### Using Medicated Feeds Containing Chlortetracycline for Beef Cattle

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The animal health products and the U.S. Food and Drug Administration (FDA) approved uses of products discussed in these proceedings are current as of February 2017. Keep in mind that new products may enter the marketplace and current products may change their label directions following an FDA approval process. FDA-approved label directions supersede anything else that you may hear or read about feed medications, including these proceedings. Extra-label use of feed medications has always been and continues to be <u>STRICTLY PROHIBITED</u>. The intent of these proceedings is not to promote any particular product, but to serve as an unbiased resource for proper use of medicated feeds containing chlortetracycline for beef cattle.

Chlortetracycline (CTC) is an antibiotic used in beef cattle feed and/or drinking water for the control or aid in the control of anaplasmosis caused by *Anaplasma marginale*; for the reduction of liver condemnation due to liver abscesses; for the control and treatment of bacterial enteritis (scours) caused by *Escherichia coli*; and for the treatment of bacterial pneumonia (shipping fever) associated with *Pasteurella multocida*. When used in or top-dressed onto beef cattle feed or mineral mixes, CTC requires a veterinary feed directive (VFD). When used in drinking water, CTC requires a prescription (Rx).

#### What products containing CTC are currently available for use in beef cattle?

There are several brand name products that contain CTC. The following table lists the products containing CTC currently available for use in beef cattle, the manufacturer, whether the product requires a veterinary feed directive (VFD) or prescription (Rx), and whether or not it is FDA-approved for use in free-choice formulations.

Product name	Manufacturer	VFD	Rx	FDA-approved for use in free-choice formulations
Aureomycin® 50 Granular	Zoetis	$\checkmark$		yes
Aureomycin® 50 Granular A	Zoetis	$\checkmark$		yes
Aureomycin® 50 Granular Blend	Zoetis	$\checkmark$		yes
Aureomycin® 90 Granular	Zoetis	$\checkmark$		yes
Aureomycin® 90 Meal	Zoetis	$\checkmark$		yes
Aureomycin® 100 Granular	Zoetis	$\checkmark$		yes
Aureomycin® Soluble Powder Concentrate	Huvepharma		$\checkmark$	no
Aureo S 700 <sup>®</sup> Granular 35G	Zoetis	$\checkmark$		no
ChlorMax® 50	Zoetis	$\checkmark$		no
Chloronex <sup>®</sup> Soluble Powder	Huvepharma		$\checkmark$	no
CLTC® 100 MR	Phibro	$\checkmark$		no

Product name	Manufacturer	VFD	Rx	FDA-approved for use in free-choice formulations
Pennchlor 50®	Pharmgate Animal Health	$\checkmark$		no
Pennchlor 50 G®	Pharmgate Animal Health	$\checkmark$		no
Pennchlor 64® Soluble Powder Concentrate	Pharmgate Animal Health		$\checkmark$	no
Pennchlor 90 G®	Pharmgate Animal Health	$\checkmark$		no
Pennchlor 100 G®	Pharmgate Animal Health	$\checkmark$		no
Pennchlor 100 Hi-Flo®	Pharmgate Animal Health	$\checkmark$		no
Pennchlor-S®	Pharmgate Animal Health	$\checkmark$		no
VitaFerm® Cattleman's Blend™ with CTC 3G	BioZyme		$\checkmark$	no
VitaFerm® Cattleman's Blend™ with IGR & CTC 1.4G	BioZyme		$\checkmark$	no

#### How can CTC be fed to beef cattle?

Chlortetracycline can be fed to beef cattle either on a daily basis or in free-choice formulations based on FDA approved directions. Unless specifically stated on the product label and on a VFD, CTC must be fed on a daily basis.

#### Daily feeding

Most FDA approved uses of CTC require feeding on a daily basis, and sometimes for only a defined, short period of time. For example, CTC cannot be fed for more than 5 days for the treatment of bacterial enteritis or bacterial pneumonia, and must be fed on a daily basis when treating those diseases. When fed on a daily basis, CTC may either be mixed in the daily ration or administered as a top-dress, depending on label directions. For example, the label for Aureomycin<sup>®</sup> specifically states that the "appropriate amount of Aureomycin-containing feed supplement may be mixed in the cattle's daily ration or administered as a top-dress. If the Aureomycin-containing feed supplement is administered as a top-dress, it must be spread uniformly on top of the ration and sufficient space must be provided so that all cattle can eat at the same time".

