DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Veterinary Medicine
Rockville, MD 20855

June 17, 2016

RE: Over-the-Counter (OTC) Animal Drugs Becoming Veterinary Feed Directive (VFD) or Prescription (Rx)

Dear Animal Food Facility:

We are contacting you because you are a potential distributor (retailer) of one or more animal drug products whose marketing status will be changing at the end of calendar year 2016. As you may be aware, over the past several years, the Food and Drug Administration (FDA) has taken important steps toward changing how antimicrobials that are important in human medicine ("medically important antimicrobials") can be legally used in feed or water for food-producing animals.

In Guidance For Industry (GFI) #213[1], the FDA asked animal drug sponsors of medically important antimicrobials administered in medicated feed or drinking water of food-producing animals to voluntarily remove from their product labels those indications for production purposes (i.e. growth promotion and feed efficiency), and bring the remaining therapeutic uses of these products under the oversight of a veterinarian by December 2016 – changes that are critical to ensure these drugs are used judiciously and only when appropriate for specific animal health purposes.

All of the affected drug sponsors have committed to making the changes we requested. On January 1, 2017, the marketing status of the affected drugs will change from over-the-counter (OTC) to either prescription (Rx) status for drugs administered in medicated drinking water or veterinary feed directive (VFD) status for drugs administered in or on medicated feed. In some cases, drug sponsors may choose to withdraw a product approval completely. Drugs that have either an Rx or VFD marketing status can only be prescribed or authorized for use in animals by a licensed veterinarian. Distributors that are unable to meet the applicable State and Federal requirements for selling and distributing Rx and VFD animal drugs may no longer be able to sell these products once they have transitioned to their new marketing status. If this is the situation, distributors may need to return their unsold inventory to the manufacturer or wholesaler.

In addition, FDA recently published the VFD final rule, which outlines the revised process for authorizing use of VFD drugs (animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian) and provides veterinarians in all U.S. States with a framework for authorizing the use of medically important antimicrobials in feed when needed for specific animal health purposes. The VFD final rule became effective

[1] "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" - http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM299624.pdf

on October 1, 2015, and applies to veterinarians who authorize VFDs, distributors who distribute VFD feed, and clients who use VFD feed.

To ensure that a clear process is applied to implement the changes outlined in GFI #213 by the January 1, 2017 target date, CVM has provided additional information in the attached Appendices. These documents provide information on the products that will be transitioning from OTC status to Rx (water) or VFD (feed) status, VFD distributor requirements, and describe the timing of actions on addressing current and future inventory of products affected by GFI #213.:

- Appendix 1 outlines the changes in marketing status of drugs administered in water that are transitioning from OTC to Rx status.
- Appendix 2 outlines changes in marketing status of drugs administered in or on feed that are transitioning from OTC to VFD status.
- Appendix 3 outlines requirements for distributors under the VFD final rule.
- Appendix 4 outlines the plan for transitioning approved products to the new (GFI #213-aligned) labeling requirements by January 1, 2017.

Please note that the documents attached are intended to offer a general understanding of the process and products involved. We understand and expect that issues and questions will arise as the process unfolds – please contact us as questions arise.

For any questions, please contact the FDA Center for Veterinary Medicine at AskCVM@fda.hhs.gov.

Sincerely,

/s/

William T. Flynn, D.V.M., M.S.
Deputy Director for Science Policy
U.S. Food and Drug Administration
Center for Veterinary Medicine

Appendices (4)

Appendix 1

Drugs Transitioning from Over-the-Counter (OTC) to Prescription (Rx) Status

Sales of Rx products

CVM expects that certain water soluble antimicrobial animal drug products will transition from over-the-counter (OTC) to prescription (Rx) marketing status on January 1, 2017, as part of FDA's strategy to ensure the judicious use of medically important antimicrobial new animal drug products as outlined in Guidance for Industry #213 (GFI #213). Retailers and other establishments planning to distribute these products after January 1, 2017, will be subject to both State and Federal regulations applicable to the dispensing of Rx drugs.

