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## Drug Clearances Summary for 2023

On the following pages are listings of new and revised drug clearances during 2023 based on information derived from the Federal Register, the CFR (Code of Federal Regulations), NADA (New Animal Drug Application) data, Bluebird labels, and manufacturer drug labels.

### Updated Animal Classification for Bambermycins in Cattle

Drug Clearance	Previous Classification	Updated Classification
Bambermycins 1 to 4 gm/ton: For increased rate of weight gain and feed efficiency	Cattle fed in confinement for slaughter	Growing beef steers and heifers fed in confinement for slaughter
Bombermycins 2 to 80 gm/ton: For increased rate of weight gain	Pasture Cattle (slaughter, stocker, and feeder cattle, and dairy and beef replacement heifers)	Growing beef steers and heifers on pasture (stocker, feeder, and slaughter), and replacement beef and dairy heifers on pasture

### Updated Drug Clearance for Chlortetracycline - Monensin combination

NADA	Name	Drugs	Sponsor	Indications
141-564	Pennchlor & Rumensin	Chlortetracycline Monensin	Pharmgate	<p><b>Replacement beef and dairy heifers</b> Treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline. For prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>Eimeria zuernii</i>.</p>
				<p><b>Replacement beef and dairy heifers</b> Treatment of bacterial enteritis caused by <i>E. coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> organisms susceptible to chlortetracycline. For increased rate of weight gain.</p>



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### Updated Drug Clearance for Chlortetracycline - Monensin combination

NADA	Name & Drug	Sponsor	Indications
200-748	Pennchlor Monovet  Chlortet- racycline  Monensin	Huvepharma	<p><b>Beef calves 2 months of age and older</b></p> <ol style="list-style-type: none"> <li>1. For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline and for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> in beef calves 2 months of age and older.</li> </ol> <p><b>Growing beef steers and heifers fed in confinement for slaughter</b></p> <ol style="list-style-type: none"> <li>1. For control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline and for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> in growing beef steers and heifers fed in confinement for slaughter over 700 lbs.</li> <li>2. For control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter over 700 lbs.</li> <li>3. For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline and for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> in growing beef steers and heifers fed in confinement for slaughter.</li> <li>4. For treatment of bacterial enteritis caused by <i>Escherichia coli</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter.</li> <li>5. For the reduction of the incidence of liver abscesses and for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> in growing beef steers and heifers fed in confinement for slaughter over 400 lbs.</li> <li>6. For the reduction of the incidence of liver abscesses and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter over 400 lbs.</li> <li>7. For control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline and for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> in growing beef steers and heifers fed in confinement for slaughter under 700 lbs.</li> <li>8. For control of active infection of anaplasmosis caused by <i>Anaplasma marginale</i> susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter under 700 lbs.</li> <li>9. For the control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella spp.</i> susceptible to chlortetracycline and for the prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>Eimeria zuernii</i> in growing beef steers and heifers fed in confinement for slaughter.</li> <li>10. For the control of bacterial pneumonia associated with shipping fever complex caused by <i>Pasteurella spp.</i> susceptible to chlortetracycline and for improved feed efficiency in growing beef steers and heifers fed in confinement for slaughter.</li> </ol>



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## Drug Clearances Summary for 2023

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All Safe-Guard (fenbendazole) / Lincomix (lincomycin) combination drug clearances approved for use in swine feed have been deleted from the medicatedfeed.com database as per the FDA announcement detailed below.

### **FDA Announces Voluntary Withdrawal of Fenbendazole and Lincomycin Combination for use in Swine to Veterinarians, Feed Manufacturers, and Pork Producers**

June 30, 2023

Dear Veterinarians, Feed Manufacturers, and Pork Producers:

The Food and Drug Administration's (FDA) Center for Veterinary Medicine (CVM) is announcing the voluntary withdrawal of the **combination medicated feed containing** Safe-Guard (fenbendazole) and Lincomix (lincomycin), under the New Animal Drug Application (NADA) 140-954, for use in swine. The sponsor requested that CVM withdraw the application. This combination is used for removal of certain internal parasites and for the treatment and control of swine dysentery, and for reduction in the severity of swine mycoplasmal pneumonia. Because lincomycin is a veterinary feed directive (VFD) drug, any use of lincomycin, alone or in a combination, requires a VFD order from a veterinarian. Because this application has been withdrawn, mixing these two drugs in combination is **no longer permitted, and VFD orders** authorizing their use in combination **may no longer be issued**.

