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*, 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