

Salinomycin in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(iv) 40 to 60 .....	Bacitracin methylenedisalicylate, 100 to 200.	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , and as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin.	Feed continuously as sole ration. To control necrotic enteritis, start medication at first clinical signs of disease; vary dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton). Do not feed to laying chickens. May be fatal if fed to adult turkeys or to horses. Salinomycin as provided by No. 016592; bacitracin methylenedisalicylate as provided by No. 054771 in §510.600(c) in this chapter.	054771
(v) 40 to 60 .....	Bacitracin zinc, 10 to 50.	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , and for increased rate of weight gain.	Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to layers. May be fatal if accidentally fed to adult turkeys or horses. Bacitracin zinc as provided by No. 054771 in §510.600(c) of this chapter.	016592 054771
(vi) 40 to 60 .....	Bambermycins, 1 to 3.	Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , and <i>E. mivati</i> , and for improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying chickens. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses. Salinomycin and bambermycins as provided by No. 016592 in §510.600(c) in this chapter.	016592

(2) Game birds—

Salinomycin in grams/ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 50 .....	.....	Quail: For the prevention of coccidiosis caused by <i>E. dispersa</i> and <i>E. lettyae</i> .	Feed continuously as sole ration. Not approved for use with pellet binders. Do not feed to laying hens producing eggs for human consumption. May be fatal if accidentally fed to adult turkeys or horses.	.....
(ii) [Reserved] ..	.....	.....	.....	.....

(3) Salinomycin may also be used in combination with:

- (i) Chlortetracycline as in § 558.128.
- (ii) Lincomycin as in § 558.325.
- (iii) Oxytetracycline as in § 558.450.
- (iv) Virginiamycin as in § 558.635.

■ 87. In § 558.625, revise paragraphs (b)(1) through (4) to read as follows:

**§ 558.625 Tylosin.**

\* \* \* \* \*

(b) \* \* \*

(1) No. 016592: Type A medicated articles containing 40 or 100 grams per pound (g/lb).

(2) No. 054771: Type A medicated article containing 40 g/lb.

(3) No. 058198: Type A medicated articles containing 10, 40, or 100 g/lb.

(4) No. 066104: Type A medicated articles containing 20 or 40 g/lb.

\* \* \* \* \*

Dated: March 5, 2019.  
**Lowell J. Schiller,**  
*Acting Associate Commissioner for Policy.*  
 [FR Doc. 2019-04226 Filed 3-12-19; 8:45 am]  
**BILLING CODE 4164-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 520**

[Docket No. FDA-2018-N-0002]

**New Animal Drugs; Withdrawal of Approval of New Animal Drug Application**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notification of withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is withdrawing

approval of a new animal drug application (NADA) and an abbreviated new animal drug application (ANADA) at the sponsors' request because these products are no longer manufactured or marketed.

**DATES:** Withdrawal of approval is effective March 25, 2019.

**FOR FURTHER INFORMATION CONTACT:** Sujaya Dessai, Center for Veterinary Medicine (HFV-212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-5761, [sujaya.dessai@fda.hhs.gov](mailto:sujaya.dessai@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140, has requested that FDA withdraw approval of NADA 140-939 for use of RUMENSIN (monensin) and TYLAN (tylosin phosphate) Type A medicated articles in the manufacture of combination drug Type C medicated cattle feeds because the product is no longer manufactured or marketed.

Also, Sergeant's Pet Care Products, Inc., 10077 S 134th St., Omaha, NE 68138 has requested that FDA withdraw approval of ANADA 200–600 for WORMX (pyrantel pamoate) Flavored Tablets because the product is no longer manufactured or marketed.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with § 514.116 *Notice of withdrawal of approval of application* (21 CFR 514.116), notice is given that approval of NADA 140–939 and ANADA 200–600, and all supplements and amendments thereto, is hereby withdrawn, effective March 25, 2019.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary withdrawal of approval of these applications.

Dated: March 4, 2019.

