indication for use of an approved diagnostic radiopharmaceutical.

In response to the requirements of section 122 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), FDA published a final rule in the **Federal Register** of May 17, 1999 (64 FR 26657), amending its regulations by adding provisions that clarify the Agency's evaluation and approval of in vivo radiopharmaceuticals used in the diagnosis or monitoring of diseases. The regulation describes the kinds of indications of diagnostic radiopharmaceuticals and some of the criteria that the Agency would use to evaluate the safety and effectiveness of a diagnostic radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) (the FD&C Act) and section 351 of the Public Health Service Act (42 U.S.C. 262) (the PHS Act). Information about the safety or effectiveness of a diagnostic radiopharmaceutical enables FDA to properly evaluate the safety and effectiveness profiles of a new diagnostic radiopharmaceutical or a new indication for use of an approved diagnostic radiopharmaceutical.

The rule clarifies existing FDA requirements for approval and evaluation of drug and biological products already in place under the authorities of the FD&C Act and the PHS Act. The information, which is usually submitted as part of a new drug application or biologics license application or as a supplement to an approved application, typically includes, but is not limited to, nonclinical and clinical data on the pharmacology, toxicology, adverse events, radiation safety assessments, and chemistry, manufacturing, and controls. The content and format of an application for approval of a new drug are set forth in § 314.50 (21 CFR 314.50). Under part 315, information required under the FD&C Act and needed by FDA to evaluate the safety and effectiveness of in vivo radiopharmaceuticals still needs to be reported.

Based on the number of submissions (that is, human drug applications and/or new indication supplements for diagnostic radiopharmaceuticals) that FDA receives, the Agency estimates that it will receive approximately two submissions annually from two applicants. The hours per response refers to the estimated number of hours that an applicant would spend preparing the information required by the regulations. Based on FDA's experience, the Agency estimates the time needed to prepare a complete application for a diagnostic radiopharmaceutical to be approximately 10,000 hours, roughly one-fifth of which, or 2,000 hours, is estimated to be spent preparing the portions of the application that would be affected by these regulations. The regulation does not impose any additional reporting burden for safety and effectiveness information on diagnostic radiopharmaceuticals beyond the estimated burden of 2,000 hours because safety and effectiveness information is already required by § 314.50 (collection of information approved under OMB control number 0910–0001). In fact, clarification in these regulations of FDA's standards for evaluation of diagnostic radiopharmaceuticals is intended to streamline overall information collection burdens, particularly for diagnostic radiopharmaceuticals that may have well-established, low-risk safety profiles, by enabling manufacturers to tailor information submissions and avoid unnecessary clinical studies. Table 1 of this document contains estimates of the annual reporting burden for the preparation of the safety and effectiveness sections of an application that are imposed by existing regulations. This estimate does not include the actual time needed to conduct studies and trials or other research from which the reported information is obtained.

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 (in hours)	Total hours
315.4, 315.5, and 315.6	2	1	2	2,000	4,000

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

Dated: July 16, 2014.

Peter Lurie,

Associate Commissioner for Policy and Planning.

[FR Doc. 2014–17079 Filed 7–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Joint Meeting of the Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees: Bone, Reproductive and Urologic Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

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

Date and Time: The meeting will be held on September 18, 2014, from 8 a.m. to 1 p.m.

Location: College Park Marriott Hotel and Conference Center, 3501 University Blvd. East, Hyattsville, MD 20783. The hotel's telephone number is 301–985–7300.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., WO31–2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, email: *BRUDAC@fda.hhs.gov,* 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: The committees will discuss new drug application (NDA) 206089 (oral testosterone undecanoate tablets), submitted by Clarus Therapeutics, for the proposed indication of testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone: Primary hypogonadism (congenital or acquired) and hypogonadotropic hypogonadism (congenital or acquired).

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 September 3, 2014. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.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 August 25, 2014. 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 August 26, 2014.

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 Kalyani Bhatt 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: July 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17081 Filed 7–18–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; 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: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; Synthesis of Therapeutic Agents for Treatment of Infectious Disease.

Date: August 7, 2014.

Time: 12:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Room 3119, 6700B Rockledge Drive, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Jay Bruce Sundstrom, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700B Rockledge Drive, MSC–7616 Bethesda, MD 20892, (301) 496–7042, *sundstromj@niaid.nih.gov.*

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel; NIH Support for Conferences and Scientific Meetings (Parent R13/U13).

Date: August 19–22, 2014.

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

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3201 B, 6700B Rockledge Drive, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Travis J. Taylor, Ph.D., Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700–B Rockledge Dr., MSC–7616, Bethesda, MD 20892–7616, 301–496–2550, *Travis.Taylor@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: July 15, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–16981 Filed 7–18–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

Extension of Agency Information Collection Activity Under OMB Review: Exercise Information System (EXIS)

AGENCY: Transportation Security Administration, DHS.

ACTION: 30-day Notice.

SUMMARY: This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652–0057, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on May 1, 2014 (79 FR 24742). EXIS is a web portal designed to serve stakeholders in the transportation industry in regard to security training exercises. EXIS provides stakeholders with transportation security exercise scenarios and objectives, best practices and lessons learned, and a repository of the user's own historical exercise data for use in future exercises. It also allows stakeholders to design their own security exercises based on the unique needs of their specific transportation mode or method of operation. Utilizing