The sponsors requested withdrawal of approval of the NADA's because the drug products are no longer being marketed. This final rule removes 21 CFR 520.704, 522.514, and 522.1880, and amends 21 CFR 522.540 and 522.1720 to reflect the withdrawal of approval of these NADA's.

In addition, 21 CFR 510.600(c) is amended to remove the entries for the three sponsors from the list of approved drug sponsors because they no longer hold any approved NADA's.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520 and 522

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entries for ''Akorn, Inc.,'' ''Parke-Davis, Division of Warner-Lambert Co.,'' and ''Veterinary Research and Development, Inc.'' and in the table in paragraph (c)(2) by removing the entries for ''000071,'' ''017478,'' and ''057428.''

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.704 [Removed]

4. Section 520.704 *Diphenylhydantoin sodium capsules* is removed.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.514 [Removed]

6. Section 522.514 *Copper disodium edetate injection* is removed.

§ 522.540 [Amended]

7. Section 522.540 *Dexamethasone injection* is amended by removing paragraph (d)(2)(ii) and by redesignating paragraph (d)(2)(iii) as paragraph (d)(2)(ii).

§ 522.1720 [Amended]

8. Section 522.1720 *Phenylbutazone injection* is amended in paragraph (b)(1) by removing the phrase ''000031, 017220, 015579, and 017478'' and adding in its place ''000031, 017220, and 015579''.

§ 522.1880 [Removed]

9. Section 522.1880 *Sterile prednisolone suspension* is removed.

Dated: December 4, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–30123 Filed 12–11–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, Division of Eli Lilly and Co. The supplemental NADA provides for use of an approved monensin Type A medicated article to make a revised formulation of a monensin Type C medicated feed/free-choice mineral granule fed to pasture cattle for increased rate of weight gain.

EFFECTIVE DATE: December 12, 1995.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–2701.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 95–735, which provides for use of 80 grams(g) per pound monensin Type A articles to make a monensin Type C medicated feed/free-choice mineral granule containing 1,620 g per ton monensin. The Type C feed/free-choice mineral granules are fed to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) for increased rate of weight gain. The supplemental NADA provides for a revised formulation Type C free-choice mineral granule. The revised formulation does not affect the safety or effectiveness data and information upon which the application is approved. The supplemental NADA is approved as of December 12, 1995, and the regulations are amended in 21 CFR 558.355 by adding new paragraph (f)(3)(x) to reflect the approval.

Use of a Type A medicated article to make a free-choice Type C medicated feed/ mineral granule requires an approved Form FDA 1900 as in 21 CFR 510.455.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval does not qualify for marketing exclusivity because the supplement does not contain reports of new clinical or field investigations or new human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

A freedom of information summary for this approval is not required because it involves approval of a revised formulation which does not affect the basis of approval of the product. A summary of the data and information submitted to support the original approval may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(iii) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.355 is amended by adding new paragraph (f)(3)(x) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(x) *Amount per ton.* Monensin, 1,620 grams as monensin sodium (810 milligrams per pound).

(a) Indications for use. For increased rate of weight gain.

(b) Specifications. Use as free-choice Type C medicated feed formulated as mineral granules as follows:

Ingredient	Percent	International feed no.
Monocalcium phosphate (21% phosphorus, 15% calcium)	29.49	6–01–080
Sodium chloride (salt)	24.25	6–04–152
Dried cane molasses	20.0	4–04–152
Ground limestone (33% calcium)	13.75	6–02–632
Cane molasses	3.0	4–04–696
Processed grain by-products (as approved by AAFCO)	5.0	
Vitamin/trace mineral premix[1]	2.5	
Monensin Type A article, 80 grams per pound	1.01	
Antidusting oil	1.0	

[1]Content of the vitamin/trace mineral premix may be varied. However, they should be comparable to those used for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. The amount of selenium and ethylenediamine dihydroiodide (EDDI) must comply with the published requirements. (For selenium see 21 CFR 573.920; for EDDI see 51 FR 11483 (April 3, 1986).)

(c) Limitations. Medicated mineral granules to be fed free-choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) weighing more than 400 pounds. Feed continuously on a free-choice basis at the rate of 50 to 200 milligrams per head per day. During the first 5 days of feeding, cattle should receive no more than 100 milligrams per day. Do not feed additional salt or minerals. Do not mix with grain or other feeds. Monensin is toxic to cattle when consumed at higher than approved levels. Stressed and/or water deprived cattle should be adapted to the pasture and to unmedicated mineral supplement before using this product. Do not feed to lactating dairy cattle. Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. The product's effectiveness in cull cows and bulls has not been established. Each use of this free-choice Type C feed must be the subject of an approved medicated feed application (MFA or Form FDA 1900) or supplemental MFA as required by § 510.455 of this chapter.

* * * * *

Dated: November 22, 1995.

Nicholas E. Weber,

Director, Division of Chemistry, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95–30124 Filed 12–11–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 162

[CGD–94–026]

RIN 2115–AE78

Inland Waterways Navigation Regulations; Wrangell Narrows, AK

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is increasing the maximum width allowable for single barge tows transiting Wrangell Narrows, Alaska. In accordance with the goals of the Presidential Regulatory Reinvention Initiative, this action is being taken to better meet maritime industry needs in Southeast Alaska. The current size restriction for single barge tows in Wrangell Narrows is 80 feet in width overall. An increase in the maximum barge width to 100 feet in width overall will allow barge operators to carry more cargo on each barge to meet the increasing needs of their Alaskan consumers. Increasing the restriction to 100 feet in width overall will have no adverse effects on navigation and marine safety in Wrangell Narrows.

EFFECTIVE DATE: January 11, 1996.

ADDRESSES: Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at the office of the Executive Secretary, Marine Safety Council (G–LRA/3406) (CGD 94–026), U.S. Coast Guard Headquarters, 2100 Second Street SW., Washington, DC 20593–0001, or may be delivered to room 3406 at the above address between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (202) 267–1477.

FOR FURTHER INFORMATION CONTACT: Diane Schneider Appleby, Project Manager, (202) 267–0352.

SUPPLEMENTARY INFORMATION:

Regulatory History

On September 15, 1995, the Coast Guard published a notice of proposed rulemaking entitled Inland Waterways Navigation Regulations: Wrangell Narrows, Alaska in the Federal Register (60 FR 179). The Coast Guard received four comments on the proposal. No public meeting was requested, and none was held.

Background and Purpose

Wrangell Narrows is a navigable waterway of the United States located in Southeast Alaska. It connects Frederick Sound on the north end to Sumner Strait on the south. It is approximately 24 miles long and narrows to 300 feet in five places. The longest of the 300 foot wide sections is approximately 5.5 nautical miles in length. The other four sections vary from approximately 600 yards to approximately 1.3 nautical miles in length.

The primary users of Wrangell Narrows are passenger ferries, log carriers, pleasure craft and container barges. Container barges are used to transport consumer goods throughout South East Alaska which is vital to the every day life of Alaskan citizens.

The increased demand for consumer goods in Southeast Alaska has created a greater demand on providers of these goods. The current regulations limit the width of single barge tows allowed to