and/or amino acid supplementation alone. Subsequent to this approval, the USPTO received a patent term restoration application for RAVICTI (U.S. Patent No. 5,968,979) from Hyperion Therapeutics, Inc., and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated May 2, 2014, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of RAVICTI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for RAVICTI is 2,126 days. Of this time, 1,719 days occurred during the testing phase of the regulatory review period, while 407 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* April 10, 2007. The applicant claims April 8, 2006, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was April 10, 2007, when the IND was removed from clinical hold.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the FD&C Act:* December 23, 2011. FDA has verified the applicant's claim that the new drug application (NDA) for RAVICTI (NDA 203284) was submitted on December 23, 2011.

3. *The date the application was approved:* February 1, 2013. FDA has verified the applicant's claim that NDA 203284 was approved on February 1, 2013.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,450 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by June 16, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 14, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08845 Filed 4–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Addressing Inadequate Information on Important Health Factors in Pharmacoepidemiology Studies Relying on Healthcare Databases; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA) is announcing a public workshop, cosponsored by FDA and the University of Maryland Center for Excellence in Regulatory Science and Innovation, entitled ''Methodological Considerations to Address Unmeasured Information About Important Health Factors in Pharmacoepidemiology Studies that Rely on Electronic Healthcare Databases to Evaluate the Safety of Regulated Pharmaceutical Products in the Postapproval Setting.'' The purpose of the public workshop is to engage in constructive dialogue among regulators, academicians, pharmaceutical industry, clinicians, other stakeholders and the general public on potential strategies to improve availability of information on important health factors in pharmacoepidemiology studies that rely on electronic healthcare databases to evaluate the safety of pharmaceutical products in the postapproval setting. Electronic healthcare databases are increasingly being used in the postapproval assessment of the safety profile of pharmaceutical drug products.

Date and Time: The public workshop will be held on May 4, 2015, 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Contact Person: Leslie Wheelock, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4345, Silver Spring, MD, 301–796–4580, FAX: 301–847–8106, *leslie.wheelock@fda.hhs.gov*.

Registration: Submit your online registration information (including name, title, firm name, address, telephone and fax numbers) by April 30, 2015, at: *http://www.pharmacy.umaryland.edu/centers/cersievents/biasinbigdata/*. There is no registration fee for University of Maryland faculty, students, and staff, University of Maryland Center for Excellence in Regulatory Science and Innovation Industrial Consortia Members, and Federal Government employees. There is a $50.00 registration fee for all other participants. Early registration is recommended because seating is limited. There will be no onsite registration.

If you need special accommodations due to a disability, please contact Leslie Wheelock (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

In many instances, these resources allow for the timely evaluation of drug-related adverse events since data on healthcare utilized by a large number of individuals are readily available. However, because these data are typically collected for administrative purposes, information on important health factors necessary to evaluate drug-outcome relationship may be

absent or incomplete in these data sources. Examples include tobacco/smoking use and history, alcohol consumption, weight and height, patient and family medical history, or use of over-the-counter medications. Incomplete capture or the absence of this information can result in biased or uncertain estimates for the drug-outcome relationship of interest leading to inadequate evaluation of the safety profile of prescription drug products.

Webcast: Please be advised that as soon as possible after a Webcast of the public workshop is available, it will be accessible at: *http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm429136.htm.*

Dated: April 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–08846 Filed 4–16–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Drug Abuse; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council on Drug Abuse.

The meeting will be open to the public as indicated below, 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.

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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Drug Abuse.

Date: May 5–6, 2015.

Closed: May 5, 2015, 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Open: May 6, 2015, 8:30 a.m. to 2:00 p.m.

Agenda: This portion of the meeting will be open to the public for announcements and reports of administrative, legislative, and program developments in the drug abuse field.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852.

Contact Person: Susan R.B. Weiss, Ph.D., Director, Division of Extramural Research, Office of the Director, National Institute on Drug Abuse, NIH, DHHS, 6001 Executive Boulevard, NSC, Room 5274, MSC 9591, Rockville, MD 20892, 301–443–6487, *sweiss@nida.nih.gov.*

Any member of the public interested in presenting oral comments to the committee may notify the Contact Person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives of organizations may submit a letter of intent, a brief description of the organization represented, and a short description of the oral presentation. Only one representative of an organization may be allowed to present oral comments and if accepted by the committee, presentations may be limited to five minutes. Both printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the committee by forwarding their statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.drugabuse.gov/NACDA/NACDAHome.html* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos.: 93.279, Drug Abuse and Addiction Research Programs, National Institutes of Health, HHS)

Dated: April 13, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–08800 Filed 4–16–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

The meeting will be open to the public as indicated below, 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.

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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Nursing Research.

Date: May 19–20, 2015.

Open: May 19, 2015, 1:00 p.m. to 5:00 p.m.

Agenda: Discussion of Program Policies and Issues.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Room 6, Bethesda, MD 20892.

Closed: May 20, 2015, 9:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Building 31, 31 Center Drive, 6th Floor, C Wing, Room 6, Bethesda, MD 20892.

Contact Person: Ann R. Knebel, DNSC, RN, FAAN, Deputy Director, National Institute of Nursing Research, National Institutes of Health, 31 Center Drive, Building 31, Room 5B05, Bethesda, MD 20892, 301–496–8230, *knebelar@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nih.gov/ninr/a_advisory.html*, where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.361, Nursing Research, National Institutes of Health, HHS)