reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, 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)(i) 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 520

–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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

–1. 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).

§ 520.2220a [Amended]

–2. Section 520.2220a *Sulfadimethoxine oral solution and soluble powder* is amended in paragraph (b) by removing ''000069, 054273, and 057561'' and adding in its place ''000069, 054273, 057561, and 059130''.

Dated: April 8, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–11084 Filed 4–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Amikacin Sulfate Injection

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of amikacin sulfate injection for the treatment of the following conditions in dogs: genitourinary tract infections (cystitis) caused by susceptible strains of *Escherichia coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli.*

EFFECTIVE DATE: April 30, 1997.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, has filed ANADA 200–178, which provides for the use of amikacin sulfate injection for the treatment of the following conditions in dogs: genitourinary tract infections (cystitis) caused by susceptible strains of *E. coli* and *Proteus* spp. and skin and soft tissue infections caused by susceptible strains of *Pseudomonas* spp. and *E. coli.*

–The ANADA is approved as a generic copy of Fort Dodge Laboratories, Inc., NADA 127–892, Amiglyde-V® Injection (amikacin sulfate 50 milligrams per milliliter). ANADA 200–178 is approved as of March 14, 1997, and the regulations are amended in 21 CFR 522.56 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, 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)(i) 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 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 part 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

––1. 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).

§ 522.56 [Amended]

–2. Section 522.56 *Amikacin sulfate injection* is amended in paragraph (b) by removing ''000856'' and adding in its place ''Nos. 000856 and 059130''.

Dated: April 7, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–11085 Filed 4–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Amikacin Sulfate Solution

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for intrauterine use of amikacin sulfate solution in horses for the treatment of uterine infections.

EFFECTIVE DATE: April 30, 1997.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, has filed ANADA 200–181, which provides for intrauterine use of amikacin sulfate solution for the treatment of uterine infections (endometritis, metritis, and pyometra) in mares, when caused by susceptible

organisms including *Escherichia coli, Pseudomonas* spp., and *Klebsiella* spp.

–The ANADA is approved as a generic copy of Fort Dodge Laboratories' NADA 127–892, Amiglyde-V® (amikacin sulfate solution). ANADA 200–181 is approved as of March 18, 1997, and the regulations are amended in 21 CFR 529.50 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, 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)(i) 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 529

–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 part 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

–1. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.50 [Amended]

–2. Section 529.50 *Amikacin sulfate intrauterine solution* is amended in paragraph (b) by adding the phrase ''and 059130'' after ''000856''.

Dated: April 7, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–11080 Filed 4–29–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD08–97–008]

RIN 2115–AE84

Amendment to Regulated Navigation Area Regulations; Lower Mississippi River

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: On March 18, 1997, the Coast Guard established a temporary regulated navigation area affecting the operation of downbound tows in the Lower Mississippi River from mile 437 at Vicksburg, MS to mile 88 above Head of Passes. These regulations were subsequently amended on March 21, March 28, April 4 and April 15. The amendments added additional operating requirements for vessels of 1600 gross tons or greater, increased the operating limitations on tank barges and ships carrying hazardous chemicals and gasses, and extended the RNA to the boundary of the territorial sea at the approaches to Southwest Pass. On April 15, in response to moderating river conditions, the regulations were relaxed to permit tows of up to 30 barges to operate when being pushed by tow boats of 9,000 brake horsepower or greater.

The threat posed by high water and currents on the Lower Mississippi River has continued to abate. The water level at the Baton Rouge Gauge crested on March 26 at 43.8 feet. By April 14, it had fallen to 39.6 feet and has continued to fall. It is projected to reach 37.0 feet on April 20, 1997. Similarly, the river current at the Baton Rouge Gauge had fallen from a high of approximately 9 miles per hour on March 26 to 7.3 miles per hour as of 14 April. On April 20, it is projected to be 6 miles per hour. After consultation with marine industry groups, state government agencies, and river pilots organizations, the district commander has decided to further amend the regulations. This amendment will permit the tow boat and barge limitations and chemical and gas ship operating restrictions to expire as scheduled at 12 p.m. on April 20, 1997, while maintaining the regulations affecting self-propelled vessels of 1,600 gross tons or greater.

The regulated navigation area is needed to protect vessels, bridges, shore-side facilities and the public from a safety hazard created by deep draft vessel operations along the Lower Mississippi River during the periods of high water in late spring and early summer. Self-propelled vessels of 1600 or more gross tons are prohibited from operating in this area unless they are in compliance with this regulation.

DATES: This amended regulation is effective at 12 p.m. on April 20, 1997 and terminates at 12 p.m. on July 1, 1997.

FOR FURTHER INFORMATION CONTACT: CDR Harvey R. Dexter, Marine Safety Division, USCG Eighth District at New Orleans, LA (504) 589–6271.

SUPPLEMENTARY INFORMATION:

Background and Purpose

On March 18, 1997 (62 FR 14637, March 27, 1997), the Coast Guard established a temporary regulated navigation area affecting the operation of downbound tows in the Lower Mississippi River from mile 437 at Vicksburg, MS to mile 88 above Head of Passes. On March 21, 1997 (62 FR 15398, April 1, 1997), the Coast Guard amended the temporary regulated navigation area by extending the southern limit of the regulated navigation area to the boundary of the territorial sea at the approaches to Southwest Pass and included operating requirements affecting the operation of self-propelled vessels of 1600 gross tons or greater. Increasing high water conditions caused the Coast Guard to amend this regulation for a second time on March 28, 1997 (62 FR 16081, April 4, 1997) to establish additional safety measures applicable to U.S. flagged and foreign-flagged vessels authorized to carry cargoes listed under Title 46, Code of Federal Regulations Part 151 (chemical barges) and Parts 153–154 (chemical and gas ships).

Although Lower Mississippi River floodwater levels had receded somewhat by April 4, river current remained at a record high level at that time. The loss of control of a tow as it entered the Mississippi River from the Port Allen lock and several near-misses involving tows longer than 600 feet exiting locks into the Mississippi River evidenced the need to further limit the length of tows. It was determined that, by limiting the maximum length of tows during the critical period when they were entering or exiting locks along the Mississippi River to or from the relatively still water of a lock forebay, towboats would be able to exercise greater control of the tow during that critical period. Therefore, on April 4, 1997 (62 FR 17704, April 11, 1997) the district commander amended this regulation for the third time to prohibit