for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Karl Koerper,

Reports Clearance, Officer.

[FR Doc. 2014–11055 Filed 5–13–14; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0234]

Draft Guidance for Industry on Clinical Pharmacology Data To Support a Demonstration of Biosimilarity to a Reference Product; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product.'' This guidance is intended to assist sponsors in developing a clinical pharmacology program to support a decision that a proposed therapeutic biological product is *biosimilar* to, that is not clinically meaningfully different from, its reference product. Specifically, the guidance discusses some of the overarching concepts related to clinical pharmacology studies for biosimilar products, approaches for developing the appropriate clinical pharmacology database, and the utility of modeling and simulation for designing clinical trials. This draft guidance is one in a series of guidances that FDA is developing to implement the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 12, 2014.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Sandra Benton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6340, Silver Spring, MD 20993–0002, 301–796–2500, email: *sandra.benton@fda.hhs.gov;* or Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Clinical Pharmacology Data to Support a Demonstration of Biosimilarity to a Reference Product.'' Clinical pharmacology studies are part of a stepwise approach to develop the data and information needed to support a demonstration of biosimilarity. Adequate and well-conducted clinical pharmacology studies can address the residual uncertainty in biosimilarity assessment from clinical perspectives and inform the design of subsequent studies to assess clinically meaningful differences between the biosimilar and the reference products. The draft guidance discusses some critical considerations related to clinical pharmacology testing for biosimilar products, approaches for developing the appropriate clinical pharmacology database, and the utility of modeling and simulation for designing clinical trials. In its description of how to design and use clinical pharmacology studies to add to the totality of evidence that a proposed biological product is biosimilar to its reference product, the draft guidance is meant to assist sponsors in designing such studies in support of applications submitted under section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)). Scientific principles described in the draft guidance may also be informative for the development of certain biological products under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355).

This draft guidance is one in a series that FDA is developing to implement the BPCI Act and 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 this topic. 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. The Paperwork Reduction Act of 1995

The draft guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information submitted under section 351(k) applications for biosimilars is approved under OMB control number 0910–0719. The collection of information submitted under 21 CFR part 312 is approved under OMB control number 0910–0014.

III. Comments

Interested persons may submit either electronic comments regarding the draft guidance 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.*

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.*

gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or *http://www.regulations.gov.*

Dated: May 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11053 Filed 5–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–P–1107]

Oxiplex®/SP Gel; FzioMed, Incorporated's Petition for Review of the Food and Drug Administration's Denial of Premarket Approval; 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 topic to be discussed is the Center for Device and Radiological Health's (CDRH's) denial of a premarket approval application (PMA) for Oxiplex®/SP Gel (OXIPLEX) submitted by FzioMed, Inc.—the sponsor for OXIPLEX. The meeting will be open to the public.

Name of Committee: Medical Devices Dispute Resolution Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on scientific disputes between CDRH and sponsors, applicants, and manufacturers.

Date and Time: The meeting will be held on June 10, 2014, from 8 a.m. to 6 p.m.

Location: The meeting will be held at the Hilton Washington DC/North, salons A, B, C, and D of the Ballroom, 620 Perry Pkwy., Gaithersburg, MD. The hotel's telephone number is 1–301–977–8900.

Contact Person: Pamela D. Scott, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3611, Silver Spring, MD 20993, 301–796–5433, FAX: 301–847–8510, email: *pamelad.scott@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 affect 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.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions from persons other than FzioMed and CDRH may be made to the docket on or before June 3, 2014. Submit electronic comments to *http://www.regulations.gov*. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD, 20852. It is only necessary to send one set of comments. Identify all written and electronic comments and submissions with the docket number found in brackets in the heading of this document. All written and electronic comments and submissions will be considered to be publicly disclosable.

Oral presentations from persons other than FzioMed and CDRH will be scheduled between approximately 12:45 and 1:15 p.m. on June 10, 2014. If you wish to make an oral presentation during the meeting, you should register on or before May 27, 2014. Send registration information (including name, title, firm name, address, telephone, email, and FAX number), and requests to make oral presentations to Pamela D. Scott (see *Contact Person*). You should provide the docket number appearing in the heading of this notice. You also should submit a brief summary of the presentation, including the discussion topic(s) that will be addressed and the approximate time requested for your presentation. The amount of time to be allotted to each presenter may be limited to provide opportunities to as many persons wishing to present as possible. 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 that session. We encourage individuals and organizations with common interests to consolidate or coordinate their presentations to allow adequate time for each request for presentation. Pamela D. Scott will notify interested persons regarding their request to speak by June 2, 2014. On the day of the meeting scheduled open public speakers should identify themselves at the registration desk.

After the scheduled speakers have spoken, the Chair of the advisory committee may ask them to remain if the advisory committee wishes to question them further. The Chair may recognize unscheduled speakers should time allow.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing that, in accordance with section 515(g)(2) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360e(g)(2)), a public advisory committee will review CDRH's denial of a PMA for OXIPLEX submitted by FzioMed—the sponsor for OXIPLEX.

On August 21, 2007, FzioMed submitted a PMA (PMA P070023) for OXIPLEX. OXIPLEX is an absorbable, clear, viscoelastic gel designed to be applied in the lower back during lumbar spine surgery. The device's proposed indication is for use as a surgical adjuvant in adult patients with primary leg pain and severe baseline back pain undergoing first surgical intervention (i.e., open or endoscopic posterior lumbar laminectomy, laminotomy, or discectomy) for diagnosed unilateral herniation of lumbar intervertebral disc material associated with radiculopathy. The proposed intended use is for one-time use, up to 3 milliliters, after hemostasis during wound closure, as an adjunct to primary surgical intervention to improve patient outcomes by reducing leg pain, back pain and neurologic symptoms.

On October 9, 2012, CDRH issued a decision upholding a not approvable letter in response to the PMA P070023 for OXIPLEX. CDRH determined that PMA P070023 is not approvable based on its conclusion that the data and information offered in support of the PMA do not provide a reasonable assurance that the device is safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling, as required by section 515(d)(2) of the FD&C Act.

On November 5, 2012, FzioMed requested administrative review of CDRH's decision to uphold its not approvable letter. Submitted in the form of a petition for reconsideration under 21 CFR 10.33 (see § 814.44 (21 CFR 814.44(f)(2))), FzioMed's petition for review (petition) stated that, in accordance with § 814.44(f), FzioMed