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,

mixtures, or exposures (collectively called ''substances'') in our environment that pose a cancer hazard for people in the United States. The NTP prepares the RoC on behalf of the Secretary of Health and Human Services.

The NTP follows an established, four-part process for preparation of the RoC (*http://ntp.niehs.nih.gov/go/rocprocess*). A RoC monograph is prepared for each candidate substance selected for review for the RoC. Trichloroethylene was selected as a candidate substances following solicitation of public comment, review by the NTP Board of Scientific Counselors on June 21–22, 2012, and approved by the NTP Director (*http://ntp.niehs.nih.gov/go/9741*). A draft RoC monograph consists of (1) a cancer evaluation component that reviews all information that may bear on a listing decision, assesses its quality and sufficiency for reaching a listing decision, applies the RoC listing criteria to the relevant scientific information, and recommends a listing status for the candidate substance in the RoC and (2) a substance profile that contains the NTP's preliminary listing recommendation and a summary of the scientific evidence considered key to reaching that recommendation. This meeting is planned for peer review of the draft RoC Monograph on TCE.

Trichloroethylene (CASRN 79–01–6) is a halogenated alkene used primarily in the past as a degreaser for metal parts and more currently as an intermediate for hydrofluorocarbon (e.g., refrigerant) production. It is a common drinking water contaminant and has also been found in contaminated air and soil, and is an ingredient in many consumer products (e.g., aerosols or degreasers for hobbies, crafts and home and automobile maintenance). It is currently listed as *reasonably anticipated to be a human carcinogen* in the 12th RoC. Additional information about the review of TCE for the RoC is available at *http://ntp.niehs.nih.gov/go/37899.*

Meeting and Registration

This meeting is open to the public with time set aside for oral public comment. The public may attend the meeting at NIEHS, where attendance is limited only by the space available, or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to provide oral comments (see below) are encouraged to register online at the meeting Web site (*http://ntp.niehs.nih.gov/go/38853*) by August 5, 2014, to facilitate planning for the meeting.

The preliminary agenda and draft monograph should be posted on the NTP Web site (*http://ntp.niehs.nih.gov/go/38853*) by June 30, 2014. Additional information will be posted when available or may be requested in hardcopy, see **FOR FURTHER INFORMATION CONTACT**. Following the meeting, a report of the peer review will be prepared and made available on the NTP Web site. Registered attendees are encouraged to access the meeting Web page to stay abreast of the most current information regarding the meeting.

Visitor and security information is available at *http://www.niehs.nih.gov/about/visiting/index.cfm.* Individuals with disabilities who need accommodation to participate in this event should contact Ms. Danica Andrews at phone: (919) 541–2595 or email: *andrewsda@niehs.nih.gov.* TTY users should contact the Federal TTY Relay Service at (800) 877–8339. Requests should be made at least five business days in advance of the event.

Request for Comments

The NTP invites written and oral public comments on the draft monograph. The deadline for submission of written comments is July 30, 2014, to enable review by the peer-review panel and NTP staff prior to the meeting. Registration to provide oral comments is by August 5, 2014, at *http://ntp.niehs.nih.gov/go/38853.* Public comments and any other correspondence on the draft monographs should be sent to the **FOR FURTHER INFORMATION CONTACT**. Persons submitting written comments should include their name, affiliation, mailing address, phone, email, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the NTP Web site, and the submitter will be identified by name, affiliation, and/or sponsoring organization.

Public comment at this meeting is welcome, with time set aside for the presentation of oral comments on the draft monograph. In addition to in-person oral comments at the meeting at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The lines will be open from 8:30 a.m. until adjournment on August 12, 2014, and oral comments will be received only during the formal public comment period indicated on the preliminary agenda. Each organization (sponsoring organization or affiliation) is allowed one time slot. At least 7 minutes will be allotted to each speaker, and if time permits, may be extended to 10 minutes at the discretion of the chair.

Persons wishing to make an oral presentation are asked to register online at *http://ntp.niehs.nih.gov/go/38853* by August 5, 2014, and if possible, to send a copy of their slides and/or statement or talking points at that time. Written statements can supplement and may expand the oral presentation. Registration for in-person oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for registered speakers and will be determined by the number of speakers who register on-site.

Background Information on the RoC

Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. The 12th RoC, the latest edition, was published on June 10, 2011 (available at *http://ntp.niehs.nih.gov/go/roc12*). The 13th RoC is under development. For each listed substance, the RoC contains a substance profile, which provides information on: Cancer studies that support the listing—including those in humans, animals, and studies on possible mechanisms of action—information about potential sources of exposure to humans, and current Federal regulations to limit exposures.

Background Information on NTP Peer-Review Panels

NTP panels are technical, scientific advisory bodies established on an ''as needed'' basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. The NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide a current *curriculum vita* to the **FOR FURTHER INFORMATION CONTACT.** The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: June 4, 2014.

John R. Bucher,

Associate Director, National Toxicology Program.

[FR Doc. 2014–13481 Filed 6–9–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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 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 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; ''NIAID Investigator Initiated Program Project Applications (P01)''.

Date: July 1, 2014.

Time: 1:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3117, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Richard W. Morris, Ph.D., Scientific Review Officer, Scientific Review Program, DEA/NIAID/NIH/DHHS, 6700–B Rockledge Drive, MSC–7616, Room 3251, Bethesda, MD 20892–7616, 301–451–2663, *rmorris@niaid.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: June 4, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–13468 Filed 6–9–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Arthritis and Musculoskeletal and Skin Diseases; Notice of Closed Meeting

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 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 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 Arthritis and Musculoskeletal and Skin Diseases Special Emphasis Panel; Mentored Career Development, Institutional Research Training & Pathways to Independence Applications.

Date: June 30, 2014.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Charles H Washabaugh, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute of Arthritis, Musculoskeletal and Skin Diseases, NIH, 6701 Democracy Boulevard, Suite 800, Bethesda, MD 20892 (301) 496–9568 *washabac@mail.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.846, Arthritis, Musculoskeletal and Skin Diseases Research, National Institutes of Health, HHS)

Dated: June 4, 2014.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–13472 Filed 6–9–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

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 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 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; Opportunities for Collaborative Research at the NIH Clinical Center (U01).

Date: July 9, 2014.

Time: 9:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3122, 6700B Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Brenda Lange-Gustafson, Ph.D., Scientific Review Officer, NIAID/NIH/DHHS, Scientific Review Program, Room 3122, Bethesda, MD 20892–7616, *bgustafson@niaid.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: June 4, 2014.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2014–13473 Filed 6–9–14; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

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 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 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.