

Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter

Guidance for Industry

Draft Guidance

This guidance document is being distributed for comment purposes only.

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Additional copies of this draft guidance document may be requested from the Policy and Regulations Staff (HFV-6), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Place, Rockville MD 20855, and may be viewed on the Internet at either <https://www.fda.gov/Animal-Veterinary> or <https://www.regulations.gov>.

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

I. Introduction

This guidance is intended for sponsors of approved applications and abbreviated applications for new animal drugs containing medically important antimicrobials for use in non-food (companion), food-producing animals, or both, that are currently approved with over-the-counter marketing status. The guidance contains information for sponsors of such new animal drugs to facilitate voluntary changes to the approved conditions of use of these drugs to prescription marketing status.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. Background

On April 13, 2012, FDA finalized a guidance document entitled "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (GFI #209). In GFI #209, FDA stated that the development of resistance to antimicrobial drugs of importance to human medicine (medically important antimicrobial drugs), and the resulting loss of their effectiveness as antimicrobial therapies, poses a serious public health threat. To further address this issue, FDA recommended the following two principles to help ensure the appropriate or judicious use of medically important antimicrobial drugs in animals:

- (1) Limit medically important antimicrobial drugs to uses in animals that are considered necessary for assuring animal health, and
- (2) Limit medically important antimicrobial drugs to uses in animals that include veterinary oversight or consultation.

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In December 2013, FDA finalized a guidance document 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” (GFI #213). Based on recommendations in that final guidance, sponsors of medically important antimicrobial drugs approved for use in or on the feed or drinking water of food-producing animals worked with FDA to voluntarily withdraw approval of indications that were not considered necessary for assuring animal health (production indications), and voluntarily change all remaining approved uses of such new animal drugs from over-the-counter (OTC) to either Veterinary Feed Directive (VFD) or prescription (Rx) marketing status, as applicable. FDA, working in conjunction with sponsors of the affected animal drug products, successfully completed implementation of GFI #213 in December 2016. <https://www.fda.gov/animal-veterinary/cvm-updates/fda-announces-implementation-gfi-213-outlines-continuing-efforts-address-antimicrobial-resistance>.

On September 14, 2018, FDA unveiled a 5-year action plan for supporting antimicrobial stewardship in veterinary settings.¹ This plan builds upon the important steps the Center for Veterinary Medicine (CVM) has already taken to support the judicious use of antimicrobials in animals,² and is driven by the concept that medically important antimicrobial drugs should only be used in animals when necessary for the treatment, control, or prevention of specific diseases. One action item included in this plan is to ensure that any medically important antimicrobial new animal drugs that continue to remain available as OTC products are brought under the oversight of licensed veterinarians. The purpose of this guidance is to provide sponsors with specific recommendations on how to facilitate voluntary changes to the approved conditions of use of these drugs to prescription marketing status. The voluntary process outlined in this guidance will help to ensure new animal drugs containing antimicrobials of human importance are administered only under veterinary oversight and only for therapeutic uses.

III. Medically Important Antimicrobial Drugs

In 2003, FDA issued Guidance for Industry (GFI) #152, entitled “Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern.” GFI #152 contains an appendix in which FDA ranked antimicrobial drugs according to their relative importance to human medicine: “critically important,” “highly important,” or “important.” At this time, FDA considers all antimicrobial drugs listed in Appendix A to GFI #152 (Appendix A) to be “medically important.” The scope of this guidance (GFI #263) encompasses all antimicrobial new animal drugs that are considered “medically important” and that currently remain approved with an OTC marketing status.

The list of medically important antimicrobial drugs in Appendix A reflects FDA’s current thinking and thus is not static; FDA will periodically reassess and update this list. The Agency’s periodic reassessment will take into consideration such factors as the development of new antimicrobials for human therapy, the emergence of diseases in humans, and changes in prescribing practices in the United States. Therefore, the antimicrobial products affected by this

¹ <https://www.fda.gov/media/115776/download>

² <https://www.fda.gov/animal-veterinary/safety-health/antimicrobial-resistance>

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guidance may change in the future if this reassessment process results in a change to the list of antimicrobial drugs that are considered medically important.

IV. Voluntary Adoption of Judicious Use Principles

FDA intends to work with affected drug sponsors to help them to voluntarily change the marketing status of their medically important antimicrobial new animal drug products from OTC to Rx. Based on the positive feedback received regarding the approach taken to successfully implement the recommendations outlined in GFI #209 and GFI #213, FDA believes a voluntary approach is an effective and efficient way to achieve the common goal of judicious use of medically important antimicrobials in animals.

