regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Wolfgang Kainz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1115, Silver Spring, MD 20993–0002, 301–661–7595.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance to provide an assessment paradigm for RF-induced heating on or near multicomponent or multiconfiguration passive medical devices in the MR environment. During MR scanning, applied RF excitation pulses induce currents that can cause heating of electrically conductive materials. RF-induced heating of medical devices made with conductive materials may lead to patient burns. To minimize the risk of patient burns during MR scanning, sponsors should comprehensively assess devices in all configurations and combinations. However, multicomponent passive devices, such as orthopedic fixation devices, may permit a very large number of possible device configurations and combinations of individual components. Testing all possibilities may be impractical and unnecessary. This guidance provides an approach to identify a manageable number of device configurations or combinations for the testing of RF-induced heating in the MR environment. Additionally, this guidance provides recommendations on how to assess the RF-induced device heating for multiconfiguration passive medical devices.

In the **Federal Register** of June 29, 2015 (80 FR 36996), the Agency announced the issuance of the draft guidance entitled ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices.'' Interested persons were invited to comment by August 28, 2015.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the assessment of RF-induced heating of multicomponent, or multiconfiguration, passive medical devices in the MR environment. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500001 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 814, subparts B and E, are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, are approved under OMB control number 0910–0332; the collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910–0485; and the collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' are approved under OMB control number 0910–0756.

Dated: March 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06361 Filed 3–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

2016 Parenteral Drug Association/Food and Drug Administration Joint Conference: Aligning Manufacturing Goals With Patient Needs Through Successful Innovation and Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference, to be held in cosponsorship with the Parenteral Drug Association (PDA), entitled ''Aligning Manufacturing Goals with Patient Needs through Successful Innovation and Compliance.'' The conference will cover current issues affecting the industry as well as explore strategies to facilitate the development and continuous improvement of safe and effective medical products. The conference establishes a unique forum to discuss the foundations, emerging technologies, and innovations in regulatory science, as well as the current quality and compliance areas of concerns. Meeting participants will hear from FDA and industry speakers about the requirements and best practices to consider while implementing robust quality systems in order to deliver the best quality product.

DATES: The public conference will be held on September 12, 2016, from 7 a.m. to 7:30 p.m.; September 13, 2016, from

7 a.m. to 9:30 p.m.; and September 14, 2016, from 7 a.m. to 12:30 p.m.

ADDRESSES: The public conference will be held at the Renaissance Washington, DC Downtown Hotel, 999 Ninth Street NW., Washington, DC 20001, 202–898–9000, FAX: 202–289–0947.

FOR FURTHER INFORMATION CONTACT: Wanda Neal, Parenteral Drug Association, PDA Global Headquarters, Bethesda Towers, 4350 East West Hwy., Suite 150, Bethesda, MD 20814, 301–656–5900, ext. 111, FAX: 301–986–1093, email: *info@pda.org;* or Ken Nolan, Office of Communications, Food and Drug Administration 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8629, email: *kenneth.nolan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The PDA/FDA Joint Regulatory Conference offers the unique opportunity for participants to join FDA representatives and industry experts in face-to-face dialogues. Each year, FDA speakers provide updates on current efforts affecting the development of global regulatory strategies, while industry professionals from pharmaceutical companies present case studies on how they employ global strategies in their daily processes.

Through a series of sessions and meetings, the conference will provide participants with the opportunity to hear directly from FDA experts and representatives of global regulatory authorities on best practices, including:

- Product Quality
- Data Integrity
- Breakthrough Therapies
- Regulatory Challenges and Opportunities
- Lifecycle Management
- Clinically Relevant Specifications
- Food and Drug Administration Safety and Innovation Act
- Quality Metrics/Quality Culture
- Manufacturing of the Future With Submissions
- Continuous Verification and Validation
- Continuous Manufacturing
- ''Fishbowl'' Role Play
- Quality Systems
- Contract Manufacturing Organizations
- Maturity of Quality Systems
- Investigations
- Case Studies for Quality
- Quality Submissions
- Prescription Drug User Fee Act
- Risk-Based Control Strategies
- Supply Chain
- Quality Risk Management Systems
- Drug Shortages
- Customer Complaint Reviews and Trending
- Human Factors
- Office of Pharmaceutical Quality and Program Alignment Group
- Patient Perspective
- Compliance Update
- Center Initiatives—Regulatory Submission Update

To help ensure the quality of FDA-regulated products, the workshop helps to achieve objectives set forth in section 406 of the FDA Modernization Act of 1997 (21 U.S.C. 393), which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

II. Registration and Accommodations

A. Registration

Attendees are encouraged to register at their earliest convenience. The PDA registration fees cover the cost of facilities, materials, and refreshments. Seats are limited; please submit your registration as soon as possible. Conference space will be filled in order of receipt of registration. Those accepted for the conference will receive confirmation. Registration will close after the conference is filled. Onsite registration will be available on a space available basis beginning at 1 p.m. on September 11, 2016, and at 7 a.m. from September 12 through 14, 2016. The cost of registration is as follows:

COST OF REGISTRATION

Affiliation	Before July 1, 2016	July 1–August 2, 2016	After August 2, 2016
Premier Package (Includes Conference and Workshop Registration)			
Member	$3,740	$4,190	$4,640
Nonmember	4,199	4,649	5,099
Conference Only			
Member	2,395	2,795	2,995
Nonmember	2,654	3,054	3,254
Government/Health Authority Member	700	700	700
Government/Health Authority Nonmember [1]	800	800	800
Academic Member	700	700	700
Academic Nonmember [1]	800	800	800
Student Member	280	280	280
Student Nonmember [1]	310	310	310

[1]For this member type, online registration is not available and must be faxed in.