CVM expects that the water soluble products listed below will transition from OTC to Rx marketing status on January 1, 2017. The prescribing or dispensing of Rx drug products for use in animals must be authorized by a licensed veterinarian under federal law and also under state law in most states. Once the approvals for the affected products are revised to reflect the transition from OTC to Rx marketing status, such products can only be used in compliance with regulations governing the dispensing of Rx drugs, even if the product still has the old OTC labeling.

FDA intends to initiate surveillance and compliance activities for the transitioned products beginning on January 1, 2017. Please contact the relevant state authority, such as the Board of Pharmacy, Board of Veterinary Medicine, or other agency regarding regulations that apply to the dispensing of Rx drugs in your state.

Refer to the complete list of affected applications at the following website for the most up-to-date information on actions taken with respect to specific antimicrobial drug products: http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm.

FDA recommends that parties involved in the production and/or distribution of the affected products proactively manage product inventories in order to minimize the amount of OTC-labeled product that will remain on shelves at the time the marketing status of these products changes to Rx on January 1, 2017.

Water Soluble Drugs Transitioning From OTC to Rx Status

This list represents the antimicrobials approved for use in water that are affected by GFI #213. The complete list of affected applications will continue to be updated as changes are made, and can be located here:

http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm

Upon completion of the voluntary transition by drug sponsors of the following antimicrobial new animal drugs from OTC to Rx, all water uses of these drugs will require a prescription from a veterinarian as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the approved drug application:

Established drug name	Examples of proprietary drug name(s)
chlortetracycline	Aureomycin, Aureomycyn, Chlora-Cycline, Chloronex, Chlortetracycline, Chlortetracycline Bisulfate, Chlortet-Soluble-O, CTC, Fermycin, Pennchlor
erythromycin	Gallimycin
gentamicin	Garacin, Gen-Gard, GentaMed, Gentocin, Gentoral
lincomycin	Linco, Lincomed, Lincomix, Lincomycin, Lincomycin Hydrochloride, Lincosol, Linxmed-SP
lincomycin/spectinomycin*	Lincomycin S, Lincomycin-Spectinomycin, L-S, SpecLinx
neomycin	Biosol Liquid, Neo, Neomed, Neomix, Neomycin, Neomycin Liquid, Neomycin Sulfate, Neo-Sol, Neosol, Neosol-Oral, Neovet
oxytetracycline	Agrimycin, Citratet, Medamycin, Oxymarine, Oxymycin, Oxy-Sol, Oxytet, Oxytetracycline, Oxytetracycline HCL, Oxy WS, Pennox, Terramycin, Terra-Vet, Tetravet-CA, Tetroxy, Tetroxy Aquatic, Tetroxy HCA
penicillin	Han-Pen, Penaqua Sol-G, Penicillin G Potassium, R-Pen, Solu-Pen
spectinomycin	Spectam
sulfadimethoxine	Agribon, Albon, Di-Methox, SDM, Sulfabiotic, Sulfadimethoxine, Sulfadived, Sulfamed-G, Sulforal, Sulfasol
sulfamethazine	SMZ-Med, Sulfa, Sulmet
sulfaquinoxaline	S.Q. Solution, Sulfa-Nox, Sulfaquinoxaline Sodium, Sulfaquinoxaline Solubilized, Sul-Q-Nox, Sulquin
tetracycline	Duramycin, Polyotic, Solu/Tet, Solu-Tet, Supercycline, Terra-Vet, Tet, Tetra-Bac, Tetracycline, Tetracycline Hydrochloride, Tetramed, Tetra-Sal, Tetrasol, Tet-Sol, TC Vet

Note: apramycin, carbomycin/oxytetracycline*, chlortetracycline/sulfamethazine*, streptomycin, sulfachloropyrazine, sulfachlorpyridazine, and sulfamerazine/sulfamethazine/sulfaquinoxaline* are also approved for water use and are expected to transition to Rx status, but are not marketed at this time. If they return to the market on or after January 1, 2017, their use in water will require a prescription from a veterinarian.

