

# Guidance for Feed-use Antibiotics in Livestock Production

## **ICA Fact Sheet**

January 2014

#### Overview

On Dec. 12, the Food and Drug Administration (FDA) published their final Guidance #213 and a proposal for revisions to the current Veterinary Feed Directive (VFD). Guidance #213 is part of FDA's larger strategy for judicious use of the antibiotics important in human medicine in an effort to reduce antibiotic resistance. The new guidance provides two recommended principles to limit medically important antimicrobial drug use in animals that:

- 1. Are considered necessary for assuring animal health.
- 2. Include veterinary oversight or consultation.

This guidance only pertains to the medically important antibiotic products approved for use in feed and water. Medically important antibiotics in injectable form do not come under this guidance.

## **Animal Drug Classification**

New animal drugs and combination products are approved with one of the following marketing statuses and respective directions for application:

- 1. Over-the-counter (OTC) lay person is provided adequate directions for use.
- 2. Veterinary prescription (Rx) lay person cannot use safely, need veterinarian oversight.
- 3. Veterinary feed directive (VFD) lay person cannot use safely, need veterinarian oversight.

With the provisions in Guidance #213, all medically important antibiotics used in feed and water will require a VFD or Rx, respectively, in order to obtain these products.

#### **Judicious Drug Use**

FDA guidance seeks to eliminate the sub-therapeutic use of medically important antibiotics in feed and water for growth promotion. A VFD or Rx for antibiotic use in feed or water can be obtained provided one of the following cases exists:

- 1. **Prevention** consideration by the veterinarian of relevant factors, such as avoiding a newly attained group of feeder calves from getting a respiratory infection.
- 2. **Control** –administration to decrease the spread of disease in a herd while clinically ill animals are treated, such as limiting the spread of BRD in a feedlot.
- 3. **Treatment** used in a therapeutic manner to remedy a condition or disease, such as applying a treatment additive for pneumonia.

#### **Guidance Compliance**

The FDA intends to work with affected drug sponsors to help them <u>voluntarily implement</u> the principles. Although FDA is committed to completing this rulemaking process within 3 years they are prepared to extend the timeframe, as necessary, to ensure that it coincides with the implementation of the revised VFD requirements. At this time producers are not required to follow components of Guidance #213 until December 2016, when it will become mandatory.

#### **Affected Cattle Drugs**

The list of affected drugs was determined by antibiotic classes important for use in treating infections in human medicine such as: aminoglycosides, lincosamides, macrolides, streptogramins, sulfonamides, and tetracyclines.

Current use of antibiotics in cattle feed is primarily for the prevention and control of conditions/diseases such as liver abscesses, coccidiosis and anaplasmosis. The products below will still be available to add to feed and water for control, treatment or prevention; however, oversight of a veterinarian will be required by either VFD or Rx.

<b>Antibiotic Class</b>	Active Ingredient	Trade Name	Use
Aminoglycoside	Neomycin Sulphate	Biosol	Treatment and control of bacterial
			enteritis.
Macrolide	Tylosin Phosphate	Tylan	Premix reduces the incidence of liver
			abscesses.
Macrolide	Tylosin Phosphate	Tylovet	Prevention and control of coccidiosis and
			liver abscesses.
Tetracycline	Chlortetracycline (CTC)	Aureomcyin	Treatment of bacterial enteritis and
			pneumonia. Feed < 5 days.
Tetracycline	Chlortetracycline (CTC)	Pennchlor	Control of anaplasmosis in feedlot cattle
			and pneumonia in calves.
Tetracycline	Oxtytetracycline	Terramycin	Control of bacterial enteritis and
			pneumonia.
Tetracycline	Oxytetracycline	Pennox	Control of bacterial enteritis and
	Hydrochloride		pneumonia.

Guidance #213 <u>does not</u> pertain to ionophores, unless used in combination with a medically important antibiotic such as: MGA 100 / Rumensin / Tylan. This additive would require a valid VFD.

Guidance #213 <u>does</u> pertain to any feedstuff or supplement that contains any of the above active ingredients, such as medicated mineral.

### **VFD Record Keeping**

The producer, veterinarian, and supplier must currently maintain records for two years with records readily available for FDA inspection and copying. The proposed changes to the VFD reduce this record-keeping time from two years to one year. Records must include:

- Time period antibiotic was available for livestock.
- Target animals must be specified pen number / tag number.
- Labeling must have cautionary statement.

Iowa cattle producers that utilize antibiotics in feed or water are strongly encouraged to contact their veterinarian to discuss the new changes provided in Guidance #213. The list of antibiotics included on the affected list will continue to change and develop as antibiotic resistance is studied in livestock. This topic and related details are constantly shifting, so stay tuned to the Association for more updates.

Call 515.296.2266 with any questions.