Please visit PDA's Web site: *www.pda.org/pdafda2016* to confirm the prevailing registration fees. (FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

If you need special accommodations due to a disability, please contact Wanda Neal (see **FOR FURTHER INFORMATION CONTACT**), at least 7 days in advance of the conference.

Registration Instructions: To register, please submit your name, affiliation, mailing address, telephone, fax number, and email address, along with a check or money order payable to ''PDA.'' Mail to: PDA, Global Headquarters, Bethesda Towers, 4350 East West Hwy., Suite 150, Bethesda, MD 20814. To register via the Internet, go to PDA's Web site: *www.pda.org/pdafda2016.*

The registrar will also accept payment by major credit cards (VISA/American Express/MasterCard only). For more information on the meeting, or for questions on registration, contact PDA (see **FOR FURTHER INFORMATION CONTACT**).

B. Accommodations

Attendees are responsible for their own accommodations. To make reservations, contact the Renaissance Washington Hotel (see **ADDRESSES**) and reference ''the 2016 PDA/FDA Joint Regulatory Conference'' to receive the PDA group rate. Room rates are: Single: $305 plus 14.5 percent State and local taxes. Requests will be processed on a first-come, first-served basis.

Transcripts: As soon as a transcript is available, it can be obtained in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. The Freedom of Information office address is available on the Agency's Web site at *http://www.fda.gov.*

Dated: March 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06366 Filed 3–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences, Notice of Closed Meetings

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 meetings.

The meetings 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 Environmental Health Sciences Special Emphasis Panel; Evaluation of the U01 Engineered Nanomaterials (ENMs) Grant Applications.

Date: April 4, 2016.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Sheraton Chapel Hill Hotel, 1 Europa Drive, Chapel Hill, NC 27517.

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (919) 541–0670, *worth@niehs.nih.gov.*

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Small Business Innovation Research (SBIR) Applications Teleconference Review.

Date: April 7, 2016.

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

Agenda: To review and evaluate grant applications.

Place: NIEHS, Keystone Building, 530 Davis Drive, Suite 3118, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC–30/Room 3171, Research Triangle Park, NC 27709, (919) 541–0670, *worth@niehs.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: March 15, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–06337 Filed 3–21–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development and Commercialization of Cancer Immunotherapy

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Midissia Therapeutics (''MIDISSIA'') located in San Francisco, California, USA.

Intellectual Property

United States Provisional Patent Application No. 60/476,467, filed June 5, 2003, entitled ''Immunogenic Peptides and Peptide Derivatives For The Treatment of Prostate And Breast Cancer Treatment'' [HHS Reference No. E–116–2003/0–US–01]; International Patent Application No. PCT/US2004/17574 filed June 2, 2004 entitled ''Immunogenic Peptides and Peptide Derivatives or The Treatment of Prostate And Breast Cancer Treatment'' [HHS Reference No. E–116–2003/0–PCT–02]; United States Patent No.7,541,035, issued June 2, 2009, entitled ''Immunogenic Peptides and Peptide Derivatives For The Treatment of Prostate And Breast Cancer Treatment'' [HHS Reference No. E–116–2003/0–US–03]; United States Patent No. 8,043,623, issued 25 Oct 2011, entitled ''Immunogenic Peptides and Peptide Derivatives For The Treatment of Prostate And Breast Cancer Treatment'' [HHS Reference No. E–116–2003/0–US–04]; United States Provisional Patent Application No. 61/915,948, filed December 13, 2013, entitled ''Multi-Epitope TARP Peptide Vaccine and Uses Thereof'' [HHS Reference No. E–047–2014/0–US–01]; International Patent Application No. PCT/US2014/070144 filed December 12, 2014 entitled ''Multi-Epitope TARP Peptide Vaccine and Uses Thereof'' [HHS Reference No. E–047–2014/0–PCT–02]; and all continuation applications, divisional applications and foreign counterpart applications claiming priority to the US provisional application no. 61/915, 948 and U.S. Provisional Application No. 62/248,964 filed October 30, 2015 titled ''Compositions and Methods for the Treatment of HER2-Expressing Solid Tumors'' [HHS Reference No. E–187–2015/0–US–01] and continuation applications, divisional applications and foreign counterpart applications claiming priority to the US provisional application no. 62/248,964.

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of Licensed Patent Rights for the following:

(1) Development and commercialization of a therapeutic cancer vaccine specifically in combination with Licensee's proprietary or exclusively in-licensed vectors/adjuvants and ME–TARP;

(2) Development and commercialization of a combination product using Licensee's proprietary or