*Fixed-ratio, combination drug

Current Rx Water Soluble Drugs

Established drug name	Examples of proprietary drug names
tylosin	Tylan, Tylomed, Tylosin, Tylosin Tartrate, Tylovet

This information was published online on January 19, 2016, and is available at: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482106.htm. As the affected products transition, CVM anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates: http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm

Additional Resources:

- National Association of State Boards of Pharmacy: https://www.nabp.net/boards-of-pharmacy
- List of drugs transitioning from over-the-counter (OTC) to prescription (Rx) Status, printer-friendly PDF: http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/UCM482255.pdf

Appendix 2

Drugs Transitioning from Over-the-Counter (OTC) to Veterinary Feed Directive (VFD) Status

Drugs Transitioning From OTC to VFD Status

CVM expects that certain antimicrobial animal drug products approved for use in animal feed will transition from over-the-counter (OTC) to veterinary feed directive (VFD) marketing status on January 1, 2017, as part of FDA's strategy to ensure the judicious use of medically important antimicrobial new animal drug products as outlined in Guidance for Industry #213 (GFI #213). The list below represents the antimicrobials approved for use in or on animal feed affected by GFI #213. The complete list of affected applications will continue to be updated as changes are made and can be located here: http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/ucm390429.htm

Upon completion of the voluntary transition by animal drug sponsors of the following antimicrobial new animal drugs from OTC to VFD marketing status, all feed uses of the these drugs, alone and in a combination, will require a VFD as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the approved drug application:

Established drug name	Examples of proprietary drug name(s)[§]
chlortetracycline (CTC)	Aureomycin, CLTC, CTC, Chloratet, Chlorachel, ChlorMax, Chlortetracycline, Deracin, Inchlor, Pennchlor, Pfichlor
chlortetracycline/sulfamethazine[*]	Aureo S, Aureomix S, Pennchlor S
chlortetracycline/sulfamethazine/penicillin[*]	Aureomix 500, Chlorachel/Pficlor SP, Pennchlor SP, ChlorMax SP
hygromycin B	Hygromix
lincomycin	Lincomix
oxytetracycline (OTC)	TM, OXTC, Oxytetracycline, Pennox, Terramycin
oxytetracycline/neomycin[*]	Neo-Oxy, Neo-Terramycin
penicillin[+]	Penicillin, Penicillin G Procaine
sulfadimethoxine/ormetoprim[*]	Rofenaid, Romet
tylosin	Tylan, Tylosin, Tylovet
tylosin/sulfamethazine[*]	Tylan Sulfa G, Tylan Plus Sulfa G, Tylosin Plus Sulfamethazine
virginiamycin	Stafac, Virginiamycin, V-Max

Note: apramycin, erythromycin, neomycin (alone), oleandomycin[+], sulfamerazine, and sulfaquinoxaline are also approved for use in feed and are expected to transition to VFD status, but are not marketed at this time. If they return to the market after January 1, 2017, they will require a VFD.

[$]Type A medicated articles used to manufacture medicated feed, all products may not be marketed at this time

*Fixed-ratio, combination drug

[+]Currently only approved for production uses

Current VFD Drugs

Established drug name	Proprietary drug name(s)[$]
avilamycin	Kavault
florfenicol	Aquaflor, Nuflor
tilmicosin	Pulmotil, Tilmovet

[$]Type A medicated articles used to manufacture medicated feed

This information was published online on January 19, 2016, and is available at: http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm482107.htm. As the affected products transition from OTC to VFD marketing status, CVM anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates: http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm

Additional Resources:

- List of Drugs Transitioning from Over-the-Counter (OTC) to Veterinary Feed Directive (VFD) Status, printer-friendly PDF: http://www.fda.gov/downloads/AnimalVeterinary/DevelopmentApprovalProcess/UCM482258.pdf
- Blue Bird Labels: http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm

Appendix 3

Requirements for Distributors under the VFD Final Rule

Sales of VFD products

Under VFD regulation, a "distributor" means any person who distributes a medicated feed containing a VFD drug to another person (21 CFR 558.3(b)(9)). Therefore, if you are a retailer or other establishment who will be selling animal feed containing a VFD drug, whether to the end user or another distributor, you will be considered a "distributor" under the VFD final rule, and are responsible for compliance with 21 CFR 558.6, including the distributor-specific requirements outlined below.

