DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2768]

Collecting On-Farm Antimicrobial Use and Resistance Data; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA), in collaboration with the U.S. Department of Agriculture (USDA) and the Centers for Disease Control and Prevention (CDC), is announcing plans for a jointly sponsored public meeting to obtain public input on possible approaches for collecting additional on-farm antimicrobial drug use and resistance data. Such data are important for assessing the impact of measures being implemented to foster the judicious use of medically important antimicrobial drugs in food-producing animals.

Date and Time: The public meeting will be held September 30, 2015, from 8 a.m. to 4:30 p.m. Although you can comment on the interagency plan for collecting on-farm antimicrobial drug use and resistance data at any time, to ensure that the Agencies consider your comment before updating this plan, submit either electronic or written comments by November 30, 2015.

Location: The public meeting will be held in the USDA Jefferson Auditorium (South Building), 1400 Independence Avenue SW., Washington, DC 20250. Please arrive between 7 a.m. and 7:30 a.m. to provide time to get through security. Attendees must provide a valid government issued photo ID (Driver's License, Identification Card, or Passport) to enter the facility. Attendees should enter the building via Wing 5 on the Independence Avenue side of the building. The South Building is accessible by the Smithsonian Metro station (exit Metro station through the ''Independence Avenue Exit'' and walk toward 15th Street on Independence Avenue to reach Wing 5). For more information on directions and parking, visit *http://smithsonianassociates.org/ticketing/help/locations/jefferson.htm.*

Contact Person: Kelly Covington, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5661, FAX: 240–276–9020, email: *Kelly.Covington@fda.hhs.gov.*

Registration and Requests for Oral Presentations: Registration is required for this public meeting. Please send registration information (including name, title, organization, address, telephone and fax numbers) by email to *Kelly.Covington@fda.hhs.gov* by September 18, 2015. There is no fee to register for the public meeting, and registration will be on a first-come, first-served basis. If you need special accommodations due to a disability, please contact Kelly Covington (see *Contact Person*) at least 7 days in advance.

Oral presentations can be made by members of the public during the open public comment period of the public meeting. These presentations will be scheduled between approximately 3 p.m. and 4 p.m. on September 30, 2015. Those persons desiring to make an oral presentation should notify the contact person listed in this notice by September 16, 2015, and submit a brief statement of the general nature of information they wish to present. In an effort to accommodate all who desire to speak, time allotted for each presentation may be limited. The contact person will inform each speaker prior to the meeting of the time they are scheduled to speak.

Comments: Regardless of attendance at the public meeting, interested persons may submit either electronic comments to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, by (see *Date and Time*). 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.*

SUPPLEMENTARY INFORMATION:

I. Background

Antimicrobial drugs have been widely used in human and veterinary medicine for more than 50 years, with tremendous benefits to both human and animal health. The development of resistance to this important class of drugs, and the resulting loss of their effectiveness as antimicrobial therapies, poses a serious threat to public and animal health. Because antimicrobial drug use can contribute to the emergence of drug-resistant organisms, these important drugs must be used judiciously in both animal and human medicine to slow the development of resistance.

In December 2013, FDA published Guidance for Industry (GFI) #213 (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf*), which calls on animal drug sponsors of approved medically important antimicrobials administered through medicated feed or water to voluntarily remove production (growth promotion and feed efficiency) uses from their product labels, and bring the remaining therapeutic uses of these products (to treat, control, or prevent disease) under the oversight of a veterinarian by the end of December 2016. All 25 affected drug sponsors have committed to implementing the changes described in GFI #213 by the December 2016 target date. Once the changes are fully implemented, it will be illegal to use these medically important antibiotics for production purposes, and animal producers will need to obtain authorization from a licensed veterinarian to use them for prevention, control, or treatment of a specifically identified disease.

On March 27, 2015, the White House released the National Action Plan for Combating Antibiotic-resistant Bacteria (''National Action Plan'') (*https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf*). Developed in response to Executive Order 13676, which was issued by President Barack Obama on September 18, 2014, the National Action Plan is intended to guide the activities of the U.S. Government as well as the actions of public health, health care, and veterinary partners in a common effort to address the urgent and serious public health threat of drug-resistant bacterial infections. Objective 2.4 of the National Action Plan is to enhance monitoring of antibiotic resistance patterns, as well as antibiotic sales, usage, and management practices, at multiple points in the production chain for food animals and retail meat. The public meeting being announced in this **Federal Register** notice is consistent with Sub-Objective 2.4.3 of the National Action Plan, which calls for the USDA and FDA to seek public input on a plan for collecting drug use and resistance data on farms.

In April 2015, USDA's Animal and Plant Health Inspection Service published an Info Sheet entitled ''Proposed Initiatives From the USDA Antimicrobial Resistance Action Plan'' (*http://www.aphis.usda.gov/animal_health/nahms/amr/downloads/ProposedInitiatives.pdf*). The Info Sheet provides a brief synopsis of initiatives

proposed in the USDA Action plan, including a number of initiatives related to collecting on-farm antibiotic use and resistance data.

Gathering information on the way medically important antimicrobials are used in food-producing animals is essential to measuring the impact of the FDA's GFI #213. FDA is collaborating with USDA and CDC to develop a plan for collecting additional on-farm data on antimicrobial use and resistance. Such data are intended to supplement existing information, including data on the quantity of antimicrobials sold or distributed for use in food-producing animals (reported under section 105 of the Animal Drug User Fee Amendments of 2008) and data on antimicrobial resistance (*e.g.,* collected under the National Antimicrobial Resistance Monitoring System and the National Animal Health Monitoring System). Data from multiple sources are needed to provide a comprehensive and science-based picture of antimicrobial drug use and resistance in animal agriculture.

A data collection plan is needed to obtain additional information necessary to: (1) Assess the rate of adoption of changes outlined in the FDA's GFI #213; (2) help gauge the success of antibiotic stewardship efforts and guide their continued evolution and optimization; and (3) assess associations between antibiotic use practices and resistance. FDA is continuing to work with the USDA and CDC in developing this plan, and is holding this public meeting in order to obtain input from the public. This meeting is the first opportunity for public input as part of our ongoing effort to develop and implement plans for collecting additional on-farm antimicrobial drug use and resistance data.

II. Agenda

The public meeting will provide an opportunity for public comment on possible approaches for collecting additional antimicrobial drug use data. The final agenda for the public meeting will be made available on the Agency's Web site at *http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/ucm456380.htm* no later than 2 weeks prior to the meeting.

III. Transcript

FDA will prepare a meeting transcript and make it available on the Agency's Web site (see section II) after the meeting. FDA anticipates that the transcript will be available approximately 60 business days after the meeting. A copy of the transcript will be available for public examination at the Division of Dockets Management (see *Comments*) between 9 a.m. and 4 p.m., Monday through Friday. In addition, copies of the transcript will be available 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: August 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Bone, Reproductive, and Urologic 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: Bone, Reproductive, and Urologic 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 November 3, 2015, from 8:30 a.m. to 5 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: Kalyani Bhatt, 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, email: *BRUDAC@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 new drug application (NDA) 207959, enclomiphene citrate 12.5 milligram (mg) and 25 mg capsules, submitted by Repros Therapeutics, Inc., for the proposed treatment of secondary hypogonadism in fertile men (men with more than 15 million sperm/milliliter (ml)), younger than 60 years of age with a Body Mass Index (BMI) over 25 kilograms (kg)/meters squared (m2).

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 October 20, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 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 October 9, 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