merck/Schering-Plough) Singapore Company, LLC. Simvastatin lowers lipids (fats that circulate in the bloodstream, including cholesterol) by inhibiting 3-hydroxy-3-methyl-glutaryl-CoA reductase, which is an enzyme involved in producing lipids in the body, and ezetimibe lowers lipids by inhibiting the absorption of cholesterol from the intestine. The proposed indication (use) of ZETIA in combination with simvastatin or VYTORIN is to reduce major cardiovascular events in patients with chronic kidney disease based on the results of the Study of Heart and Renal Protection (SHARP). SHARP was a clinical trial that studied the effect of VYTORIN compared with placebo on the occurrence of major cardiovascular events in patients with chronic kidney disease who did not have a history of myocardial infarction or coronary revascularization (heart bypass surgery or opening heart vessels with a balloon or stents). The primary outcome of major cardiovascular events was defined as the first occurrence of either nonfatal myocardial infarction, cardiac death, stroke, or coronary or noncoronary revascularization (including nontraumatic amputation). The primary analysis demonstrated that assignment to VYTORIN significantly reduced the relative risk of a major cardiovascular event by 16% compared to placebo.

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: 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 October 19, 2011. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. 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 October 11, 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 October 12, 2011.

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 Paul Tran 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: September 1, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–22863 Filed 9–7–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; Comment Request; The SSA–NIH Collaboration To Improve the Disability Determination Process: Validation of IRT–CAT Tools

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 Clinical Center, 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: The SSA–NIH Collaboration to Improve the Disability Determination Process: Validation of IRT–CAT tools. *Type of Information Collection Request:* NEW. *Need and Use of Information Collection:* The Epidemiology and Biostatistics section in RMD will be collecting information through a contractor (Boston University—Health and Disability Research Institute (BU–HDR)) and subcontractor for validation of the Computer Adaptive Tests which are being developed to assist in the SSA disability determination process. The utilization of CAT technology could potentially allow the SSA to collect more relevant and precise data about human functioning in a faster, more efficient fashion. To validate the CAT assessments that have been developed, the contractor will administer both the BU–HDR CAT and established legacy instruments in a small sample of adults who report their current employment status as ''permanently disabled''. Individuals will complete the CAT tools for the functional domains of Physical Demands and Interpersonal Interactions along with established legacy instruments. For the domain of physical function, individuals will complete the BU–HDR CAT; the PROMIS Item Bank v 1.0—Physical Functioning © PROMIS Health Organization and PROMIS Cooperative Group; and The Short Form (36) Health Survey™ (SF–36). For the domain of interpersonal interactions, individuals will complete the BU–HDR CAT, the SF–36 and the BASIS–24© (Behavior and Symptom Identification Scale). Data collected will be used to validate the BU–HDR CAT tools. Without this information, completion of the BU–HDR CAT tools will not be possible. *Frequency of Response:* Once. *Affected Public:* Individuals who have opted in to participate in web surveys through a survey research firm. *Type of Respondents:* Adults who indicate ''permanently disabled'' as a working status. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report. The annual reporting burden is as follows:

A.12–1—ESTIMATES OF HOUR BURDEN

Type of respondents	Number of respondents	Frequency of response	Average time per response	Annual hour burden
Patients	1,000	1	0.5	500.00
Totals				500.00

Request for Comments: Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate 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) Evaluate 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) Enhance the quality, utility, and clarity of the information to be collected; and (4) 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.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Ms. Meghan Gleason, Rehabilitation Medicine Department, Clinical Research Center, NIH, Building 10, Room 1–2420, 9000 Rockville Pike, Bethesda, MD 20892, or call non-toll-free number (301) 443–9085 or E-mail your request, including your address to: *meghan.gleason@nih.gov.*

DATES: *Comments Due Date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: August 29, 2011.

Elizabeth K Rasch,

Chief, Epidemiology and Biostatistics Section, Rehabilitation Medicine Department, Clinical Research Center, National Institutes of Health.

[FR Doc. 2011–22999 Filed 9–7–11; 8:45 am]

BILLING CODE 4140–01–P