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 to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–7800. 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov*.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:

For information concerning human drug products: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD, 20993–0002, 301–796–1874.

For information concerning human biological products: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD, 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Providing Submissions in Electronic Format—Postmarketing Safety Reports.'' This draft guidance provides general information pertaining to electronic submission of postmarketing safety reports (ICSRs, ICSR attachments, and other postmarketing safety reports) for the following products:

- Drug products marketed for human use with approved new drug applications (NDAs) and abbreviated new drug applications (ANDAs);
- Prescription drug products marketed for human use without an approved NDA or ANDA;
- Biological products, other than vaccines, marketed for human use with approved biologic license applications (or BLAs);
- Nonprescription (over-the-counter or OTC) human drug products marketed without an approved application.

This draft guidance does not apply to vaccines, human cells, tissues, and cellular and tissue-based products regulated under section 361 of the Public Health Service Act, whole blood, components of whole blood, or lot distribution reports.

This draft guidance revises and replaces the draft guidance for industry entitled ''Providing Regulatory Submissions in Electronic Format—Postmarketing Individual Case Safety Reports,'' issued on June 12, 2008 (73 FR 33436). Elsewhere in this issue of the **Federal Register,** we are publishing a final rule to require that mandatory postmarketing safety reports for human drug and biological products be submitted to FDA in an electronic format that the Agency can process, review, and archive. The revised draft guidance is intended to help persons subject to mandatory postmarketing safety reporting requirements comply with the final rule. Along with other information, the revised draft guidance provides updated information about the following: (1) Options for submitting postmarketing safety reports to FDA in electronic format, (2) the notification that submitters will receive when FDA has received the electronic postmarketing safety report, and (3) procedures for requesting temporary waivers from the electronic submission requirement.

The 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 submission of postmarketing safety reports in electronic format. 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 to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. 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.

III. Paperwork Reduction Act of 1995

The information collection resulting from this draft guidance is covered by the information collection provisions of the final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements,'' which is published elsewhere in this issue of the **Federal Register**. The information collection provisions of the final rule have been submitted to the Office of Management and Budget (OMB) for review, as required under section 3507(d) of the Paperwork Reduction Act. Prior to the effective date of the final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in the final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

IV. Electronic Access

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

Dated: June 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13479 Filed 6–9–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0012]

Kidney Health Initiative (R18)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Drug Evaluation and Research/Office of Medical Policy's Kidney Health Initiative Program. FDA, Center for Drug Evaluation and Research (CDER), Office of Medical Policy (OMP) is announcing its intent to accept and consider a single source application for the award of a grant to the American Society of Nephrology (ASN) to support the Kidney Health Initiative (KHI).

DATES: The application due date is June 30, 2014, by 11:59 p.m., EST.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov*.

For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Mark Lauda, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, White Oak, Bldg. 51, Rm. 2212, Silver Spring, MD 20993, 301–796–0381, email: *Mark.Lauda@fda.hhs.gov*; or Lisa Ko, Office of Acquisition & Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD, 240–402–7592, email: *Lisa.Ko@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.grants.gov*. Search by Funding Opportunity Number: RFA–FD–14–018.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–14–018
93.103

A. Background

A memorandum of understanding (MOU) between FDA and ASN signed in September 2012 served as the basis for the establishment of KHI. This award will be made to ASN to enable FDA's support of KHI by defraying some of the direct and indirect costs associated with KHI and KHI projects. The ASN is a 501(c)(3) non-profit organization whose mission is to fight against kidney disease by educating health professionals, sharing new knowledge, advancing research, and advocating the highest quality care for patients.

KHI is a public-private partnership whose mission is to advance scientific understanding of the kidney health and patient safety implications of new and existing medical products and to foster development of therapies for disease that affect the kidney by creating a collaborative environment in which FDA and the greater nephrology community can interact to optimize evaluation of drugs, devices, biologics, and food products. KHI membership is broad and includes stakeholders from government, patient advocacy groups and foundations, pharmaceutical and device companies, professional societies, dialysis providers, and research institutions. KHI helps to effect change through the conduct of projects that address barriers to innovation, facilitate critical evidence generation, and/or elucidate safety concerns. KHI projects may be submitted for consideration by any of its member organizations (including FDA). Candidate projects are developed and refined through Web-based interactions and during stakeholder meetings. Candidate projects that are successfully developed and receive the endorsement of the KHI Board of Directors are conducted on a volunteer basis by work groups largely (but not exclusively) staffed by individuals from KHI member organizations.

The opportunity for meaningful interaction with a broad set of stakeholders committed to improving the evaluation of products that impact kidney health offers significant value to FDA and the public. Since its inception, KHI has undertaken several projects that have advanced the FDA mission, including (but not limited to) projects elucidating endpoints for lupus nephritis trials and also providing guidance for generating pharmacokinetic data for critical drugs often used in the setting of continuous renal replacement therapies.

B. Research Objectives

The goals of this program are to develop and maintain an administrative and scientific infrastructure to support the creation and execution of a series of projects under the auspices of KHI, to complement the goals of FDA.