V. Veterinary Oversight of Medically Important Antimicrobials

While the principles for judicious use of medically important antimicrobials recommended in GFI #209 are nominally specific to the use of such drugs in food-producing animals, FDA believes it is appropriate to apply these same judicious use principles to the use of medically important antimicrobial drugs in all animals. Based on the available scientific evidence concerning antimicrobial resistance, including information about resistance trends associated with the use of medically important antimicrobial drugs, FDA believes the judicious use of medically important antimicrobial drugs intended for use in animals should involve the scientific and clinical training of a licensed veterinarian. The involvement of a veterinarian is needed because judicious use of antimicrobial drugs requires an accurate diagnosis of the bacterial disease that is present, or likely to be present, and the selection of a suitable antimicrobial drug to address that disease.

The decision by the veterinarian to use a specific approved drug is generally based on multiple factors, such as the mode of antibacterial action, drug distribution in specific tissues, the duration of effective drug levels at the site of infection, past treatment outcomes, local burden of illness information, and concurrent animal health issues. Other important factors veterinarians generally consider when determining the appropriateness of a given antimicrobial use include whether: (1) there is evidence of effectiveness, (2) such use is consistent with accepted veterinary practice, (3) the use is linked to a specific etiologic agent, (4) the use is appropriately targeted to animals with or at risk of developing a specific disease, and (5) no reasonable alternatives for intervention exist. FDA believes that veterinarians are uniquely qualified to make these decisions and to determine appropriately timed administration of the antimicrobial to treat, control, or prevent disease in animals.

Accordingly, FDA recommends that sponsors of medically important antimicrobial new animal drugs that are currently approved with OTC marketing status voluntarily revise the conditions of use of these drug products to reflect the need for professional oversight of a licensed veterinarian (i.e., change the drug from OTC to Rx marketing status).

VI. Timeline for Voluntarily Implementing Changes

FDA encourages all sponsors of affected new animal drugs (i.e., medically important antimicrobial new animal drugs that are currently approved with OTC marketing status) to

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initiate steps to change the product labeling and approved conditions of use for such products through the voluntary process outlined in this guidance.

To ensure continued progress under the cooperative framework outlined in this guidance and provide for an orderly implementation process, FDA will monitor progress to assess whether these changes are being adopted along the timelines discussed below. FDA is confident that the objective of phasing in these changes can be met through the cooperative process discussed in this guidance, which is why we are initially pursuing this voluntary approach. To assist FDA in effectively monitoring the rates of participation in the industry, we request that sponsors of affected products notify the Agency³ of their intentions to engage in the voluntary process to modify their product labeling within 3 months from the date of publication of the final version of this guidance.

FDA anticipates that sponsors of affected products should be able to have revised labeling approved that incorporates the changes discussed in this guidance within 2 years from the date of publication of the final version of this guidance. The 2-year timeframe for voluntary implementation is intended to provide a sufficient amount of time for animal drug sponsors to make these changes across all affected new animal drug applications in an efficient and practical manner, and for other stakeholders (e.g., veterinarians, animal producers and owners, and distributors of animal health products) to prepare for the resulting changes in management/business practices that may occur. If we determine that adequate progress has not been made by the end of the 2-year timeframe, we will consider whether further action under the existing provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for addressing matters related to the safety of approved new animal drugs may be appropriate.

Concurrently with the publication of this draft guidance, FDA is making public on its website a listing of all medically important antimicrobial new animal drugs that currently have OTC marketing status. FDA considers all drugs that appear in this listing to be covered by this guidance.⁴

VII. Supplemental New Animal Drug Applications (Pioneer Drugs)

Sponsors of new animal drug application(s) (NADAs) affected by this guidance should either (1) propose to change the marketing status to Rx, or (2) request to voluntarily withdraw the approval of the application. These two options apply even if the affected OTC product is not currently marketed.

A. Changing Marketing Status

³ Sponsors of pioneer or generic applications should mail these notifications of intent to the attention of the Division of Therapeutic Drugs for Food Animals in the Office of New Animal Drug Evaluation, CVM (HFV-130), at the following address: MPN 2, Room E150, 12225 Wilkins Avenue, Rockville, MD 20852. Future labeling supplements should be submitted to the appropriate target animal review division for each application.

⁴ This listing also includes the small number of combination drugs currently approved for OTC use in animals that include one or more medically important antimicrobials as a component of the combination drug.

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The procedures in this section (VII.A.) apply to the situation where no new indications, or other substantive changes to the application are being proposed.⁵ The recommendations in this section describe how sponsors may submit supplemental new animal drug applications to voluntarily change the approved marketing status of their affected drugs from OTC to Rx.

