

clinical trial staff, investigators, and institutional review boards (IRBs). Individual FDA representatives will discuss the informed consent process including the informed consent documents, regulations relating to drugs, devices, and biologics, as well as inspections of clinical investigators, of IRBs, and of research sponsors.

**Date and Time:** The public workshop will be held on March 12 and 13, 2014, from 8 a.m. to 5 p.m.

**Location:** The public workshop will be held at the Hyatt Regency Newport Beach Hotel, 1107 Jamboree Rd., Newport Beach, CA 92660, 949-729-6061. Attendees are responsible for their own accommodations. Please mention SoCRA to receive the hotel room rate of \$152.00 plus applicable taxes (available until February 18, 2014, or until the SoCRA room block is filled).

**Contact:** Jane Kreis, Food and Drug Administration, 1301 Clay St., Suite 1180N, Oakland, CA 94612, 510-287-2708, FAX: 510-287-2739, or Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914, 800-762-7292 or 215-822-8644, FAX: 215-822-8633, email: [SoCRAmail@aol.com](mailto:SoCRAmail@aol.com), Web site: [www.socra.org](http://www.socra.org).

**Registration:** The registration fee will cover actual expenses including refreshments, lunch, materials, and speaker expenses. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. The cost of registration is as follows:

SoCRA member .....	\$575
SoCRA nonmember (includes membership).	\$650
Federal Government SoCRA member.	\$450
Federal Government SoCRA non-member.	\$525
FDA Employee .....	Fee Waived

If you need special accommodations due to a disability, please contact SoCRA, 800-762-7292 or 215-822-8644, FAX: 215-822-8633, or email: [SoCRAmail@aol.com](mailto:SoCRAmail@aol.com) at least 21 days in advance.

Extended periods of question and answer and discussion have been included in the program schedule. SoCRA designates this education activity for a maximum of 13.3 Continuing Education (CE) credits for SoCRA CE and continuing nurse education (CNE). SoCRA designates this live activity for a maximum of 13.3 American Medical Association

Physicians Recognition Award Category 1 Credit(s)<sup>TM</sup>. Physicians should claim only the credit commensurate with the extent of their participation. *Continuing Medical Education for physicians:* SoCRA is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. *CNE for nurses:* SoCRA is an approved provider of CNE by the Pennsylvania State Nurses Association (PSNA), an accredited approver by the American Nurses Credentialing Center's Commission on Accreditation (ANCC). ANCC/PSNA Provider Reference Number: 205-3-A-09.

**Registration Instructions:** To register, please submit a registration form with your name, affiliation, mailing address, telephone, fax number, and email, along with a check or money order payable to "SoCRA". Mail to: Society of Clinical Research Associates (SoCRA), 530 West Butler Ave., Suite 109, Chalfont, PA 18914. To register via the Internet, go to: [http://www.socra.org/html/FDA\\_Conference.htm](http://www.socra.org/html/FDA_Conference.htm). (FDA has verified the Web site addresses throughout this document, but we are not responsible for any subsequent changes to the Web sites after this document is published in the **Federal Register**).

Payment by major credit card is accepted (Visa/MasterCard/AMEX only). For more information on the meeting registration, or for questions on the public workshop, contact SoCRA, 800-762-7292 or 215-822-8644, FAX: 215-822-8633, or email: [SoCRAmail@aol.com](mailto:SoCRAmail@aol.com).