The following KHI activities are supported by this grant:

- Maintaining an adequate administrative and scientific infrastructure to implement all related projects under this collaborative effort.
- Identifying and/or hiring a sufficient number of qualified personnel to conduct the necessary research and project-management of all related activities, including review of project milestones for degree of completion, preparation/reporting of project findings, periodic and final reports, and subsequent distribution in the public domain.
- Developing plans for the conduct of identified research plans.
- Identifying, securing, and/or building, and effectively leveraging other resources for the conduct of identified projects.
- Upon completion of a given project, generating project results and recommendations and proposing related studies/projects, if needed, to build on the findings of the project and continuing to leverage established resources and personnel.

C. Eligibility Information

The following organization is eligible to apply: American Society of Nephrology (ASN).

II. Award Information/Funds Available

A. Award Amount

This is a multi-year grant. FDA/CDER intends to fund up to $500,000 in total costs (direct and indirect) in fiscal year (FY) 2014. Awards are contingent upon the availability of funds.

Subject to the availability of Federal funds and successful performance of the FOA's stated goals and objectives, 4 additional years of support may be available. Funding beyond the first year will be noncompetitive and will depend on: (1) Satisfactory performance during the preceding year and (2) the availability of Federal FY funds.

Application budgets need to reflect the actual needs of the proposed project and should not exceed the following in total costs (direct and indirect):

Year 1: $500,000
Year 2: $500,000
Year 3: $500,000
Year 4: $500,000
Year 5: $500,000

B. Length of Support

The scope of the proposed project should determine the project period. The maximum project period is 5 years.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at *http://www.grants.gov*. Search by Funding Opportunity Number: RFA–FD–14–018. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp*. Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp*. After you have followed these steps, submit

electronic applications to: *http://www.grants.gov*.

Dated: June 4, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13443 Filed 6–9–14; 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 Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Medical Devices Dispute Resolution Panel scheduled for June 10, 2014, is cancelled. This meeting was announced in the **Federal Register** of May 14, 2014.

FOR FURTHER INFORMATION CONTACT: Pamela D. Scott, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 3611, Silver Spring, MD 20993–0002, 301–796–5433, FAX: 301–847–8510, email: *pamelad.scott@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The meeting of the Medical Devices Dispute Resolution Panel (the panel) of the Medical Devices Advisory Committee scheduled for June 10, 2014, is cancelled. On June 10, 2014, the panel was slated to discuss the Center for Device and Radiological Health's (CDRH's) denial of a premarket approval application (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 Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360e(d)(2)).

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(f)(2) (21 CFR 814.44(f)(2)), FzioMed's petition for review (petition) stated that, in accordance with § 814.44(f), FzioMed considered the decision to uphold the not approvable letter to be a denial of approval of PMA P070023 under § 814.45). Under section 515(d)(4) of the FD&C Act, FzioMed requested review of this denial under section 515(g)(2) of the FD&C Act.

Accordingly, as required by § 814.45(e)(3), CDRH issued an order denying approval of the PMA for OXIPLEX on October 21, 2013. Under section 515(g)(2) of the FD&C Act, on October 25, 2013, FDA granted FzioMed's petition for review of the order denying PMA P070023. In the **Federal Register** of May 14, 2014 (79 FR 27623), the Office of the Commissioner referred PMA P070023 and the basis for the order denying its approval to the Medical Devices Dispute Resolution Panel, and announced that the panel was scheduled to meet to discuss the clinical and scientific issues raised by CDRH's Denial Order on June 10, 2014.

Since the panel meeting announcement on May 14, 2014, the parties have agreed that the panel meeting should not go forward on June 10, 2014. The Agency is thereby cancelling the June 10, 2014, meeting.

Dated: June 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13565 Filed 6–6–14; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Report on Carcinogens Monograph on Trichloroethylene; Availability of Documents; Request for Comments; Notice of Meeting

SUMMARY: The notice announces a meeting to peer review the Draft Report on Carcinogens (RoC) Monograph on Trichloroethylene (TCE). This document was prepared by the Office of the Report on Carcinogens (ORoC), Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS). The peer-review meeting is open to the public. Registration is requested for both public attendance and oral comment and required to access the webcast. Information about the meeting and registration are available at *http://ntp.niehs.nih.gov/go/38853.*

DATES:

Meeting: August 12, 2014, 8:30 a.m. Eastern Daylight Time (EDT) to adjournment. Document Availability: Draft monograph will be available by June 30, 2014, at *http://ntp.niehs.nih.gov/go/38853.*

Written Public Comments Submissions: Deadline is July 30, 2014.

Registration for Meeting, Oral Comments, and/or to View Webcast: Deadline is August 5, 2014. Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Agency Meeting Web page: The draft monographs, draft agenda, registration, and other meeting materials will be posted at *http://ntp.niehs.nih.gov/go/38853.*

Webcast: The URL for viewing the webcast will be provided to those who register.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, NTP Designated Federal Official, Office of Liaison, Policy and Review, DNTP, NIEHS, P.O. Box 12233, MD K2–03, Research Triangle Park, NC 27709. Phone: (919) 541–9834, Fax: (301) 480–3272, Email: *whiteld@niehs.nih.gov.* Hand Delivery/Courier: 530 Davis Drive, Room 2136, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Background

The RoC is a congressionally mandated, science-based, public health report that identifies agents, substances,