CVM expects that the medically important antimicrobials administered to food producing animals in medicated feed (see Appendix 2 above) will transition from OTC to VFD marketing status on January 1, 2017. A veterinary feed directive is not required for current OTC products transitioning to VFD status until January 1, 2017. On January 1, 2017, all products with approvals that have transitioned from OTC to VFD must be used in compliance with the VFD regulations, even if the product has the old OTC labeling. At the time of transitioning from OTC to VFD marketing status, these products will become subject to the requirements in the VFD rule that went into effect on October 1, 2015[2].

A lawful VFD is required to obtain and use medicated feed containing a VFD drug (VFD feed). Beginning January 1, 2017, FDA intends to initiate surveillance and compliance activities to ensure that the products making this transition are being used in compliance with the applicable VFD requirements.

FDA recommends that parties involved in the production and/or distribution of the affected VFD products proactively manage product inventories to limit the amount of OTC-labeled product that will remain on shelves when these products are transitioned to VFD status on January 1, 2017.

Internet pharmacies

A VFD drug is not a prescription drug[3]. If an internet pharmacy distributes VFD feed to another distributor or to the end user/client, they would be considered a VFD distributor and therefore would need to notify FDA of their intent to distribute VFD feed and follow the distributor requirements in the VFD rule that went into effect on October 1, 2015, before distributing VFD feed. The requirements applicable to VFD distributors are discussed below. FDA has also

[2] Final Rule: Veterinary Feed Directive. https://www.federalregister.gov/articles/2015/06/03/2015-13393/veterinary-feed-directive
[3] 21 U.S.C. 354(c).

issued a guidance (GFI #120) that addresses the requirements of the VFD rule in detail[4].

Distributor Responsibilities - *21 CFR 558.6(c)*

If you intend to distribute an animal feed containing a VFD drug or a combination VFD drug, you must:

- file a one-time notice with FDA of intent to distribute animal feed containing a VFD drug;
- notify FDA within 30 days of any change in ownership, business name, or business address;
- fill a VFD order only if the VFD contains all required information;
- ensure that the animal feed you distribute containing the VFD drug or combination VFD drug complies with the terms of the VFD and is manufactured and labeled in conformity with the approved, conditionally approved, or indexed conditions of use for such drug;
- ensure all labeling and advertising prominently and conspicuously display the following cautionary statement: "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian.";
- retain VFD orders for two years from date of issuance;
- retain records of the receipt and distribution of all medicated animal feed containing a VFD drug for 2 years;
- provide VFD orders for inspection and copying by FDA upon request;
- retain records of VFD manufacturing for 1 year in accordance with 21 CFR part 225 and make such records available for inspection and copying by FDA upon request;
- if you are the originating distributor (consignor), you must obtain an acknowledgement letter from the receiving distributor (consignee) before the feed is shipped; and
- if you are a consignor distributor, you are required to retain a copy of each consignee distributor's acknowledgement letter for 2 years.

"One-Time" Distributor Notification - *21 CFR 558.6(c)(5)*

If you intend to distribute animal feed containing a VFD drug or a combination VFD drug, you must file a one-time notice with FDA before you begin distributing VFD feed.

The VFD distributor notification letter can be done in a number of ways as long as it contains the following required information:

1. The distributor's complete name and business address;
2. The distributor's signature or the signature of the distributor's authorized agent; and
3. The date the notification was signed.