**SUPPLEMENTARY INFORMATION:** The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The public workshop will provide those engaged in FDA-regulated (human) clinical trials with information on a number of topics concerning FDA requirements related to informed consent, clinical investigation requirements, IRB inspections, electronic record requirements, and investigator initiated research. Topics for discussion include the following: (1) The Role of the FDA District Office Relative to the Bioresearch Monitoring Program (BIMO); (2) Modernizing FDA's Clinical Trials/BIMO Programs; (3) What FDA Expects in a Pharmaceutical Clinical Trial; (4) Medical Device Aspects of Clinical Research; (5) Adverse Event Reporting—Science, Regulation, Error, and Safety; (6) Working with FDA's Center for Biologics Evaluation and Research; (7) Ethical Issues in Subject Enrollment; (8) Keeping Informed and Working

Together; (9) FDA Conduct of Clinical Investigator Inspections; (10) Investigator Initiated Research; (11) Meetings with FDA—Why, When, and How; (12) Part 11 Compliance—Electronic Signatures; (13) IRB Regulations and FDA Inspections; (14) Informed Consent Regulations; (15) The Inspection is Over—What Happens Next? Possible FDA Compliance Actions; and (16) Question and Answer Session/Panel Discussion.

FDA has made education of the drug and device manufacturing community a high priority to help ensure the safety and effectiveness of FDA-regulated drugs and devices. The public 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 public 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.

Dated: January 16, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-01300 Filed 1-22-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0001]

#### Risk Communication Advisory Committee; Notice of Postponement of Meeting

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is postponing the meeting of the Risk Communication Advisory Committee scheduled for February 3 and 4, 2014. The meeting was announced in the **Federal Register** of January 3, 2014 (79 FR 398). The meeting is postponed due to unavoidable operational changes. Future meeting dates will be announced in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Luis G. Bravo, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3274, Silver Spring, MD 20993, 240-402-5274, or email: [RCAC@fda.hhs.gov](mailto:RCAC@fda.hhs.gov) or FDA Advisory Committee Information

Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the Information Line for up-to-date information on this meeting.

Dated: January 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-01312 Filed 1-22-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0001]

#### Science Board to the Food and Drug Administration; Amendment of Notice

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing an amendment to the notice of meeting of the Science Board to the Food and Drug Administration. This meeting was announced in the **Federal Register** of January 9, 2014 (79 FR 1645). The amendment is being made to reflect a change in the *Date and Time* and the *Agenda* portions of the document. There are no other changes.

**FOR FURTHER INFORMATION CONTACT:**

Martha Monser, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 4286, Silver Spring, MD 20993, 301-796-4627, [martha.monser@fda.hhs.gov](mailto:martha.monser@fda.hhs.gov), or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). Please call the information line for up-to-date information on this meeting.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of January 9, 2014, FDA announced that a meeting of the Science Board to the Food and Drug Administration would be held on February 5, 2014.

1. On page 1645, in the second column, the *Date and Time* portion of the document is changed to read as follows:

*Date and time:* The meeting will be held on February 5, 2014, from approximately 8:30 a.m. until 1 p.m.

2. On page 1645, in the second column, under *Agenda*, in the first paragraph, after the third sentence, the following sentence is added to read as follows:

The Office of Women's Health (OWH) will seek input from the Board on the development of the OWH Research Roadmap.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to the advisory committees.

Dated: January 17, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014-01298 Filed 1-22-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-E-0456]

#### Determination of Regulatory Review Period for Purposes of Patent Extension; DALIRESP

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) has determined the regulatory review period for DALIRESP and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit electronic comments to <http://www.regulations.gov>. Submit written petitions (two copies are necessary) and written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to <http://www.regulations.gov> at Docket No. FDA 2013-S-0610.

**FOR FURTHER INFORMATION CONTACT:**

Beverly Friedman, Office of Management, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993-0002, 301-796-7900.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis

for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product DALIRESP (roflumilast). DALIRESP is indicated as a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Subsequent to this approval, the U.S. Patent and Trademark Office received a patent term restoration application for DALIRESP (U.S. Patent No. 5,712,298) from Nycomed GmbH, and the U.S. Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated August 7, 2012, FDA advised the U.S. Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of DALIRESP represented the first permitted commercial marketing or use of the product. Thereafter, the U.S. Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for DALIRESP is 4,237 days. Of this time, 3,645 days occurred during the testing phase of the regulatory review period, while 592 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355(i)) became effective:* July 26, 1999. The applicant claims December 19, 1999, as the date the investigational