SWINE WATER MEDICATIONS TRANSITIONING FROM OVER-THE-COUNTER (OTC) TO PRESCRIPTION (RX) STATUS

FDA’s Antibiotic Changes for Swine
By: Sarah Schieck, Swine Extension Educator

OVERVIEW

On January 1, 2017, the U.S Food and Drug Administration’s (FDA) new regulation addressing on-farm antibiotic use in food-animal production will take effect. The purpose of this publication is to identify which swine medications will be affected by these changes. FDA’s effort is aimed to eliminate the use of medically important (to human illness) antibiotics for growth promotion purposes in food-animal production and to bring therapeutic use of antibiotics in feed and water – to treat, control, or prevent specific disease – under additional veterinary oversight. The new requirements will affect producers, veterinarians, feed mills and suppliers.

SWINE WATER SOLUBLE MEDICATIONS TRANSITIONING FROM OTC TO RX STATUS

Upon completion of their voluntary transition from OTC to Rx, all uses of the following medications will require a prescription from a veterinarian as of January 1, 2017.

<table>
<thead>
<tr>
<th>Established Drug Name</th>
<th>Examples of Trade Name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlortetracycline</td>
<td>Aureomycin®, Chloronex, Chlortetracycline, Chlortetracycline Bisulfate, Chlortet-Soluble-O, Fernymycin, Pennchlor™</td>
</tr>
<tr>
<td>Gentamicin</td>
<td>Garacin®, GenGard®, GentaMed™, Gentocin®, Gentoral®</td>
</tr>
<tr>
<td>Lincomycin</td>
<td>Linco, Lincomix®, Lincomycin, Lincomycin Hydrochloride, Lincosol, Lincomed,</td>
</tr>
<tr>
<td>Neomycin</td>
<td>Biosol®, Neo, NeoMed®, Neomycin, Neomycin liquid, Neomycin Sulfate, Neomix®, Neo-Sol®, Neosol-Oral</td>
</tr>
<tr>
<td>Oxytetracycline</td>
<td>Agrimycin™, Oxy-Tet™, Oxytet®, Oxytetracycline HCL, Terramycin®, Tetroxy®, Tetroxy® HCA</td>
</tr>
<tr>
<td>Sulfamethazine</td>
<td>SMZ-Med™, Sulmet®, Purina® Sulfamethazine Soluble, Purina® Sulfapyridine,</td>
</tr>
<tr>
<td>Tetracycline</td>
<td>Duramycin, Polyotic®, Tetra-Bac, Tetracycline, Tetracycline hydrochloride, TetraMed®, Tet-Sol®, Tetrasol</td>
</tr>
</tbody>
</table>

Note: Apramycin, carbomycin/oxytetracycline*, Chlortetracycline/sulfamethazine*, streptomycin, sulfachloropyrazine, sulfachloropyridazine, and sulfamerazine/sulfamethazine/sulfadiazine* are expected to transition to Rx status, but are not marketed at this time. If they return to the market after January 1, 2017, they will require a prescription from a veterinarian.

CURRENT SWINE RX WATER SOLUBLE MEDICATIONS THAT WILL REMAIN RX MEDICATIONS

<table>
<thead>
<tr>
<th>Established drug name</th>
<th>Trade Name(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tylosin</td>
<td>Bilovet™, Tylan®</td>
</tr>
</tbody>
</table>
WATER SOLUBLE MEDICATIONS NOT AFFECTED BY FDA’S ANTIBIOTIC CHANGES

Antimicrobials that are not medically important

- Bacitracin (Solu-tracin, BMD® Soluble)
- Tiamulin (Denagard®, Tiagard™, Tiagard™, Triamulox™)

Other medications (that are not antimicrobials)

- Anthelmentics (dewormers): Fenbendazole (Safe-Guard® AquaSol)

What does “medically important” mean?

An antibiotic is considered medically important if it is used, or antibiotics in the same family of medications, is used in human or animal medicine.

FDA’S NEW ANTIBIOTIC REGULATIONS DEFINED

- Medically important antibiotics will be limited to the therapeutic purposes of treatment, control, and prevention of specific diseases.
- Non-therapeutic use of medically important antibiotics will not be permitted. Antibiotics will no longer be labeled for growth promotion.
- Veterinary oversight will increase for the remaining therapeutic applications of treatment, control, and prevention. This applies to both in-feed and water-delivered antibiotics.
- Over-the-counter usage of medically important antibiotics used in mass medication (feed or water) will be eliminated. A veterinary feed directive (VFD) will be needed to purchase medicated feed and a prescription (Rx) will be needed to purchase water medication.
- Medicated feed cannot be used in extra label fashion so manufacturers’ labels on in-feed medications must be followed.

Note: This information was adapted from a FDA fact sheet and was up-to-date as of August 2016. As the industry transitions, Center for Veterinary Medicine anticipates additional changes during the coming months to this information. Please check the link below for the most recent updates: http://z.umn.edu/FDAVFDchanges

REFERENCES AND ADDITIONAL RESOURCES

- Food and Drug Administration - http://z.umn.edu/FDAVFDchanges
- National Pork Board - www.pork.org/antibiotics
- University of Minnesota Swine Extension - www.extension.umn.edu/swine

Questions or Comments?
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