

capabilities should be incorporated? If not, why not?

4. If certain changes are desirable as additional safeguards for the devices, how feasible is it to retrofit existing units in the field?

5. Should manufacturers standardize their display format to ensure that treatment settings, protocols, and collimator positions are displayed taking human factors into consideration and are recorded for physician review?

6. Should manufacturers submit more data to FDA as part of their premarket submissions for approval or clearance of devices, related to the safety of these devices? If so, why, and what data should be submitted? If not, why not?

7. Should there be a mandatory "time-out" built into the equipment, similar to what already has been implemented for surgical procedures, to confirm that all settings for the equipment are correct and allow adequate time for QA? If not, why not?

8. Should manufacturers provide better instructions and specifics (i.e. QA methodology) for acceptance testing and/or commissioning due to new and/or unique features/capabilities? If so, why and what should be included?

9. Other than requiring a facility to report to FDA, how can FDA ensure that facilities report to FDA significant under-doses and over-doses? Should there be a quantitative metric used to define a medical event similar to that used by the Nuclear Regulatory Commission (e.g. +/- 20% variation from intended dose)?

10. What prevents users from participating in voluntary reporting?

11. How can FDA encourage reporting and prevent workarounds even when no clinically significant adverse event occurs?

#### *B. User Training*

1. Should manufacturers provide training to ensure equipment users have adequate understanding of equipment capabilities, operating principles for the technology, general information about patient dose, and specific dose-related equipment features? If so, why, and what training should be provided? If not, why not?

2. If manufacturers provide such training, which personnel should receive it? In your response, please consider dosimetrists, physicists, radiation therapists or technologists in other specialties and departmental administrators as well as physicians in all medical specialties who may operate radiation therapeutic equipment.

3. If manufacturers provide such training, what is the most effective timing for a new installation and how

frequently should it be repeated for optimum implementation? Should manufacturers recommend an internal training program for use by the facility to insure continued staff competence?

4. For software patches and upgrades, how is the software tested for hazard analysis, verification and validation? Should manufacturers perform additional testing to adequately test software patches?

5. Would standardizing terminology and standardizing design of control panels facilitate safe use of the equipment?

6. Should custom-tailored educational material, such as pamphlets, pocket cards, videos etc. that highlight unique features of the equipment, be provided with new equipment?

#### *C. Quality Assurance Measures*

1. Is there a model QA program that exists which is widely accepted? If so, please describe.

2. What types of QA should be the responsibility of the facility, the physicist, the operator, others?

3. Should manufacturers provide QA procedures to medical facilities and users of radiation therapy devices? If so, why, and what instructions should be provided? If not, why not? How extensive should they be?

4. Should manufacturers provide training on QA practices? If so, why, what type of training should be provided, and to which personnel? If not, why not and who should?

#### **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), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD. 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 Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: May 3, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-10754 Filed 5-6-10; 8:45 am]

**BILLING CODE 4160-01-S**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, May 28, 2010, 12 p.m. to May 28, 2010, 2:30 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on April 28, 2010, 75 FR 22412.

The meeting has been changed to an Internet assisted meeting. The meeting time has been changed to 8 a.m. to 7 p.m. The meeting location remains the same. The meeting is closed to the public.

Dated: April 29, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-10873 Filed 5-6-10; 8:45 am]

**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **National Institutes of Health**

#### **Center for Scientific Review; Amended Notice of Meeting**

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, May 19, 2010, 12 p.m. to May 19, 2010, 5 p.m., Tata Communications, 2355 Dulles Corner Boulevard, 7th Floor, Herndon, VA 20171 which was published in the **Federal Register** on April 26, 2010, 75 FR 21641.

The meeting has been changed to a Hybrid meeting. The meeting date, time and location remain the same. The meeting is closed to the public.

Dated: April 29, 2010.

**Jennifer Spaeth,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 2010-10871 Filed 5-6-10; 8:45 am]

**BILLING CODE 4140-01-P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2010-N-0001]**

#### **Food Protection Workshop; Public Workshop**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of public workshop.

**SUMMARY:** The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Southwest Regional Office (SWRO), in co-sponsorship with the University of Arkansas (UA) Institute of Food Science and Engineering, is announcing a public workshop entitled "Food Protection Workshop." This public workshop is intended to provide information about food safety, food defense, the regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), and other related subjects to the Food Protection Plan as it relates to food establishments such as farms, manufacturers, processors, distributors, retailers, and restaurants.

**Date and Time:** This public workshop will be held on June 9 and 10, 2010, from 8 a.m. to 5 p.m.

**Location:** The public workshop will be held at the Continuing Education Center, Two East Center St., Fayetteville, AR (located downtown).

