vivo pharmacokinetic BE study from a parallel study design to a crossover study design, but is the same in all other respects.

In January 2005, Warner Chilcott, Inc., submitted a citizen petition requesting that FDA stay final approval and/or the effective date of final approval of any ANDA that relies on Estrace Cream as the reference listed drug unless the ANDA meets certain requirements related to demonstrating bioequivalence. FDA reviewed the issues raised in the petition and is responding to the petition (see FDA letter to Warner Chilcott, Inc, Docket No. FDA–2005–P–0006, available at *http://www.regulations.gov*).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the design of BE studies to support ANDAs for estradiol vaginal cream. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: September 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–22450 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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: Orthopaedic and Rehabilitation Devices Panel of the Medical Devices 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 December 12, 2014, from 8 a.m. to 6 p.m.

Location: Holiday Inn Washington-College Park, 10000 Baltimore Ave., College Park, MD 20740. The hotel phone number is 1–800–315–2621.

Contact Person: S.J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1643, Silver Spring MD 20993–0002, *Sara.Anderson@fda.hhs.gov,* 301–796–7047, 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 December 12, 2014, the committee will discuss, make recommendations, and vote on information regarding the premarket approval application for the Superion InterSpinous Spacer device sponsored by Vertiflex Incorporated. The proposed Indication for Use for the Superion InterSpinous Spacer device, as stated in the PMA, is as follows: the Superion InterSpinous Spacer (the Superion ISS) is intended to treat skeletally mature patients suffering from pain, numbness, and/or cramping in the legs (neurogenic intermittent claudication) secondary to a diagnosis of moderate lumbar spinal stenosis, with or without Grade 1 spondylolisthesis, confirmed by X-ray, MRI and/or CT evidence of thickened ligamentum flavum, narrowed lateral recess, and/or central canal or foraminal narrowing. The Superion ISS is indicated for those patients with impaired physical function who experience relief in flexion from symptoms of leg/buttock/groin pain, numbness, and/or cramping, with or without back pain. The Superion ISS may be implanted at one or two adjacent lumbar (L) levels in patients in whom treatment is indicated at no more than two levels, from L1 to L5.

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 November 13, 2014. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on December 12, 2014. 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 November 5, 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 November 6, 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 AnnMarie Williams, at 301–796–5966. *Annmarie.williams@fda.hhs.gov* 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 16, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–22444 Filed 9–19–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

First Annual Neonatal Scientific Workshop—Roadmap for Applying Regulatory Science to Neonates; Notice of Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public scientific workshop to discuss the roadmap for applying regulatory science to neonates. This public scientific workshop is being co-sponsored with the FDA, the Critical Path Institute (C-Path) and the Burroughs Welcome Fund (BWF).

The purpose of the public scientific workshop is to initiate constructive discussion among regulators, researchers, health care providers, representatives from the pharmaceutical industry and health care organizations, and the general public to determine whether there is sufficient interest on the part of stakeholders to develop a neonatal consortium and to discuss potential working groups dedicated to the regulatory science required to develop neonatal therapeutics.

DATES: The public scientific workshop will be held on October 28 and 29, 2014, from 8 a.m. to 5 p.m. Section II provides attendance and registration information.

ADDRESSES: The public scientific workshop will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public scientific 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.*

FOR FURTHER INFORMATION CONTACT: Indira Hills, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 21, Rm. 4508, Silver Spring, MD 20993, 301–796–9686, FAX: 301–796–9907, *indira.hills@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

C-Path and BWF, in cooperation with FDA and various stakeholders, including industry, academia, professional organizations, patient advocacy groups, and other government Agencies, are proposing to establish the Neonatal Consortium in order to leverage resources and expertise toward mutually beneficial goals and in the interest of public health. Some of the potential priorities of the Neonatal Consortium to be discussed at the public scientific workshop would be the following:

1. Developing and qualifying biomarkers, clinical outcome assessments, and other drug development tools. Valid and reliable endpoints are presently lacking in neonatal clinical trials.

2. Developing physiologically-based pharmacokinetic modeling and simulation to predict on and off target responses to drugs.

3. Optimizing clinical trial designs for the neonatal population. One aspect of clinical trial design in neonates is the need for long-term studies to properly evaluate the effects of an intervention. There is also interest in examining bioethical questions related to neonatal care and their solutions.

4. Maximizing the use of registry data. Such registries may be useful in long-term studies.

5. Developing Clinical Data Interchange Standards Consortium data standards for registry data, electronic health record information, and clinical trial data.

6. Building a neonatal database in which standardized data pooled from industry and academic neonatal trials could reside. Such a database would be an invaluable resource for the neonatal community.

II. Attendance and Registration

The FDA Conference Center at the White Oak location is a Federal facility with security procedures and limited seating. Individuals who wish to participate in the public scientific workshop (in person or via web) must register on or before October 20, 2014, by visiting *http://www.cvent.com/d/34qr03* and contacting Indira Hills (see **FOR FURTHER INFORMATION CONTACT**) or Kerrie Bennymadho, Project Coordinator, Critical Path Institute, 520–382–1377, Cell: 760–636–3046, *kbennymadho@c-path.org* regarding registration. Early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Onsite registration on the day of the public scientific workshop will be based on space availability. The registration deadline is October 20, 2014.

FDA will provide additional background information at the time the **Federal Register** notice is published and an agenda approximately 2 weeks before the public scientific workshop at FDA Meeting Information page, which is available online at *http://www.fda.gov/Drugs/NewsEvents/ucm410863.htm.*

If you need special accommodations because of disability, please contact Indira Hills (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the public scientific workshop.

A live Webcast of this public scientific workshop will be viewable at Adobe Connect Link: *https://collaboration.fda.gov/nsw2014/* on the day of the public scientific workshop. A video record of the public scientific workshop will be available at the same Web address for 1 year.

III. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305). A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn