4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-1046]

Veterinary Oversight of Antimicrobial Use in Livestock: Impact on Stakeholders; Public Meetings; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meetings; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing plans for five meetings to provide an opportunity for public dialogue and feedback on challenges faced by the animal agriculture industry and practicing veterinarians as FDA implements its initiative for the judicious use of medically important antimicrobials in medicated feed or drinking water of food-producing animals. Particular emphasis will be placed on challenges faced by animal producers in areas that may lack access to adequate veterinary services. The meetings are jointly sponsored by FDA and the U.S. Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS).

DATES: See the SUPPLEMENTARY INFORMATION section for meeting dates.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Dates, Times, and Locations:

- April 9, 2013, from 8:30 a.m. to 12:30 p.m., Western Kentucky University–Carroll Knicely Conference Center (Auditorium rm. 138), 2355 Nashville Rd., Bowling Green, KY 42101; 270-745-1908; FAX: 270-745-1911; http://www.wku.edu/.
- April 23, 2013, from 8:30 a.m. to 12:30 p.m., Evergreen State College (Library 4300), 2700 Evergreen Pkwy. NW, Olympia WA 98505; 360-867-6192 or 6000; http://www.evergreen.edu/home.htm.
- May 8, 2013, from 8:30 a.m. to 12:30 p.m., The Natural Resource Research Center, USDA Animal and Plant Health & Inspection Service, Veterinary Services, Centers for Epidemiology & Animal Health, 2150 Centre Ave. (Building B, Gray's Peak Conference Rooms A & B), Fort Collins, CO 80526-8117; 970-494-7200; FAX: 970-472-2668; http://www.aphis.usda.gov/about_aphis/programs_offices/veterinary_services/ceah.shtml.
- May 21, 2013, from 8:30 a.m. to 12:30 p.m., Best Western Ramkota Hotel & Conference Center (Amphitheater II), 920 West Sioux Ave., Pierre, SD 57501; 605-224-6877; FAX: 605-224-1042; http://pierre.bwramkota.com/.

- June 4, 2013, from 8:30 a.m. to 12:30 p.m., Texas A&M University (Memorial Student Center, rm. 2406A), Joe Routt Boulevard and Houston Street, College Station, TX 77840; 979-845-8904; FAX: 979-845-2519; http://www.tamu.edu/.

Oral Presentations: Interested persons may make oral presentations on the topic of the discussion of the meeting. Oral presentations from the public during the open public comment period will be scheduled approximately:

- April 9, 2013, from 9:45 a.m. to 11 a.m. on the day of the meeting in Bowling Green, KY;
- April 23, 2013, from 9:45 a.m. to 11 a.m. on the day of the meeting in Olympia, WA;
- May 8, 2013, from 9:45 a.m. to 11 a.m. on the day of the meeting in Fort Collins, CO;
- May 21, 2013, from 9:45 a.m. to 11 a.m. on the day of the meeting in Pierre, SD; and
- June 4, 2013, from 9:45 a.m. to 11 a.m. on the day of the meeting in College Station, TX.

Although prior notification is not required, it is recommended that those desiring to make oral presentations notify the contact person before the meeting. In an effort to accommodate all who desire to speak, time allotted for each presentation may be limited.

Registration is not required for these meetings; however, early arrival is recommended because seating may be limited. If you need special accommodations due to a disability, please contact FDA (see FOR FURTHER INFORMATION CONTACT) at least 7 days in advance.

Comments: Regardless of attendance at the public meetings, interested persons may submit either electronic or written comments regarding the topics to be discussed at these meetings. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630

Fishers Lane, rm. 1061, Rockville, MD 20852. 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. The docket will remain open for written or electronic comments for 60 days following the last of these five meetings.

FDA is concerned about the risk that antimicrobial resistance poses to public health from the use of medically important antimicrobial drugs in food-producing animals. Over the past several years, FDA's Center for Veterinary Medicine has developed a policy framework for decreasing this public health risk through the application of concepts of judicious use. Among these concepts, FDA believes that it is important to include veterinary oversight in the use of medically important antimicrobial drugs in the feed or water of food-producing animals to assure the drugs' appropriate and judicious use.

Until the early 1990s, most antimicrobial drugs were approved for over-the-counter (OTC) use in food-producing animals. However, since that time increasing concerns about antimicrobial resistance and evolving understanding of the science related to the issue have resulted in greater scrutiny of the conditions under which these drugs are approved. As a result, since the early 1990s all new approvals for antimicrobial drug products for use in food-producing animals have been labeled with veterinary prescription (Rx) or veterinary feed directive (VFD) marketing status, with the exception of approvals of generic copies of existing OTC products and approvals of combination medicated feeds using existing OTC antimicrobial Type A medicated articles. This shift to a marketing status requiring veterinary oversight has been viewed as an important step to mitigate the microbial food safety risks of antimicrobial new animal drugs, particularly for those drugs considered to be medically important.