**Contact:** David Arvelo, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, suite 900, Dallas, TX 75204, 214-253-4952, FAX: 214-253-4970, or e-mail: [david.arvelo@fda.hhs.gov](mailto:david.arvelo@fda.hhs.gov).

For information on accommodation options, visit [http://www.uark.edu/ua/foodpro/Workshops/Food\\_Safety\\_Defense\\_Workshop.html](http://www.uark.edu/ua/foodpro/Workshops/Food_Safety_Defense_Workshop.html) or contact Steven C. Seideman, 2650 North Young Ave., Institute of Food Science & Engineering, University of Arkansas, Fayetteville, AR 72704, 479-575-4221, FAX: 479-575-2165, or e-mail: [seideman@uark.edu](mailto:seideman@uark.edu).

**Registration:** You are encouraged to register by May 26, 2010. The University of Arkansas has a \$250 registration fee to cover the cost of facilities, materials, speakers, and breaks. There is no fee for FDA employees. Seats are limited; please submit your registration as soon as possible. Course space will be filled in order of receipt of registration. Those accepted into the course will receive confirmation. Registration will close after the course is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is \$350 payable to: "The University of Arkansas." If you need special accommodations due to a disability, please contact Steven C. Seideman (see *Contact*) at least 14 days in advance.

To register, please visit [http://www.uark.edu/ua/foodpro/Workshops/Food\\_Safety\\_Defense\\_Workshop.html](http://www.uark.edu/ua/foodpro/Workshops/Food_Safety_Defense_Workshop.html) to

register online or submit a check or money order for \$250 payable to the "The University of Arkansas." Mail to: Institute of Food Science & Engineering, University of Arkansas, 2650 North Young Ave., Fayetteville, AR 72704 along with the following information: Your name, affiliation, mailing address, phone number, fax, e-mail, and whether special accommodations are required.

**Transcripts:** Transcripts of the public workshop will not be available due to the format of this workshop. Workshop handouts may be requested at cost through the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the public workshop at a cost of 10 cents per page.

**SUPPLEMENTARY INFORMATION:** This public workshop is being held in response to the large volume of food protection concerns from food establishments (such as farms, manufacturers, processors, distributors, retailers, and restaurants) originating from the area covered by the FDA Dallas District Office. The SWRO presents this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of the Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's guidance, requirements, and compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), as outreach activities by Government agencies to small businesses.

The goal of this public workshop is to present information that will enable food establishments (such as farms, manufacturers, processors, distributors, retailers, and restaurants) to better comply with any regulations authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) relevant to such establishments, and to be aware of recommendations in food protection guidance, especially in light of growing concerns about food safety and defense. Information presented will be based on regulations, guidances, and information previously

made available to the public. Topics to be discussed at the workshop include: (1) Food defense programs, (2) good manufacturing practices, (3) reportable food registry, (4) Hazard Analysis Critical Control Point (HACCP), (5) good agricultural practices, (6) food recalls, (7) pathogens of public health concern, and (8) risk management and vulnerability assessments and other related topics. For more information, please visit [http://www.uark.edu/ua/foodpro/Workshops/Food\\_Safety\\_Defense\\_Workshop.html](http://www.uark.edu/ua/foodpro/Workshops/Food_Safety_Defense_Workshop.html). FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the regulatory and guidance perspectives on food protection and increase voluntary compliance and food defense awareness.

Dated: May 3, 2010.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2010-10792 Filed 5-6-10; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****National Institutes of Health****Office of the Director, Office of Biotechnology Activities; Notice of a Safety Symposium**

There will be a safety symposium entitled "Gene-Modified T Cells: Challenges in Clinical Trial Design with Novel Receptors." The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. For further information concerning this meeting contact Ms. Chezelle George, Administrative Assistant, Office of Biotechnology Activities, Office of the Director, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892-7985, 301-496-9838, [georgec@mail.nih.gov](mailto:georgec@mail.nih.gov).

**Name of Committee:** Recombinant DNA Advisory Committee.

**Date:** June 15, 2010.

**Time:** 8 a.m. to 5:30 p.m.

**Agenda:** The Office of Biotechnology Activities (OBA) and NIH Recombinant DNA Advisory Committee will host a symposium entitled "Gene Modified T Cells: Challenges in Clinical Trial Design with Novel Receptors" on June 15, 2010 at the Rockville Hotel and Executive Center. Experts will discuss data from trials conducted to date, the selection of novel antigen targets, the