A single notification may include multiple locations. For multiple locations, each address

[4] Guidance for Industry #120, Veterinary Feed Directive Regulation Questions and Answers: http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf

must be included in the notification. A company with multiple locations may send separate VFD distributor notifications for each location. Perhaps an easier way of doing it is to submit one letter stating their intent to distribute VFD feeds at each of their locations, including each location's physical address. Both would be acceptable as long as they contain the required information mentioned above.

A letter from a company that states their intent to distribute at all of their locations, but fails to provide the address of each location would not be acceptable.

In addition, we would like to make clear that the locations listed in the VFD Distributor Notifications we receive are entered into a database, and a listing of VFD Distributors is published on the FDA.gov website available to the public. [5]

The notice should be sent by mail or faxed to Division of Animal Feeds (HFV-220); FDA, Center for Veterinary Medicine; 7519 Standish Pl., Rockville, MD 20855; FAX: 240-453-6882.

You must also notify FDA within 30 days of any change in ownership, business name, or business address.

Acknowledgment letter - *21 CFR 558.3(b)(11) and 21 CFR 558.6(c)(8)*

An acknowledgement letter is a letter that a distributor obtains from another distributor (the distributor receiving the VFD feed) when the distributor ships an animal feed containing a VFD drug in the absence of a valid VFD. Specifically, an "acknowledgement letter" is a written (nonverbal) communication provided to a distributor (consignor) from another distributor (consignee).

An acknowledgement letter must be provided either in hardcopy or through electronic media, and must affirm:

1. that the distributor will not ship such VFD feed to an animal production facility that does not have a VFD;
2. that the distributor will not ship such VFD feed to another distributor without receiving a similar written acknowledgment letter; and
3. that the distributor has complied with the distributor notification requirements in 21 CFR 558.6(c)(5).

The acknowledgment letter allows a distributor to have VFD feed on hand so that when an end user/client gives him/her a valid VFD the distributor can fill the VFD immediately.

[5] For example see:
http://www.fda.gov/downloads/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/UCM096059.pdf

An acknowledgment letter may be written to cover one or more shipments of a VFD feed with an open-ended duration. In that instance, the acknowledgment letter must be kept for two years from the date of last shipment distributed under the acknowledgment letter.

Please note: an acknowledgment letter is different than a distributor notification. As discussed above, a distributor notification is the one-time notice by a distributor to the FDA of its intent to distribute a medicated feed containing a VFD drug.

Feed Manufacturing

If you manufacture medicated feed, you are required to have a medicated feed mill license if the VFD drug you use to manufacture a medicated feed is a Category II, Type A medicated article. A license is also required in some situations involving certain liquid and free-choice medicated feeds. As a licensed feed mill, you are subject to the cGMP requirements for a licensed feed mill in 21 CFR 225.

Recordkeeping

Depending on to whom you distribute VFD feed, the following applies:

If you ship VFD feed to	**Record Required**	**Record Retained for**
Clients (end-users) only	VFD (order)	2 years
Other distributors only	Acknowledgement letter(s) or VFD (order)	2 years
Both clients and other distributors	VFD (order) from clients or other distributors and acknowledgement letter(s) from other distributors	2 years

If you manufacture VFD feed, you also need:

Manufacturing Record

Required per	**Retained for**
21 CFR 225 (cGMP)	1 year

Additional Resources:

- Veterinary Feed Directive (VFD): http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm
- Guidance for Industry #120, *Veterinary Feed Directive Regulation Questions and Answers*: http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052660.pdf

- Safe Feed webpage: http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalFeedSafetySystemAFSS/default.htm
- Blue Bird Labels: http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/MedicatedFeed/BlueBirdLabels/default.htm

Appendix 4

Plan for Transitioning to New Labeling by January 1, 2017

CVM's primary goal is that beginning on January 1, 2017, all affected products (medically important antimicrobials approved for use in animal feed or water) are to be used in the market in accordance with the changes outlined in GFIs #209 and #213 as part of FDA's strategy to ensure the judicious use of medically important antimicrobials in animal agriculture. This means that, as of that date, such products would no longer be used for production (i.e. growth promotion and feed efficiency) purposes and would only be used with the prior authorization of a licensed veterinarian.