Fenbendazole and lincomycin are marketed as separate Type A medicated articles. Fenbendazole (SafeGuard) is marketed under NADA 131-675, and lincomycin (Lincomix) is marketed under NADA 097-505. NADA 140-954 provided for the combination of these two medications to be mixed together in swine feed. Withdrawal of NADA 140-954 will mean that swine feed that contains both drugs can no longer be manufactured. Accordingly, veterinarians can no longer issue a VFD for a Type C medicated feed containing both medications. However, both fenbendazole (SafeGuard) and lincomycin (Lincomix) remain available for use **individually** according to their approved labels. Pork producers who manufacture their own medicated feeds should also be aware of this action. Specifically, that although these two medicated articles can continue to be used **individually**, as labeled, they can no longer be used **in combination**.

CVM is notifying veterinarians to stop issuing VFDs, feed mills to stop filling orders, and pork producers to stop using these medicated articles **in combination** for use in swine. **Existing** stocks of manufactured medicated feed containing this drug combination may be used according to labeled instructions.

If you have additional questions, please contact [AskCVM@fda.hhs.gov](mailto:AskCVM@fda.hhs.gov).

Sincerely,

FDA, Center for Veterinary Medicine



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## Drug Clearances Summary for 2023

Terramycin® 200 for Fish (oxytetracycline) is approved for the control of mortality due to columnaris disease associated with *Flavobacterium columnare* in catfish and freshwater-reared salmonids. The drug is a Type A medicated article used in the manufacture of a Type C medicated feed containing oxytetracycline, which is an antimicrobial.

Along with other approved uses, Terramycin® 200 for Fish is already approved to control mortality in *Oncorhynchus mykiss* due to columnaris disease associated with *Flavobacterium columnare*. *Oncorhynchus mykiss* is a type of freshwater-reared salmonid commonly called rainbow trout. This supplemental approval expands the previous approval to include catfish and all freshwater-reared salmonids.

Below are the updated drug clearances for oxytetracycline in freshwater-reared salmonids and catfish.

2.5 to 3.75 g oxytetracycline / 100 lb of fish/day	<del>Salmonids</del> Freshwater-reared salmonids:	For control of ulcer disease caused by <i>Haemophilus piscium</i> , furunculosis caused by <i>Aeromonas salmonicida</i> , bacterial hemorrhagic septicemia caused by <i>A. hydrophila</i> , and pseudomonas disease
2.5 to 3.75 g oxytetracycline / 100 lb of fish/day	Catfish	For control of bacterial hemorrhagic septicemia caused by <i>A. hydrophila</i> and pseudomonas disease
3.75 g oxytetracycline/100 lb of fish/day	Freshwater-reared salmonids	For control of mortality due to coldwater disease associated with <i>Flavobacterium psychrophilum</i> ; For control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i>
3.75 g oxytetracycline/100 lb of fish/day	Freshwater-reared <del>Oncorhynchus mykiss</del> salmonids weighing up to 55 grams:	For marking the skeletal tissue
3.75 g oxytetracycline/100 lb of fish/day	Catfish	For control of mortality due to columnaris disease associated with <i>Flavobacterium columnare</i>

### Updated Drug Clearance for Bacitracin - Narasin/Nicarbazin combination

NADA	Name	Drugs	Sponsor	Indications
141-529	Pennitracin MD & Maxiban	Bacitracin Narasin/ Nicarbazin	Pharmgate	<b>Broiler chickens</b> For prevention of mortality caused by necrotic enteritis associated with <i>Clostridium perfringens</i> For the prevention of coccidiosis caused by <i>Eimeria necatrix</i> , <i>E. tenella</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mivati</i> , and <i>E. maxima</i> .



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Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096 requested the FDA withdraw approval of the following applications associated with thiabendazole use in animal feed because the following prod-

NADA	Product Name
013-407	Equizole Horse Wormer Top Dress
013-954	Thibenzole 20% Swine Premix
015-875	TBZ 200 Medicated Feed Premix
044-654	Equizole Horse Wormer Pellets

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