TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR 514.80(b)(5)	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Records and reports concerning experience with approved new animal drugs—special drug experience report	34	1	34	2	68

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

Total annual records were calculated by multiplying the number of recordkeepers times the number of records per recordkeeper. Total hours were calculated by multiplying total annual records times the average burden per recordkeeping.

In the **Federal Register** of January 17, 2012 (77 FR 2302), FDA published a 60-day notice requesting public comment on the proposed collection of information to which three comments were received: two from organizations and one from a member of Congress. The commenters generally supported the collection of sales data, and stated that this information would be useful in assessing antimicrobial drugs used in food-producing animals to better address the problem of antimicrobial resistance. One commenter stated that the information supplied by drug companies should be submitted in a format that would allow it to be easily merged with data from other FDA databases.

Beyond the scope of this **Federal Register** notice, all commenters recommended collection of antimicrobial use information in addition to the current requirements of ADUFA II sales reporting. All commenters also recommended revisions to the public reporting of the data being collected. The commenters requested FDA report sales of antimicrobial drug classes by month, by route of administration, by indication, by over-the-counter or prescription status, or grouped by their importance in human medicine. It was recommended that FDA collect and publicly report distribution information down to the state or regional level. ADUFA II requires that no class with fewer than three distinct sponsors of approved applications shall be independently reported; it was recommended that FDA seek additional authority from Congress to report sales figures for all antimicrobial classes regardless of the number of distinct drug sponsors. There was also a recommendation that all of the information collected be made publicly available in a searchable database.

FDA has considered the comments, but at this time we can only require the submission of information on the new e-form FDA 3744a that is expressly required to be submitted by section 512(l)(3) of the FD&C Act. We are pursuing notice and comment rulemaking to codify these requirements, and are currently assessing any additional data requirements. In this regard, FDA published an Advance Notice of Proposed Rulemaking on July 27, 2012, in which FDA solicited comment on the following: (1) Whether FDA should require submission of an estimate of the amount of antimicrobial ingredient sold or distributed for use in each approved food animal species, (2) how FDA can best compile and present required summary information, and (3) alternative methods there may be for obtaining additional data and information about the extent of antimicrobial drug use in food-producing animals and are there alternative methods the Agency can employ within its existing authority.

Dated: January 17, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–01446 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

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). The meeting will be open 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 February 27, 2013 between approximately 8:30 a.m. and 2:45 p.m.

Location: National Institutes of Health (NIH) Fishers Lane Conference Center, Terrace Level, Rooms 508–510, 5635 Fishers Lane, Rockville, MD, 20852. Please enter the building through the main front entrance on Fishers Lane and take the elevators down to the T-Terrace Level. For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at *http://videocast.nih.gov.*

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). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On February 27, 2013, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2013–2014 influenza season.

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 meeting 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 February 20, 2013. Oral presentations from the public will be scheduled between approximately 12:35 p.m. and 1:35 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 February 12, 2013. 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 February 13, 2013.

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: *January 22, 2013.*

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2013–01561 Filed 1–24–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

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 meetings.

The meetings 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: Population Sciences and Epidemiology Integrated Review Group, Behavioral Genetics and Epidemiology Study Section.

Date: February 20, 2013.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sir Francis Drake Hotel, 450 Powell Street at Sutter, San Francisco, CA 94102.

Contact Person: George Vogler, Ph.D., Scientific Review Officer, PSE IRG, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3140, Bethesda, MD 20892, 301–435–0694.

Name of Committee: Immunology Integrated Review Group, Immunity and Host Defense Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Dallas Marriott Suites Medical/Market Center, 2493 North Stemmons Freeway, Dallas, TX 75207.

Contact Person: Patrick K Lai, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2215, MSC 7812, Bethesda, MD 20892, 301–435–1052, *laip@csr.nih.gov.*

Name of Committee: Emerging Technologies and Training Neurosciences Integrated Review Group, Molecular Neurogenetics Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Delfina Santa Monica Hotel, 530 West Pico Boulevard, Santa Monica, CA 90405.

Contact Person: Eugene Carstea, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5194, MSC 7846, Bethesda, MD 20892, (301) 408–9756, *carsteae@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Prokaryotic Cell and Molecular Biology Study Section.

Date: February 21, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue, NW., Washington, DC 20037.

Contact Person: Dominique Lorang-Leins, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5108, MSC 7766, Bethesda, MD 20892, 301.326.9721, *Lorangd@mail.nih.gov.*

Name of Committee: Cardiovascular and Respiratory Sciences Integrated Review Group, Myocardial Ischemia and Metabolism Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Kimm Hamann, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118A, MSC 7814, Bethesda, MD 20892, 301–435–5575, *hamannkj@csr.nih.gov.*

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group, Molecular Genetics A Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Michael M Sveda, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1114, MSC 7890, Bethesda, MD 20892, 301–435–3565, *svedam@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group, Neural Oxidative Metabolism and Death Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Fairmont Hotel San Francisco, 950 Mason Street, San Francisco, CA 94108.

Contact Person: Carol Hamelink, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4192, MSC 7850, Bethesda, MD 20892, (301) 213–9887, *hamelinc@csr.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group, Gene and Drug Delivery Systems Study Section.

Date: February 21–22, 2013.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Courtyard by Marriott, 5520 Wisconsin Avenue, Chevy Chase, MD 20815.

Contact Person: Amy L Rubinstein, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5152, MSC 7844, Bethesda, MD 20892, 301–408–9754, *rubinsteinal@csr.nih.gov.*

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group, Virology–B Study Section.

Date: February 21–22, 2013.

Time: 8:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marina del Rey Hotel, 13534 Bali Way, Marina del Rey, CA 90292.

Contact Person: John C Pugh, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 1206, MSC 7808, Bethesda, MD 20892, (301) 435–2398, *pughjohn@csr.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group, Clinical Neuroimmunology and Brain Tumors Study Section.

Date: February 21–22, 2013.

Time: 8:30 a.m. to 5:00 p.m.