#### Free-choice feeding

As seen in the table above, Aureomycin<sup>®</sup> is the ONLY CTC product that can currently be used in free-choice feeds or mineral mixes, and it can only be used free-choice when following very specific guidelines. For example, Aureomycin<sup>®</sup> can only be used in free-choice feeds as an aid in control of active infection of anaplasmosis caused by Anaplasma marginale susceptible to chlortetracycline. Aureomycin<sup>®</sup> cannot be used be used in free-choice feeds to treat or control any other disease conditions.

# Why is Aureomycin<sup>®</sup> the ONLY product containing CTC that can currently be used in free-choice feeds or mineral mixes for beef cattle?

Free-choice medicated feed formulations must be FDA-approved. The FDA requires consumption studies to be completed before a feed medication is approved for use in free-choice feeds. As of right now, Aureomycin<sup>®</sup> is the only CTC product that has undergone the necessary consumption studies to satisfy the FDA's requirement for approval in free-choice formulations containing CTC. Currently, ADM Animal Nutrition, Hubbard Feeds, Purina, and Zoetis all have proprietary, FDA-approved free-choice formulations for CTC, but they all contain Aureomycin<sup>®</sup> as the source of CTC.

# Can a feed mill substitute another CTC containing product for Aureomycin<sup>®</sup> when intended for use in a free-choice feed or mineral mix?

No; Aureomycin<sup>®</sup> is the only product containing CTC that currently has FDA approval for use in free-choice feeds or mineral mixes. If a veterinarian provides a VFD for Aureomycin<sup>®</sup> to be used in a free-choice formulation as an aid in control of active infection of anaplasmosis caused by *Anaplasma marginale*, it would be illegal for a feed distributor to substitute another chlortetracycline product for Aureomycin<sup>®</sup>. It would be wise to state this clearly on the VFD.

Are there ready-to-feed free-choice mineral mixes containing Aureomycin<sup>®</sup> available for grazing cattle? Yes; examples include MoorMan's<sup>®</sup> Special Range Minerals AU 168XFE, manufactured by ADM Animal Nutrition, and STOCKMASTER<sup>®</sup> AUREO<sup>®</sup> FC C6000, manufactured by Hubbard Feeds. These ready-to-feed free-choice mineral mixes containing Aureomycin<sup>®</sup> are available for use as an aid in control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline. Use of these products, as with any feed containing CTC, requires a VFD.

#### What other options exist for obtaining free-choice mineral mixes containing CTC?

Approved feed mills have the option of mixing their own free-choice mineral mix with Aureomycin<sup>®</sup> for use as an aid in control of active infection of anaplasmosis caused by *Anaplasma marginale* susceptible to chlortetracycline. Zoetis has a FDA-approved proprietary formulation that can be used to prepare free-choice mineral mixes containing Aureomycin<sup>®</sup>. However, Zoetis does not currently market any mineral mixes containing Aureomycin<sup>®</sup>. So, upon request, Zoetis will provide their proprietary formulation to approved feed mills, with accompanying Blue Bird labels that feed mills can use to manufacture and market their own free-choice mineral mix containing Aureomycin<sup>®</sup> for use as an aid in control of active infection of anaplasmosis. Zoetis does not charge anything for providing their proprietary formulation to feed mills.

### For additional information:

AskCVM@fda.hhs.gov Guidance for Industry #120 21 CFR 558.6 (VFD) 21 CFR 225 (cGMP) Website: http://www.fda.gov/safefeed

References:

- 1. U.S. Food and Drug Administration Veterinary Feed Directive (VFD) http://www.fda.gov/AnimalVeterinary/DevelopmentApprovalProcess/ucm071807.htm
- 2. The Compendium of Veterinary Products http://www.bayerlivestock.com/show.aspx/resources/compendium-of-veterinary-products