

**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comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 12, 2012.

**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 request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to 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 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, [william.flynn@fda.hhs.gov](mailto:william.flynn@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

This document is related to two documents published elsewhere in this issue of the **Federal Register**, wherein FDA is announcing: (1) The availability of a final guidance entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals” (GFI #209) and (2) the availability of a draft proposed regulation for veterinary feed directives.

FDA is announcing the availability of a draft guidance for industry entitled “New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing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 Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209” (draft GFI #213). The audience for this draft guidance is sponsors of approved applications for new animal drug products containing medically important antimicrobial new animal drugs for use in or on medicated feed or in drinking water of food-producing animals. The purpose of this draft guidance is to provide sponsors of the affected new animal drug products with more specific information on how to supplement their approved new animal drug applications to align with FDA’s recommendations in GFI #209.

Final GFI #209, published elsewhere in this edition of the **Federal Register**, discusses FDA’s concerns regarding the development of antimicrobial resistance in human and animal bacterial pathogens when medically important antimicrobial drugs are used in food-producing animals in an injudicious manner. GFI #209 recommends that the use of medically important antimicrobial drugs be limited to uses in animals that are considered necessary for assuring animal health and include veterinary oversight or consultation (namely through the use of prescription or veterinary feed directive products).

FDA encourages all sponsors of new animal drug products covered by draft GFI #213 to participate in the voluntary program outlined in the draft guidance. FDA believes a voluntary approach, conducted in a cooperative and timely manner, will be a far faster and less burdensome route to achieving the common goal of more judicious use of medically important antimicrobials in animal agriculture. However, FDA also believes it is critical to see meaningful progress toward reaching this goal. Therefore, in order to ensure an orderly, equitable, and timely transition, draft GFI #213 also includes clear timelines for sponsors of affected products wishing to revise their approved applications.

##### **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 FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

##### **III. Paperwork Reduction Act of 1995**

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 514 have been approved under OMB control numbers 0910–0032 and 0910–0669.

##### **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. 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.

##### **V. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: April 5, 2012.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2012–8845 Filed 4–11–12; 11:15 am]

**BILLING CODE 4160–01–P**

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

[Docket No. FDA–2010–D–0094]

#### **Guidance for Industry on 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 guidance for industry (GFI #209) entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.” This guidance is intended to inform the public of FDA’s current thinking on the use of medically important antimicrobial drugs in animal agriculture.

**DATES:** Submit either electronic or written comments on Agency guidances at any time.

**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. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance 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.

**FOR FURTHER INFORMATION CONTACT:**

William T. Flynn, Center for Veterinary Medicine (HVF-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9084, [William.flynn@fda.hhs.gov](mailto:William.flynn@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This document is related to two documents published elsewhere in this issue of the **Federal Register**, wherein FDA is announcing: (1) The availability of a draft guidance 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 Drug Sponsors for Voluntarily Aligning Product Use Conditions With GFI #209” (draft GFI #213); and (2) the availability of a draft proposed regulation for veterinary feed directives.

In the **Federal Register** of June 29, 2010 (75 FR 37450), FDA published the notice of availability for a draft guidance entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals,” giving interested persons until August 30, 2010, to comment on the draft guidance. FDA received numerous comments on the draft guidance, and those comments were considered as the guidance was finalized. Minor editorial changes were made to improve clarity.

The Agency was pleased to receive a number of comments that were generally supportive of the concepts outlined in draft GFI #209. However, other comments were more critical, based largely on the guidance’s lack of specificity related to implementation issues. FDA decided not to make any substantive changes to GFI #209 but rather to address specific issues related to implementation through issuance of a separate draft guidance document, draft GFI #213, that would afford additional opportunity for public comment. As noted earlier, a notice of availability for draft GFI #213 is published elsewhere in this issue of the **Federal Register**.

The guidance announced in this notice finalizes the draft guidance dated June 28, 2010.

**II. Significance of Guidance**

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency’s current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind

FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**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. 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.

**V. Electronic Access**

Persons with access to the Internet may obtain the guidance at either <http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm> or <http://www.regulations.gov>.

Dated: April 5, 2012.

**David Dorsey,**

*Acting Associate Commissioner for Policy and Planning.*

[FR Doc. 2012-8846 Filed 4-11-12; 11:15 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Health Resources and Services Administration**

**Recruitment of Sites for Assignment of Corps Personnel Obligated Under the National Health Service Corps Scholarship Program**

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** General notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) announces that the listing of entities, and their Health Professional Shortage Area (HPSA) scores, that will receive priority for the assignment of National Health Service Corps (NHSC) scholarship recipients (Corps Personnel, Corps members) during the period July 1, 2012, through June 30, 2013, is posted on the NHSC Web site at <http://datawarehouse.hrsa.gov/HGDWRReports/OneClickRptFilter.aspx?rptName=NHSCAppSiteList&rptFormat=HTML3.2>. This searchable database specifies all

currently approved NHSC service sites, by State, and can be utilized to determine which entities are eligible to receive assignment of Corps members who are participating in the NHSC Scholarship Program based on the threshold HPSA score set forth below. Please note that entities on this list may or may not have current job opportunities for NHSC scholars. Furthermore, not all vacancies associated with sites on the list described below will be for Corps members, but could be for NHSC Scholarship Program participants serving their obligation through the Private Practice Option.

**Eligible HPSAs and Entities**

To be eligible to receive assignment of Corps personnel, entities must: (1) Have a current HPSA designation by the Office of Shortage Designation, Bureau of Health Professions, HRSA; (2) not deny requested health care services, or discriminate in the provision of services to an individual because the individual is unable to pay for the services or because payment for the services would be made under Medicare, Medicaid, or the Children’s Health Insurance Program (CHIP); (3) enter into an agreement with the State agency that administers Medicaid and CHIP, accept assignment under Medicare, see all patients regardless of their ability to pay and post such policy, and use and post a discounted fee plan; and (4) be determined by the Secretary to have: (a) A need and demand for health manpower in the area; (b) appropriately and efficiently used Corps members assigned to the entity in the past; (c) general community support for the assignment of Corps members; (d) made unsuccessful efforts to recruit; (e) a reasonable prospect for sound fiscal management by the entity with respect to Corps members assigned there; and (f) demonstrated a willingness to support and facilitate mentorship, professional development, and training opportunities for Corps members.

Priority in approving applications for assignment of Corps members goes to sites that (1) provide primary medical care, mental health, and/or oral health services to a primary medical care, mental health, or dental HPSA of greatest shortage, respectively; (2) are part of a system of care that provides a continuum of services, including comprehensive primary health care and appropriate referrals or arrangements for secondary and tertiary care; (3) have a documented record of sound fiscal management; and (4) will experience a negative impact on its capacity to provide primary health services if a