

Changes to Antibiotic Labeling & Veterinary Feed Directive

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Outline

- Reason for changes
- What changes will occur?
- Getting prepared
- Common questions

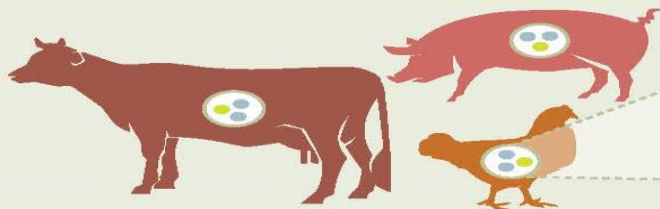


ANTIBIOTIC RESISTANCE

from the farm to the table

RESISTANCE

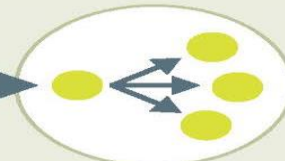
All animals carry **bacteria** in their intestines



Antibiotics are given to animals



Antibiotics kill most bacteria



But resistant bacteria survive and multiply

SPREAD

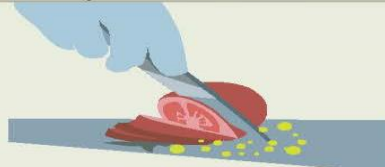
Resistant bacteria can spread to...



animal products



produce through contaminated water or soil



prepared food through contaminated surfaces



the environment when animals poop



EXPOSURE

People can get sick with resistant infections from...



contaminated food



contaminated environment

IMPACT

Some resistant infections cause...



mild illness



severe illness and may lead to death



Learn more about antibiotic resistance and food safety at www.cdc.gov/foodsafety/antibiotic-resistance.html

Summary of Changes

- These changes will impact only feed grade and water soluble antibiotics that are considered medically important by the FDA

Medically Important Antimicrobials

- Penicillins
- Tetracyclines
 - Chlortetracycline
 - Oxytetracycline
- Macrolides
 - Tylosin
 - Tilmicosin
 - Erythromycin
- Lincosamides
 - Lincomycin
- Streptogramins
 - Virginiamycin
- Aminoglycosides
 - Gentamycin
 - Neomycin
- Sulfonamides
 - Only potentiated sulfonamides are listed in GFI 152 however the FDA-CVM has indicated all sulfas are medically important

Summary of Changes

Increased rate of weight gain/improved feed efficiency indications removed from labels:

– Tetracyclines –

- Chlortetracycline (Aureomycin[®])
- Oxytetracycline (Terramycin[®])
- Chlortetracycline/Sulfamethazine (AS-700[®])

– Aminoglycosides

- Neomycin w/ oxytet combos (Neo-Terramycin[®])

– Streptogramins

- Virginiamycin (V-Max[®])

Summary of Changes

- **A Veterinary Feed Directive (VFD) will be required to:**
 - Obtain and use antibiotics that are delivered in the feed
 - Obtain and use products that already contain an antibiotic
 - Bagged feeds, mineral blocks, milk replacer, etc.
- **A prescription will be required to:**
 - Obtain and use antibiotics that are delivered in the water

Important Points

- These changes **DO NOT** apply to products such as Rumensin[®], Bovatec[®], Deccox[®] or Corid[®]
- A Veterinary Client Patient Relationship (VCPR) is required before a veterinarian can write a VFD or prescription

Important Points

- Extra-label use of feed grade antibiotics is illegal
 - Extra-label use is using a drug at a dose, by a route, for a condition or indication, or in a species not on the label
- Chlortetracycline (CTC) example
 - In cattle CTC is labeled for
 - control of anaplasmosis,
 - treatment and control of pneumonia
 - treatment of bacterial enteritis

Important Points

- Length of expiration date on a VFD is not to exceed 6 months if not specified on the antibiotic label
- The producer, veterinarian and distributor will need to keep a copy of the VFD on file for 2 years

Important Points

- Information your veterinarian will need from you to fill out a VFD
 - Production class
 - Approximate number of animals to be fed the medicated feed prior to the expiration date
 - Location of animals
 - If you are using other feed additives
 - Where you will get the medicated feed

Common Questions

- What will veterinarians charge for a VFD?
- Will injectable tetracycline and penicillin be impacted by these changes?
- I use feed or water antibiotics in animals that are not considered livestock. Will this impact me?

Common Questions

- Can I purchase CTC before the end of the year to avoid needing a VFD for awhile?
- Will I be able to continue on-farm mixing?
- Can copies of a VFD be sent to multiple distributors?
- Where can I find a list of antibiotics affected?

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

Upon completion of their voluntary transition from OTC to VFD, all feed uses of the following 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 drug application:

Drugs Transitioning From OTC to VFD Status

Established drug name	Examples of proprietary drug name(s) ⁵
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/Pficlcr SP, Pennchlor SP, ChlorMax SP
hygromycin B	Hygromix
lincomycin	Lincomix
oxytetracycline (OTC)	Aureomycin, 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

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

Upon completion of their voluntary transition from OTC to Rx, all uses of the following drugs will require a prescription from a veterinarian as of January 1, 2017, except in cases where a sponsor chooses to voluntarily withdraw the drug application:

Water Soluble Drugs Transitioning From OTC to Rx Status

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