● **Administrative Procedures and Submission Content**

FDA anticipates that the labeling changes needed to voluntarily implement the recommendations in this guidance will be straightforward. Therefore, a presubmission conference or other advance communication with FDA to discuss planned labeling changes typically should not be necessary. However, as always, sponsors may contact FDA with any specific questions in advance of submitting their labeling supplement.

Sponsors should use eSubmitter to submit a labeling supplement (“NF” subclass code, 180-day review clock⁶) to the applicable target animal review division in CVM’s Office of New Animal Drug Evaluation (ONADE) and indicate that their supplemental application is being submitted in accordance with GFI #263. The submission should include:

- A request to change the marketing status of the product from OTC to prescription (Rx) to align with the recommendations of this guidance document.
- A single copy of clean color facsimile labeling⁷ or final printed labeling (electronic FPL, eFPL) for each affected labeling component revised as follows:⁸

⁵ To facilitate orderly implementation of this guidance, sponsors wishing to propose new indications or make other substantive changes to the application (including changes to the labeling other than those described in this guidance) are encouraged to do so under a separate supplemental application, submitted after approval of the marketing status change, that includes all applicable technical sections following established procedures. These procedures are described elsewhere and are beyond the scope of this Guidance. Sponsors wishing to implement all labeling changes at a single future printing may submit the subsequent supplement at any time (e.g., immediately) after the Rx marketing status change supplement is submitted.

⁶ Sponsors should not check “yes” for the question on the eSubmitter template that asks if they are submitting a “Qualifying Labeling Supplement” (QLS) because these supplements will not qualify for a 60-day review timeframe. If this option is inadvertently selected, ONADE will change the submission review time from 60 to 180 days.

⁷ For products that are not currently marketed, and for which there are no plans to begin marketing them in the foreseeable future, FDA may accept “marked up” facsimile labeling for approval of these supplements if the sponsor is not able to provide clean color facsimile labeling. Such labeling, while not preferred, would take the form of a copy of the most recently approved label, marked with clear indicators (arrows or similar) showing the exact text to be inserted or deleted and the exact location such changes will appear, presented in a way that does not obscure any existing information on the labeling.

⁸ With the exception of minor formatting or layout adjustments necessary to add the Rx statement, updates to the component version date or number, and any other changes described in this guidance, sponsors should not propose other changes to the labeling in the context of this supplemental application. As previously noted, requests to approve other substantive changes may be submitted in a separate supplement.

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- The Rx statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.", found in section 503(f)(4) of the FD&C Act (21 U.S.C. 353(f)(4)) must be appropriately added to the label. At minimum, this statement must appear on the immediate container label. It is recommended that the statement also be included on the outer carton and package insert, if any. In the case of an immediate container label too small to accommodate the full statement, but which is packaged within an outer container, the statement may be placed on the outer container. See 21 CFR 201.105(b).
 - The Caution statement should be placed immediately below the drug product identification area of the labeling. The drug product identification information normally appears near the top or beginning of a labeling component and includes the proprietary name, established name, route of administration, dosage form, strength or concentration, pharmacologic class, and controlled substance symbol, if applicable.
- Any other labeling changes previously required by the Agency that have not yet been implemented (e.g., storage statement updates).
- If not previously implemented, FDA strongly recommends that sponsors revise or add the "Approved by FDA under NADA # XXX-XXX" statement, as required in section 502(w)(3) of the FD&C Act.⁹ If this change is made at this time, it should be implemented as follows:
 - The statement must read as follows, using the exact format and spacing shown. Replace "XXX-XXX" with the specific application number (including leading zeros):

Approved by FDA under NADA # XXX-XXX
 - Present the statement on a single straight line, unless there is insufficient space, in which case two straight lines are recommended.
 - If a labeling component currently has an older version of the statement, place the revised version in the same location.
 - If a labeling component does not currently have such a statement, add the statement as follows for each component of the labeling:
 - *Package inserts and single-panel labeling components*: place the statement near the bottom of the labeling component.
 - *Multiple-panel labeling components*: place the statement at the bottom of the front panel.

⁹ This requirement was added by section 303 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, Public Law 115-234, and requires the addition (or revision) of this statement on the labeling (except representative medicated feed labeling) of approved new animal drugs by September 30, 2023.