**Lowell J. Schiller,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 2019–04222 Filed 3–12–19; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF TRANSPORTATION

### Saint Lawrence Seaway Development Corporation

#### 33 CFR Part 401

RIN 2135–AA45

#### Seaway Regulations and Rules: Periodic Update, Various Categories

**AGENCY:** Saint Lawrence Seaway Development Corporation, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Saint Lawrence Seaway Development Corporation (SLSDC) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Regulations and Rules (Practices and Procedures in Canada) in their respective jurisdictions. Under agreement with the SLSMC, the SLSDC is amending the joint regulations by updating the Seaway Regulations and Rules in various categories. The changes update the following sections of the Regulations and Rules: Seaway Navigation; and, Information and Reports. These amendments are merely editorial or for clarification of existing requirements. The joint regulations will become effective in Canada on March 30, 2019. For consistency, because these are joint regulations under international agreement, and to avoid confusion

among users of the Seaway, the SLSDC finds that there is good cause to make the U.S. version of the amendments effective on the same date.

**DATES:** This rule is effective on March 30, 2019.

**ADDRESSES:** *Docket:* For access to the docket to read background documents or comments received, go to <http://www.Regulations.gov>; or in person at the Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

**FOR FURTHER INFORMATION CONTACT:** Carrie Mann Lavigne, Chief Counsel, Saint Lawrence Seaway Development Corporation, 180 Andrews Street, Massena, New York 13662; 315/764–3200.

**SUPPLEMENTARY INFORMATION:** The Saint Lawrence Seaway Development Corporation (SLSDC) and the St. Lawrence Seaway Management Corporation (SLSMC) of Canada, under international agreement, jointly publish and presently administer the St. Lawrence Seaway Regulations and Rules (Practices and Procedures in Canada) in their respective jurisdictions. Under agreement with the SLSMC, the SLSDC is amending the joint regulations by updating the Regulations and Rules in various categories. The changes update the following sections of the Regulations and Rules: Seaway Navigation; and, Information and Reports. These changes are to clarify existing requirements in the regulations.

*Regulatory Notices: Privacy Act:*

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit <http://www.Regulations.gov>.

The joint regulations will become effective in Canada on March 30, 2019.

#### Regulatory Evaluation

This regulation involves a foreign affairs function of the United States and therefore, Executive Order 12866 does not apply and evaluation under the Department of Transportation's Regulatory Policies and Procedures is not required.

#### Regulatory Flexibility Act Determination

I certify that this regulation will not have a significant economic impact on a substantial number of small entities. The St. Lawrence Seaway Regulations and Rules primarily relate to commercial users of the Seaway, the vast majority of who are foreign vessel operators. Therefore, any resulting costs will be borne mostly by foreign vessels.

#### Environmental Impact

This regulation does not require an environmental impact statement under the National Environmental Policy Act (49 U.S.C. 4321, *et seq.*) because it is not a major federal action significantly affecting the quality of the human environment.

#### Federalism

The Corporation has analyzed this rule under the principles and criteria in Executive Order 13132, dated August 4, 1999, and have determined that this proposal does not have sufficient federalism implications to warrant a Federalism Assessment.

#### Unfunded Mandates

The Corporation has analyzed this rule under Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4, 109 Stat. 48) and determined that it does not impose unfunded mandates on State, local, and tribal governments and the private sector requiring a written statement of economic and regulatory alternatives.

#### Paperwork Reduction Act

This regulation has been analyzed under the Paperwork Reduction Act of 1995 and does not contain new or modified information collection requirements subject to the Office of Management and Budget review.

#### List of Subjects in 33 CFR Part 401

Hazardous materials transportation, Navigation (water), Penalties, Radio, Reporting and recordkeeping requirements, Vessels, Waterways.

Accordingly, the Saint Lawrence Seaway Development Corporation is amending 33 CFR part 401 as follows:

### PART 401—SEAWAY REGULATIONS AND RULES

#### Subpart A—Regulations

■ 1. The authority citation for subpart A of part 401 continues to read as follows:

**Authority:** 33 U.S.C. 983(a) and 984(a) (4), as amended; 49 CFR 1.52, unless otherwise noted.