Federal and State governments, the dairy industry, academia, and consumer groups. FDA collaborates with the NCIMS under a memorandum of understanding between the two entities. The NCIMS requested that we conduct an assessment of animal drug residues in the milk supply to inform potential changes to milk testing program requirements. In response, we developed a multicriteria-based ranking model of selected animal drugs used in dairy cows. The risk assessment provides a science-based, analytical approach to collate and incorporate relevant available data and information (Ref. 1). It provides a decision-support tool to assist with reevaluating which animal drug residues should be included in milk testing programs. The risk assessment also may be used to identify and prioritize research needs. The risk assessment model approach has undergone an independent external peer review. FDA's response to the peer review is available electronically on the FDA Web site (Ref. 2).

The muticriteria-based ranking model is based on four overarching criteria that collectively contribute to a drug's score and rank within the group of drugs evaluated: (1) The likelihood that the drug will be administered to lactating dairy cows; (2) the likelihood that, following administration, drug residues would be present in milk (bulk tank or bulk milk pickup tanker); (3) the relative extent to which consumers could be exposed to the drug residue via consumption of milk and milk products; and (4) the potential for a human health hazard given exposure to the drug residue. The risk assessment describes the ranking model structure, the scientific data and assumptions used to inform scoring in the model, and the ranking results. The risk assessment also identifies data gaps and research needs.

FDA invites comments that can help improve:

- The ranking model approach, including the specific criteria, scoring, and weighting scheme;
- the scientific data and assumptions used to inform scoring used in the model;
- the selection of animal drugs evaluated; and
- the clarity and the transparency of the risk assessment.

II. Comments

Interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**) regarding the risk assessment. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the risk assessment at either *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm* or *http://www.regulations.gov.*

IV. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday, and are available electronically at *http://www.regulations.gov.* (We have verified the Web site addresses in this reference section, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. U.S. Food and Drug Administration (2015). ''Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products.'' Accessible at *http://www.fda.gov/Food/FoodScienceResearch/RiskSafetyAssessment/ucm443549.htm.*

2. U.S. Food and Drug Administration (2015). ''Multicriteria-Based Ranking Model for Risk Management of Animal Drug Residues in Milk and Milk Products: Peer Review Report.'' Accessible at *http://www.fda.gov/ScienceResearch/SpecialTopics/PeerReviewofScientificInformationandAssessments/default.htm.*

Dated: April 20, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10000 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Risk Communications Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Risk Communications Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 8, 2015, from 9 a.m. to 5 p.m. and June 9, 2015, from 9 a.m. to 12 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503) Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Luis G. Bravo, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3367, 240–402–5274, FAX: 301–847–3540, *RCAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

If you are unable to join us in person, we encourage you to watch the free Webcast. Visit the Risk Communication Advisory Committee Web site at *http://www.fda.gov/AdvisoryCommittees/RiskCommunicationAdvisoryCommittee.htm.* The link will become active shortly before the open session begins at 9 a.m.

Agenda: On June 8 and 9, 2015, the Committee will discuss approaches to communicating information about fetal effects in product labeling for methadone or buprenorphine maintenance therapy for opioid addiction, and about the maternal benefits and risks of treatment, to best enable patients and health care providers to make informed decisions about the use of these drugs during pregnancy.

FDA intends to make background material available to the public no later

than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/RiskCommunicationAdvisoryCommittee.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before June 1, 2015. Oral presentations from the public will be scheduled between approximately 2 p.m. and 3:30 p.m. on June 8, 2015. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 22, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by May 26, 2015. Interested persons can also log on to *http://www.fda.gov/AdvisoryCommittees/RiskCommunicationAdvisoryCommittee.htm* to see and hear the proceedings.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Luis G. Bravo at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 24, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–10024 Filed 4–29–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Endocrinologic and Metabolic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Endocrinologic and Metabolic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on June 10, 2015, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD 20877. The hotel phone number is 301–977–8900.

Contact Person: Philip Bautista, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *EMDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss the safety and efficacy of biologics license application (BLA) 125522, proposed trade name REPATHA (established name: Evolocumab) for injection, submitted by Amgen Inc., as adjunct to diet to reduce low-density lipoprotein cholesterol (LDL–C), total cholesterol (TC), apolipoprotein B (ApoB), non-high-density lipoprotein cholesterol (non-HDL–C), TC/HDL–C, ApoB/ApoA1, very low-density lipoprotein cholesterol, triglyceride, and lipoprotein A, and to increase HDL–C and ApoA1, in adults with hyperlipidemia or mixed dyslipidemia, either in combination with a statin or statin with other lipid-lowering therapies (*e.g.,* ezetimibe), or alone, or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or alone or in combination with other lipid-lowering therapies in patients for whom a statin is not considered clinically appropriate. In addition, the committee will discuss the safety and efficacy of evolocumab to reduce LDL–C, TC, ApoB, and non-HDL–C, in combination with other lipid-lowering therapies (*e.g.* statins, LDL apheresis) in patients at least 12 years of age with homozygous familial hypercholesterolemia.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before May 27, 2015. Oral presentations from the public will be scheduled between approximately 1:15 p.m. to 2:15 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before May 18,