The FDA sent a letter in September 2015 to each affected animal drug sponsor outlining the process of transitioning their products to remove approval for production use and to phase in veterinary oversight for the remaining therapeutic uses of these products by the end of December 2016. The letter also explained the approval process for each label change and outlined the materials sponsors need to submit to the agency in order to complete the transition.

Below are key time periods that were discussed in the letter to animal drug sponsors, and some of the different labeling you may see enter the market as animal drug sponsors manage product inventories and facilitate the transition to new labeling by the January 1, 2017, target date.

A. Between now and June 30, 2016

Transitional labeling: Between now and June 30, 2016, drug sponsors may use "transitional labels" provided with the existing product labeling and/or information that is printed on or affixed to the product labeling. If such "transitional labeling" is used, we would expect such labeling to be consistent with the following statements:

> ***Statement that applies to feed products:*** *Beginning January 1, 2017, this product will require a veterinary feed directive issued by a licensed veterinarian and will be subject to the following restriction:*
>
> "Caution: Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian." [6]
>
> ***Statement that applies to water products:*** *Beginning January 1, 2017, this product will require a prescription issued by a licensed veterinarian and will be subject to the following restriction:*
>
> "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian." [7]

[6] 21 CFR Sec. 558.6 (a) (6)

> ***Statement that applies to all feed or water products with production indications:*** *Effective January 1, 2017, this product will no longer be approved for [insert all production indications as they appear on labeling] which means the use of this product for that [/these] purpose[s] will no longer be legal.*

We expect all agreements on new labeling to be in place and labeling supplement materials submitted to FDA by drug sponsors by no later than June 30, 2016. Therefore, after June 30, 2016, we have asked sponsors to use discretion in deciding whether to continue to apply "transitional labeling" to new product inventory.

Given the unique circumstances and the temporary nature of this "transitional labeling," we informed sponsors that we would not object to them immediately labeling affected product with the above information. As such, distributors may see this "transitional labeling" on the market between now and June 30, 2016, and to a more limited extent, after June 30, 2016.

B. Between June 30, 2016 and January 1, 2017

Between June 30, 2016 and January 1, 2017, we expect the drug sponsors to begin manufacturing product containing the new labeling for distribution to the marketplace on or after January 1, 2017. New labeling could utilize stickers affixed to existing product labeling and/or new printed labeling.

For medicated feed products, sponsors will also need to generate updated Blue Bird labels. We have informed sponsors that it would be helpful to make available advance copies of the updated Blue Bird labels for feed manufacturers.

New animal drug sponsors have been encouraged to manage product inventory appropriately so that new labeling will not enter the market before January 1, 2017. Product labeled with new VFD drug labeling (restricting medicated feed containing the VFD drug to use by or on the order of a licensed veterinarian) will not include a "transitional statement" indicating the implementation begins January 1, 2017, and may be confusing.

Please note: a veterinary feed directive is <u>not required</u> to be issued by a licensed veterinarian for affected products transitioning from OTC to VFD status until <u>January 1, 2017</u>.

C. After January 1, 2017

As noted above, our primary goal is that beginning on January 1, 2017, all affected products are to be used in the market in accordance with the changes outlined in GFIs #209 and #213. This means that on that date, feed manufacturers will be expected to begin labeling medicated feeds with the new GFI #213-aligned Blue Bird labels.

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[7] 21 CFR Sec. 201.105 (a)(2)

Our expectation is that beginning on January 1, 2017, product is either 1) labeled with "new" final printed label, 2) has a sticker affixed to the product that includes the "new" final label language, or 3) is labeled with the "transitional label" statement(s) described above.

Additional Resources:

- Letter to Sponsors Regarding Implementation of GFI 213: http://www.fda.gov/downloads/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/UCM482139.pdf
- Judicious Use of Antimicrobials http://www.fda.gov/AnimalVeterinary/SafetyHealth/AntimicrobialResistance/JudiciousUseofAntimicrobials/default.htm