533–6800, Toll Free 1–800–CDC–INFO, Email *ocas@cdc.gov.*

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Elaine L. Baker,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 2016–22058 Filed 9–13–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–2635]

The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Establishing Appropriate Durations of Therapeutic Administration; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, we) is soliciting comments regarding the establishment of appropriately targeted durations of use of antimicrobial drugs of importance to human medicine (*i.e.,* medically important antimicrobial drugs) when they are administered in the feed or water of food-producing animals for therapeutic purposes. This activity is consistent with previous efforts by FDA to protect public health by promoting the judicious use of these drugs in food-producing animals.

DATES: Submit either electronic or written comments by December 13, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–2635 for ''Establishing Appropriate Durations of Therapeutic Administration.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cindy Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0817, *cindy.burnsteel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On September 18, 2014, the President issued Executive Order 13676 on ''Combating Antibiotic-Resistant Bacteria'' (*https://www.gpo.gov/fdsys/pkg/FR-2014-09-23/pdf/2014-22805.pdf*), underscoring the urgent need to address the global threat of antimicrobial resistance. The National Action Plan for Combating Antibiotic-Resistant Bacteria (National Action Plan) (March 2015, *https://www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibotic-resistant_bacteria.pdf*) was developed in response to this Executive order, and presents a strategy for collaborative action by the U.S. Government in coordination with individuals and organizations within the human and animal health sectors. The plan establishes specific goals and objectives within a 5-year timeframe, outlines steps for implementing certain measures, and informs national policy development in order to combat the emergence of antimicrobial-resistant bacteria.

FDA is actively engaged in several ongoing efforts to address antimicrobial resistance originating from the use of antimicrobial drugs that are important in human medicine (medically important antimicrobials) in food-

producing animals. These efforts have supported and continue to support the initiatives of the National Action Plan. Judicious use of medically important antimicrobials, which includes implementation of interventions (*e.g.,* good husbandry practices) that can reduce the spread of antimicrobial resistance, is the cornerstone of Goal 1 in the National Action Plan, to ''Slow the Emergence of Resistant Bacteria and Prevent the Spread of Resistant Infections.'' FDA's approach to ensuring the judicious use of medically important antimicrobial drugs in food-producing animals has been presented in two Guidance for Industry (GFI) documents, GFI #209, ''The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals'' [1] (GFI #209) and GFI #213, ''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'' [2] (GFI #213).

GFI #209, published in April 2012, outlines FDA's fundamental principles of judicious use. These are: (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 that include veterinary oversight or consultation. In GFI #209, FDA stated that it generally considers uses that are associated with the treatment, control, or prevention of specific diseases to be uses that are necessary for assuring the health of food-producing animals, in contrast to uses for production purposes (*e.g.,* for growth promotion or improved feed efficiency) to enhance the production of animal-derived products.

As discussed in GFI #209, FDA's current methodology for assessing antimicrobial risks associated with the use of antimicrobial new animal drugs in food-producing animals is premised on the concept that increasing the exposure of bacterial populations to antimicrobial drugs increases the risk of generating resistance to those antimicrobial drugs. Because feed or water use antimicrobial drugs are typically administered to entire herds or flocks of food-producing animals, such uses pose higher risk to public health than the administration of such drugs to individual animals or targeted groups of animals, as is done with dosage form drugs (*e.g.,* injectables, tablets, etc.). Therefore, FDA is more concerned with medically important antimicrobial new animal drugs and combination new animal drug products intended for use in feed or water of food-producing animals.

GFI #213, published in December 2013, is based on the two fundamental principles of judicious use described in GFI #209 and provides specific recommendations for drug sponsors. These recommendations for sponsors of approved medically important antimicrobial drugs administered in feed or water to food-producing animals include: (1) Removing production indications [3] (*e.g.,* increased rate of weight gain and improved feed efficiency) and (2) incorporating veterinary oversight for the remaining therapeutic indications.

FDA is working collaboratively with the sponsors of affected applications to facilitate the revision of product labeling to reflect the voluntary withdrawal of approval of production indications. Incorporating veterinary oversight is accomplished by changing the marketing status from over-the-counter (OTC) use to use by either veterinary feed directive (VFD), in the case of drugs administered in feed, or by veterinary prescription (Rx), in the case of drugs administered in water.