FDA believes that the judicious use of medically important antimicrobial drugs intended for use in food-producing animals requires the scientific and clinical training of a licensed veterinarian. In the Federal Register of April 13, 2012 (77 FR 22328), FDA announced the availability of a Guidance for Industry (GFI) #209 entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" that outlines several recommendations regarding the judicious use of medically important antimicrobials, including the need for veterinary oversight or consultation when these antimicrobials are used in medicated feed or medicated drinking water of food-producing animals (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf).

Accordingly, in the same issue of the Federal Register (77 FR 22327, April 13, 2012), FDA published a notice announcing the availability of a draft guidance for industry (GFI #213) entitled "New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals; Recommendations for Aligning Product Use Conditions With GFI #209." In draft GFI #213 (http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf), FDA is recommending that affected drug sponsors revise the conditions of use of their medically important antimicrobial new animal drugs and combination new animal drug products from OTC to VFD status for medicated feed products and from OTC to Rx status for medicated drinking water products. Also, the draft guidance proposes timelines for stakeholders wishing to comply voluntarily with the guidance.

The following antimicrobial drugs, in products administered in the feed or water of food-producing animals, are covered under draft GFI #213: Chlortetracycline, erythromycin,

lincomycin, neomycin, oxytetracycline, penicillin, spectinomycin, sulfamethazine, tylosin, and virginiamycin.[1] Ionophore drugs are not included under draft GFI #213. FDA is currently reviewing the comments it received on draft GFI #213.

After the FDA has completed its review of comments, the Agency will draft and publish final GFI #213. FDA anticipates that sponsors of affected products should be able to complete implementation of the changes discussed in this draft guidance within 3 years from the date of publication of the final version of this guidance.

Also in that same issue of the Federal Register (77 FR 22247, April 13, 2012), FDA provided the draft text of a proposed regulation (http://www.gpo.gov/fdsys/pkg/FR-2012-04-13/pdf/2012-8844.pdf) to streamline and modernize the current VFD regulation (21 CFR 558.6) which governs veterinary oversight and authorization of the use of certain animal drugs in medicated feed. The public comment period for that document remained open until July 12, 2012. FDA is currently reviewing the comments it received on the draft proposed regulation. After completion of this review, the Agency will draft and publish the proposed VFD regulation.

FDA acknowledges that changing the marketing status of certain antimicrobial drugs to require the involvement of a licensed veterinarian has practical implications for animal producers and practicing veterinarians. Once the status is changed from OTC to Rx or VFD, producers will no longer be able to purchase the animal drug or medicated feed product directly from suppliers, unless the producer has a valid prescription or order from a licensed veterinarian. The impact of this change on producers may vary depending on the extent to which a given producer already

[1] For additional information related to animal drugs in the classes of medically important antimicrobials, see Appendix A of GFI #152 entitled "Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to Their Microbiological Effects on Bacteria of Human Health Concern" (http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/ucm042450.htm).

has access to and utilizes veterinary services. This change also has potential impact on practicing veterinarians depending on their practice (business) model.

FDA is seeking additional input as it moves forward to further develop and implement its judicious-use policy, including the plan to phase in veterinary oversight or consultation in the use of medically important antimicrobial drugs. As part of this input gathering effort, FDA is partnering with APHIS to conduct a series of five meetings (see DATES AND ADDRESSES) to provide the public with opportunities to discuss and provide critical feedback on the challenges faced by stakeholders generally, and livestock producers and practicing veterinarians in particular, as FDA phases in veterinary oversight of the therapeutic use of medically important antimicrobials. During these meetings, particular emphasis will be placed on discussing the potential challenges faced by producers in areas of the country that may lack access to adequate veterinary services and on exploring possible options for minimizing such impacts. FDA also will seek public input through other forums, for example, Webinars, as it works collaboratively with the USDA, along with veterinary and producer organizations, to help address this important issue. Comments also may be made to the FDA docket at any time (see Comments).

Agenda: The meeting will allow for public comment and discussion regarding the judicious use of antimicrobial drugs in food-producing animals. The following specific questions will be discussed at the upcoming meetings:

(1) What is the current availability of veterinary services for your facility and how do you utilize this care?;

(2) How would the proposed changes in marketing status for medically important antimicrobials to VFD/Rx and proposed revisions to the VFD regulations affect your operation or practice?; and

(3) What are some possible solutions or models for access of veterinary services that would benefit your operation in light of these changes?

The agenda for the public meeting will be made available on the Agency's Web site at http://www.fda.gov/AnimalVeterinary/NewsEvents/WorkshopsConferencesMeetings/default.htm and will be posted to the docket at http://www.regulations.gov.

Dated: March 4, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-05339 Filed 03/06/2013 at 8:45 am; Publication Date: 03/07/2013]