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- A claim of categorical exclusion (CE) from the need to prepare an environmental assessment (EA) or an environmental impact statement (EIS) pursuant to 21 CFR 25.33(a). Other citations should not be used. With this claim of CE, pursuant to 21 CFR 25.15 sponsors must also include a statement that to the sponsor's knowledge, no extraordinary circumstances exist that may significantly affect the quality of the human environment as discussed under 21 CFR 25.21. Sponsors unable to provide this statement should contact the ONADE Environmental Safety Team before submitting their supplemental application.
- Permission for CVM to contact sponsors of any affected generic copies of the drug to discuss changes being made to the pioneer drug's labeling, in advance of FDA's approval of the pioneer sponsor's labeling supplement.
- If applicable, a statement that the product (or specific product(s)/formulation(s) within the application) is not currently marketed and that includes any plans and time frames for marketing the product(s) or formulation(s) in the future.
- Other technical sections/information
 - Supplemental applications to change the marketing status generally do not need to include additional safety or effectiveness data. Except in rare cases, it is not expected that sponsors will need to address any other technical sections for approval of these labeling supplements.

B. Voluntary Withdrawal of Approval of the Entire New Animal Drug Application

The procedures in this section (VII.B.) apply to the situation where the sponsor requests to voluntarily withdraw approval of the entire new animal drug application(s). As always, sponsors may contact FDA with any specific questions in advance of submitting such requests. The recommendations below apply when sponsors who wish to voluntarily pursue judicious use changes submit requests to voluntarily withdraw the approval of their application(s) without prejudice under 21 CFR 514.115(d).

● **Administrative Procedures and Submission Content**

Sponsors should submit a request for withdrawal of approval of their application without prejudice, citing 21 CFR 514.115(d), to the CVM Office of Surveillance and Compliance, Marketed Product Information Team (HFV-212). The request should include the following:

- The sponsor's acknowledgement that the request waives the sponsor's right to a notice of opportunity for a hearing in relation to the withdrawal of approval.
- Written permission for CVM to contact the sponsors of affected generic copies of the drug (if applicable) in advance of publication of notice of the withdrawal of approval in the Federal Register (FR). The sponsor should use the following language for this request:

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“<Sponsor Name> grants CVM permission to contact the sponsor(s) of affected generic copies (if applicable) in advance of Federal Register (FR) publication.”

- A claim of CE from the requirement to prepare an EA or an EIS pursuant to 21 CFR 25.33(g). Other citations should not be used. With this claim of CE, pursuant to 21 CFR 25.15 sponsors must also include a statement that to the sponsor’s knowledge, no extraordinary circumstances exist that may significantly affect the quality of the human environment as discussed under 21 CFR 25.21. Sponsors unable to provide this statement should contact the ONADE Environmental Safety Team before submitting their request to voluntarily withdraw approval of the application.

VIII. Supplemental Abbreviated New Animal Drug Applications (Generic Drugs)

Consistent with current practice, if the marketing status or other conditions of use for a new animal drug application for a medically important antimicrobial is changed, we expect that the approved labeling for any currently approved abbreviated new animal drug application(s) (ANADA) that references the original new animal drug application would be revised in a similar fashion. FDA intends to work expeditiously with the sponsors of affected generic new animal drug applications to align their products with the revised conditions of use specified in the referenced (i.e., pioneer) applications. Sponsors of generic applications affected by this guidance should either (1) align their labeling with the revised labeling of the referenced listed new animal drug (RLNAD) application, or (2) request to voluntarily withdraw the approval of the generic application. These two options apply even if the affected OTC generic product is not currently marketed.

A. Changing Marketing Status

FDA will contact sponsors of affected generic new animal drug applications after it receives a supplemental application to revise the labeling of the RLNAD. As is currently the practice, we expect that the generic sponsor will submit a supplemental application to make changes to the generic product’s labeling consistent with the revised labeling of the RLNAD within 60 days after FDA notifies the generic sponsor that the approved conditions of use for the RLNAD have been or are being revised. In addition, any future generic sponsor that wants to use a pioneer drug as its RLNAD for which the labeling has been revised as recommended in this guidance must submit labeling that is the same as the labeling approved for the RLNAD with a few exceptions not relevant here. See section 512(c)(2)(A)(vii) of the FD&C Act (21 U.S.C. 360b(c)(2)(A)(vii)).