In Section III of GFI #213, FDA states, ''all antimicrobial drugs listed in Appendix A to GFI #152 [4] (Appendix A) [are considered] to be 'medically important' in the context of implementing the recommendations outlined in GFI #209 and further discussed in this guidance document (GFI #213). We believe that the policy in GFI #209 and GFI #213 applies to all three tiers [''critically important,'' ''highly important,'' or ''important''] of medically important antimicrobial drugs at this time because each tier (and thus all of the drugs listed in Appendix A) contains drugs that have been previously assessed through the public processes used to develop GFI #152 and determined to be important for treating bacterial infections in people. . . . The current list of medically important antimicrobial drug classes that are the subject of this guidance includes: Aminoglycosides, lincosamides, macrolides, penicillins, streptogramins, sulfonamides, and tetracyclines.''

The implementation of GFI #213 is a critical step toward improving judicious use in veterinary practice, thereby minimizing the selection of antimicrobial-resistant microorganisms to help preserve the therapeutic effectiveness of medically important antimicrobial drugs. As stated previously, incorporating veterinary oversight is accomplished by changing the existing OTC marketing status of these drugs to either VFD marketing status, in the case of drugs administered in feed, or to veterinary Rx status, in the case of drugs administered in water. In GFI #213 and outreach related to the 2015 revisions made to the VFD regulations (*http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm449019.htm*), FDA has stated that, in addition to veterinary oversight, use of these antimicrobials should be linked to a specific etiologic agent and that the antimicrobial should be administered for an appropriately targeted period of time, *i.e.,* have a defined duration of use.

As explained in GFI #213, we expect, among other things, that any new indications for medically important antimicrobials, including those used in feed or in drinking water, have defined durations of use. Consistent with this expectation, the recently revised VFD regulations in 21 CFR part 558 state that a lawful VFD, among other requirements, must document the duration of use of the VFD drug contained in the medicated feed (see 21 CFR 558.6(b)(3)(x)).

Although GFI #213 sets out our expectation that new indications of medically important antimicrobial drugs used in or on feed and water will have defined durations of use, it does not address what to do with respect to some currently approved therapeutics that lack defined durations of use. Establishing defined durations of use for currently approved therapeutics will support FDA's efforts to foster stewardship of medically important antimicrobial drugs in food-producing animals and help preserve the effectiveness of these antimicrobials in animal and human medicine. Some examples of defined durations of use on the labeling of currently approved therapeutics are ''Feed continuously for 5 days,'' ''Feed continuously for 5 days as the sole ration,'' ''Feed from weaning up to 120 pounds,'' and ''Do not feed to

[1] *http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf.*

[2] *http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf.*

[3] Production uses are also referred to as ''nontherapeutic'' or ''subtherapeutic'' uses, terms that we believe lack sufficient clarity (GFI #209).

[4] GFI #152, ''Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.'' (*http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf*).

chickens over 16 weeks (112 days) of age.''

In section II, FDA invites comment on the establishment of appropriately targeted durations of use of medically important antimicrobial drugs administered to food-producing animals in feed or water for those therapeutics for which a defined durations of use is not included on currently approved labeling. Along with labeling that is silent on limits to the duration of use, some examples in which the duration of use is not defined on currently approved labeling are ''Feed continuously'' and ''Feed continuously as the sole ration.''

FDA will consider submitted comments as we develop a process by which sponsors of currently approved, medically important antimicrobial drugs, administered in feed or water to food-producing animals for therapeutic purposes, could establish appropriately targeted durations of use. We recognize that, in certain circumstances, some medically important antimicrobial drugs may have a range of safe and effective durations (see 21 CFR 514.4(b)(2)(i)). Approval of defined durations of use may be supported by existing effectiveness data, target animal safety data, human food safety studies, clinical pharmacology studies, disease pathophysiology, and/or other available information.

Based on an April 2016 review, FDA identified six species (cattle, swine, chickens, turkeys, sheep, and honey bees) for which there are approved, medically important antimicrobials administered in medicated feed or drinking water for therapeutic purposes that do not currently have a defined duration of use included on labeling. We have summarized, in tabular form, the species and disease indications for which these drugs are approved without defined durations of use (see tables 1 through 6). Indications are summarized as disease conditions (see column entitled ''Indication/Disease'') and are listed with their associated antimicrobial drugs (see column titled ''Ingredient(s)''). These tables may assist members of the public who wish to comment on establishing appropriately targeted durations of use.

II. Issues for Consideration

A key objective of FDA is to optimize the use of medically important antimicrobials by using a dosage strategy that maximizes drug effectiveness, minimizes target animal toxicity, and has an appropriately targeted duration of use to minimize the development of resistance to antimicrobial drugs of human medical importance. FDA invites comments on the questions below to assist in evaluating appropriately targeted durations of use for medically important antimicrobial drugs administered to food-producing animals in or on feed or in drinking water for those therapeutics for which a defined duration of use is not included on the currently approved labeling.

