DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–D–0094]

Draft Guidance: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance (#209) entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.” This draft guidance is intended to inform the public of FDA’s current thinking on the use of medically important antimicrobial drugs in food-producing animals.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by August 30, 2010.

ADDRESSES: Submit written requests for single copies of the guidance to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests. Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD) (HFPM–40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, or by calling 1–800–835–4709 or 301–827–1800, or e-mail: ocod@fda.hhs.gov. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to http://www.regulations.gov. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9084, e-mail: william.flynn@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance (#209) entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.” 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 public health threat. Misuse and overuse of antimicrobial drugs creates selective evolutionary pressure that enables antimicrobial resistant bacteria to increase in numbers more rapidly than antimicrobial susceptible bacteria and thus increases the opportunity for individuals to become infected by resistant bacteria. Because antimicrobial drug use contributes 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. Using these drugs judiciously means that unnecessary or inappropriate use should be avoided. Although efforts to assure judicious use should be directed at all uses of antimicrobial drugs, the focus of this document is on the use of medically important antimicrobial drugs in food-producing animals.

In regard to the use of antimicrobial drugs in animals, concerns have been raised by the public and components of the scientific and public health communities that a significant contributing factor to antimicrobial resistance is the use of medically important antimicrobial drugs in food-producing animals. Antimicrobial use in the food-producing animal industry contributes to the development of antimicrobial resistance. Significant increases in resistance to both human and veterinary medicine have been documented in the food chain. In veterinary medicine, the cost of treating resistant infections is enormous, and the economic impact of resistance is significant. FDA’s goal is to improve the judicious use of antimicrobial drugs in food-producing animals and to minimize the development of drug resistance. Antimicrobial resistance is a global public health threat and increasing resistance to currently available antimicrobials will necessitate new strategies and the development of new antimicrobials.

Despite the potential for significant benefits to both animal and public health, antimicrobial drug use in the food-producing animal industry has been subject to little regulatory oversight. As a result, antimicrobial drugs are used in food-producing animals for production or growth-enhancing purposes. This document summarizes some of the key scientific reports on the use of antimicrobial drugs in animals and outlines FDA’s current thinking on strategies for assuring that medically important antimicrobial drugs are used judiciously in food-producing animals in order to help minimize antimicrobial resistance development.

Based on a consideration of the available scientific information, FDA is making a number of recommendations regarding the appropriate or judicious use of medically important antimicrobial drugs in food-producing animals. These recommendations include phasing in such measures as follows: (1) Limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring...
animal health and (2) limiting such drugs to uses in food-producing animals that include veterinary oversight or consultation. Developing strategies for reducing antimicrobial resistance is critically important for protecting both public and animal health. Collaboration involving both the public and animal health communities on the development and implementation of such strategies is needed to assure that the public health is protected while also assuring that the health needs of animals are addressed.

This draft guidance discusses FDA’s general public health concerns regarding the potential impact of certain uses of medically important antimicrobial drugs in food-producing animals on the development of antimicrobial resistance, and provides two broad recommendations regarding such use. The agency intends to issue further guidance in the near future to provide more specific information on approaches for implementing the recommendations outlined in this draft guidance.

II. Significance of Guidance

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the public health communities on the development and implementation of such strategies is needed to assure that the public health is protected while also assuring that the health needs of animals are addressed.

III. Paperwork Reduction Act of 1995

FDA concludes that there are no collections of information under the Paperwork Reduction Act of 1995.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed 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.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either http://www.regulations.gov or http://www.animalandplanthealthinspection.usda.gov/animal-welfare/laws/animal-welfare-regulations.html.

Dated: June 10, 2010.

Leslie Kux, Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings. The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Neuroendocrinology and Fetal Alcohol

Date: July 13, 2010.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

(Telephone Conference Call).

Contact Person: Michael Selmanoff, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3134, MSC 7844, Bethesda, MD 20892, 301–435–1119, mselmanoff@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Language and Communication

Date: July 14, 2010.

Time: 2 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

(Telephone Conference Call).

Contact Person: Dana Jeffrey Phude, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3176, MSC 7848, Bethesda, MD 20892, 301–435–2309, pluded@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.