- **Administrative Procedures and Submission Content**

Sponsors should use eSubmitter to submit a labeling supplement (“NF” subclass code, 240-day review clock) to the Division of Generic Animal Drugs in ONADE and indicate that their supplemental application is being submitted in accordance with GFI #263. Sponsors should not propose labeling changes in this supplement other than those described in this guidance, except for any additional changes that may be required by the Agency. The submission should include:

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- A single copy of clean color facsimile labeling¹⁰ or final printed labeling (electronic FPL, eFPL) for each affected labeling component revised as follows:¹¹
 - The Rx statement, "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.", found in section 503(f)(4) of the FD&C Act (21 U.S.C. 353(f)(4)) must be appropriately added to the label. At minimum, this statement must appear on the immediate container label. It is recommended that the statement also be included on the outer carton and package insert, if any. In the case of an immediate container label too small to accommodate the full statement, but which is packaged within an outer container, the statement may be placed on the outer container. See 21 CFR 201.105(b).
 - The Caution statement should be placed immediately below the drug product identification area of the labeling. The drug product identification information normally appears near the top or beginning of a labeling component and includes proprietary name, established name, route of administration, dosage form, strength or concentration, pharmacologic class, and controlled substance symbol, if applicable.
 - Any other labeling changes necessary to align with the revised RLNAD labeling.
 - Any other labeling changes previously required by the Agency that have not yet been implemented.
 - If not previously implemented, FDA strongly recommends that sponsors revise or add the "Approved by FDA under ANADA # XXX-XXX" statement, as required in section 502(w)(3) of the FD&C Act.¹² If this change is made at this time, it should be implemented as follows:
 - The statement must read as follows, using the exact format and spacing shown. Replace "XXX-XXX" with the specific application number (including leading zeros):

Approved by FDA under ANADA # XXX-XXX

¹⁰ For products that are not currently marketed, and for which there are no plans to begin marketing them in the foreseeable future, FDA may accept "marked up" facsimile labeling for approval of these supplements if the sponsor is not able to provide clean color facsimile labeling. Such labeling, while not preferred, would take the form of a copy of the most recently approved label, marked with clear indicators (arrows or similar) showing the exact text to be inserted or deleted and the exact location such changes will appear, presented in a way that does not obscure any existing information on the labeling.

¹¹ With the exception of minor formatting or layout adjustments necessary to add the Rx statement, updates to the component version date or number, and any other changes described in this guidance, sponsors should not propose other changes to the labeling in the context of this supplemental application. As previously noted, requests to approve other substantive changes may be submitted in a separate supplement.

¹² This requirement was added by section 303 of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 and requires the addition (or revision) of this statement on the labeling (except representative medicated feed labeling) of approved new animal drugs by September 30, 2023.

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- Present the statement on a single straight line, unless there is insufficient space, in which case two straight lines are recommended.
- If a labeling component currently has an older version of the statement, place the revised version in the same location.
- If a labeling component does not currently have such a statement, add the statement as follows for each component of the labeling:
 - *Package inserts and single-panel labeling components*: place the statement near the bottom of the labeling component.
 - *Multiple-panel labeling components*: place the statement at the bottom of the front panel.
- A claim of CE from the need to prepare an EA or an EIS pursuant to 21 CFR 25.33(a). Other citations should not be used. With this claim of CE, pursuant to 21 CFR 25.15 sponsors must also include a statement that to the sponsor's knowledge, no extraordinary circumstances exist that may significantly affect the quality of the human environment as discussed under 21 CFR 25.21. Sponsors unable to provide this statement should contact the ONADE Environmental Safety Team before submitting their supplemental application.
- If applicable, a statement that the product (or specific product(s)/formulation(s) within the application) is not currently marketed and that includes any plans and time frames for marketing the products(s) or formulations(s) in the future.
- Other technical sections/information
 - Except in rare cases, it is not expected that sponsors of generic applications will need to address any other technical sections for approval of these labeling supplements.

B. Voluntary Withdrawal of Approval of the Entire Abbreviated New Animal Drug Application

The procedures in this section (VIII.B.) apply to the situation where the sponsor requests to voluntarily withdraw approval of the entire abbreviated new animal drug application(s). As always, sponsors may contact FDA with any specific questions in advance of submitting such requests. The recommendations below apply when sponsors who wish to voluntarily pursue judicious use changes are submitting requests to voluntarily withdraw the approval of their application(s) without prejudice under 21 CFR 514.115(d).

- **Administrative Procedures and Submission Content**

Sponsors of abbreviated new animal drug applications who do not wish to make their product labeling consistent with the revised labeling of the RLNAD should request to voluntarily

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withdraw approval of the ANADA, following the procedures described for NADAs above in section VII.B., except that there would be no need to provide permission for CVM to contact sponsors of affected generic copies.

IX. References

1. FDA 2003. Guidance for Industry #152, “Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern,” Appendix A. <https://www.fda.gov/media/69949/download>
2. FDA 2012. Guidance for Industry #209, “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.” <https://www.fda.gov/media/79140/download>
3. FDA 2013. Guidance for Industry #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.” <https://www.fda.gov/media/83488/download>