For the species and disease indications listed in tables 1 through 6, this request for comments is intended to: (1) Obtain additional information, especially from the animal agriculture, animal health, and veterinary communities, on the underlying diseases for these therapeutic indications, including periods when livestock or poultry are at risk of developing these diseases; (2) seek input on more-targeted antimicrobial use regimens for these diseases, and husbandry practices that may help avoid the need for these antimicrobials, or that may help make more-targeted antimicrobial use regimens more effective; and (3) seek comment on strategies for updating affected product labeling, as appropriate, that does not currently include a defined duration of use.

When commenting on an appropriately targeted duration of use for a medicated feed for use in a food-producing major species, please consider the target animal classes described in Appendix III of GFI #191, ''Changes to Approved NADAs—New ANDAs vs Category II Supplemental NADAs,'' [5] and the periods when that class of animal is at risk of developing that disease. For the diseases/indications and antimicrobials listed in tables 1 through 6 for which the duration of use is undefined on labeling, please address the following questions based on your current practices:

1. When is the animal/class at risk of developing the disease?

2. For how long do you administer X antimicrobial for Y indication if the labeling says ''feed continuously,'' or is silent on duration of use?

3. What factors influence your decision when determining the duration of use?

4. In addition to the drug labeling, what sources of information do you use in making a decision regarding duration of use?

a. Past personal experience;

b. drug industry representatives;

c. extension agents;

d. producer or veterinary medicine magazines;

e. online resources;

f. formularies; and

g. other.

5. What pros and cons do you see if durations of use are defined for all of these antimicrobials?

6. What reasonable alternatives to medically important antimicrobials, including other pharmaceutical or non-pharmaceutical approaches, are available for managing the diseases listed in tables 1 through 6?

In the following tables, undefined durations of use means, for example, therapeutics that include the statement ''feed continuously,'' ''feed continuously as the sole ration'' or other similar language on their labeling, or that have labeling that is silent on limits to the duration of use. *Ingredient(s)* means a medically important antimicrobial ingredient and any feed use combination approvals including that ingredient. When more than one ingredient is listed, that drug combination is only available in a fixed-ratio, combination drug Type A medicated article for use in complete Type C medicated feeds.

TABLE 1—ANTIMICROBIALS WITH APPROVED THERAPEUTIC (TREATMENT/CONTROL/PREVENTION) INDICATIONS WITH UNDEFINED DURATIONS OF USE IN CATTLE

Indication/disease	Ingredient(s)
Anaplasmosis	Chlortetracycline.
Bacterial enteritis	Chlortetracycline. Oxytetracycline.

[5] *http://www.fda.gov/downloads/animalveterinary/guidancecomplianceenforcement/guidanceforindustry/ucm052460.*

TABLE 1—ANTIMICROBIALS WITH APPROVED THERAPEUTIC (TREATMENT/CONTROL/PREVENTION) INDICATIONS WITH UNDEFINED DURATIONS OF USE IN CATTLE—Continued

Indication/disease	Ingredient(s)
Liver Abscesses	Chlortetracycline.
	Tylosin.
	Oxytetracycline.
	Neomycin With Oxytetracycline.
	Virginiamycin.
Pneumonia	Chlortetracycline.

TABLE 2—ANTIMICROBIALS WITH APPROVED THERAPEUTIC (TREATMENT/CONTROL/PREVENTION) INDICATIONS WITH UNDEFINED DURATIONS OF USE IN SWINE

Indication/disease	Ingredient(s)
Atrophic rhinitis	Tylosin.
	Tylosin With Sulfamethazine.
	Chlortetracycline.
	Sulfamethazine.
Pneumonia	Tylosin With Sulfamethazine.
	Oxytetracycline.
GI-Parasites [1]	Hygromycin B.
GI-Bacterial [2]	Tylosin With Sulfamethazine.
	Lincomycin.
	Chlortetracycline With Sulfamethazine.
	Chlortetracycline.
	Oxytetracycline.
Jowl abscesses	Chlortetracycline.

[1] An example of Gastrointestinal (GI)-Parasite indication is ''Control of infestations of large roundworms (*Ascaris suis*), nodular worms (*Oesophagostomum dentatum*), and whipworms (*Trichuris suis*).''

[2] Examples of Gastrointestinal (GI)-Bacterial indications are: ''For treatment of swine dysentery''; ''To help prevent bacterial swine enteritis''; and ''Treatment of bacterial swine enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibrionic dysentery).''

TABLE 3—ANTIMICROBIALS WITH APPROVED THERAPEUTIC (TREATMENT/CONTROL/PREVENTION) INDICATIONS WITH UNDEFINED DURATIONS OF USE IN CHICKENS

Indication/disease	Ingredient(s)
Infectious Coryza	Ormetoprim with Sulfadimethoxine.
Chronic Respiratory Disease	Oxytetracycline.
	Oxytetracycline.
Necrotic Enteritis/Colibacillosis	Ormetoprim with Sulfadimethoxine.
	Lincomycin.
	Virginiamycin.
Fowl Cholera	Ormetoprim with Sulfadimethoxine.
Gastrointestinal (GI)-Parasites [1]	Hygromycin B.
Coccidiosis	Ormetoprim with Sulfadimethoxine.

[1] An example of Gastrointestinal (GI)-Parasite indication is, ''As an aid in the control of infections of large roundworms (*Ascaris galli*), cecal worms (*Heterakis gallinae*), and capillary worms (*Capillaria obsignata*).''

TABLE 4—ANTIMICROBIALS WITH APPROVED THERAPEUTIC (TREATMENT/CONTROL/PREVENTION) INDICATIONS WITH UNDEFINED DURATIONS OF USE IN TURKEYS

Indication/disease	Ingredient(s)
Coccidiosis	Ormetoprim with Sulfadimethoxine.
Fowl Cholera	Ormetoprim with Sulfadimethoxine.

TABLE 5—ANTIMICROBIALS WITH APPROVED THERAPEUTIC (TREATMENT/CONTROL/PREVENTION) INDICATIONS WITH UNDEFINED DURATIONS OF USE IN SHEEP

Indication/disease	Ingredient(s)
Vibrionic Abortion	Chlortetracycline.
Enterotoxemia	Chlortetracycline.

TABLE 6—ANTIMICROBIALS WITH APPROVED THERAPEUTIC (TREATMENT/CONTROL/PREVENTION) INDICATIONS WITH UNDEFINED DURATIONS OF USE IN HONEY BEES

Indication/disease	Ingredient(s)
Foulbrood	Oxytetracycline.

Dated: September 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–21972 Filed 9–12–16; 11:15 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0002]

Withdrawal of Approval of Part of a New Animal Drug Application; Chlortetracycline, Procaine Penicillin, and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal of approval.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of those parts of a new animal drug application (NADA) for a 3-way, fixed-ratio, combination drug Type A medicated article that pertain to use of the procaine penicillin component for production indications in swine. This action is being taken at the sponsor's request because the 3-way Type A medicated article is no longer manufactured.

DATES: Withdrawal of approval is effective September 14, 2016.

FOR FURTHER INFORMATION CONTACT: Cindy L. Burnsteel, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–402–0817, *cindy.burnsteel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Pharmgate LLC (Pharmgate), 1015 Ashes Dr., Suite 102, Wilmington, NC 28405 has requested that FDA withdraw approval of those parts of NADA 138–934 for PENNCHLOR SP 500 (chlortetracycline, procaine penicillin, and sulfamethazine) Type A medicated article that pertain to use of the procaine penicillin component for the production indications of growth promotion and increased feed efficiency in swine. Pharmgate requested voluntary withdrawal of approval of these indications for use because PENNCHLOR SP 500 Type A medicated article is no longer manufactured.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director of the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of those parts of NADA 138–934 that pertain to use of procaine penicillin for the production indications of growth promotion and increased feed efficiency in swine are hereby withdrawn, effective September 14, 2016.

NADA 138–934 was identified as being affected by guidance for industry (GFI) #213 ''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,'' December 2013.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the withdrawal of approval of these parts of NADA 138–934.

Dated: September 6, 2016.

William T. Flynn,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 2016–21984 Filed 9–13–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

Vaccines and Related Biological Products Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Vaccines and Related Biological Products Advisory Committee scheduled for November 16, 2016, is cancelled. This meeting was announced in the **Federal Register** of August 30, 2016 (81 FR 59634).

FOR FURTHER INFORMATION CONTACT: Sujata Vijh, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6128, Silver Spring, MD 20993–0002, 240–402–7107, *sujata.vijh@fda.hhs.gov;* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: September 8, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–22051 Filed 9–13–16; 8:45 am]

BILLING CODE 4164–01–P