

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 171

Administrative practice and procedure, Food additives.

21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

21 CFR Part 180

Food additives.

21 CFR Part 184

Food additives.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 71, 73, 74, 170, 171, 172, 180, and 184 are amended as follows:

PART 71—COLOR ADDITIVE PETITIONS

■ 1. The authority citation for 21 CFR part 71 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 351, 355, 360, 360b–360f, 360h–360j, 361, 371, 379e, 381; 42 U.S.C. 216, 262.

§ 71.1 [Amended]

■ 2. Section 71.1 is amended in paragraph (c) by removing “Office of Premarket Approval (HFS–200),” and by adding in its place “Office of Food Additive Safety (HFS–200).”.

PART 73—LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

■ 3. The authority citation for 21 CFR part 73 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 73.1128 [Redesignated]

■ 4. Section 73.1128 is redesignated as § 73.1350.

§ 73.2396 [Amended]

■ 5. Section 73.2396 is amended in paragraph (d)(1) by removing “170.25” and by adding in its place “§ 70.25”.

PART 74—LISTING OF COLOR ADDITIVES SUBJECT TO CERTIFICATION

■ 6. The authority citation for 21 CFR part 74 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 74.2052 [Amended]

■ 7. Section 74.2052 is amended in paragraph (b)(9) by removing “Benzo[e]pyrene” and by adding in its place “Benzo[a]pyrene”.

PART 170—FOOD ADDITIVES

■ 8. The authority citation for 21 CFR part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

§ 170.45 [Amended]

■ 9. Section 170.45 is amended by removing the phrase “as stated in § 250.203 of this chapter” and by removing “§ 103.35(d)” and adding in its place “§ 165.110(d)”.

PART 171—FOOD ADDITIVE PETITIONS

■ 10. The authority citation for 21 CFR part 171 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 171.1 [Amended]

■ 11. Section 171.1 is amended in paragraph (c) by removing “Petitions Control Branch Food and Drug Administration Department of Health and Human Services, Washington, DC 20204.” and by adding in its place “Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740.”

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

■ 12. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

§ 172.510 [Amended]

■ 13. Section 172.510 is amended in paragraph (b) by removing “concretes” and adding in its place “concentrates”.

PART 180—FOOD ADDITIVES PERMITTED IN FOOD OR IN CONTACT WITH FOOD ON AN INTERIM BASIS PENDING ADDITIONAL STUDY

■ 14. The authority citation for 21 CFR part 180 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 371; 42 U.S.C. 241.

§ 180.37 [Amended]

■ 15. Section 180.37 is amended in paragraph (f)(2)(iii) by removing “or § 100.130”.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 16. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

§ 184.1769a [Amended]

■ 17. Section 184.1769a is amended in paragraph (c)(2) by removing “§ 103.35” and adding in its place “§ 165.110”.

Dated: February 28, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–4104 Filed 3–7–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 558****New Animal Drugs for Use in Animal Feeds; Melengestrol, Ractopamine, and 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 an abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The ANADA provides for use of single-ingredient Type A medicated articles containing melengestrol, ractopamine, and monensin to make three-way combination drug Type C medicated feeds for heifers fed in confinement for slaughter.

DATES: This rule is effective March 8, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed ANADA 200–448 for use of HEIFERMAX 500 (melengestrol acetate) Liquid Premix, OPTAFLEXX (ractopamine hydrochloride), and RUMENSIN (monensin sodium) single-ingredient Type A medicated article to make dry and liquid, three-way combination drug Type C medicated feeds for heifers fed

in confinement for slaughter. Ivy Laboratories' ANADA 200-448 is approved as a generic copy of Elanco Animal Health's NADA 141-234 for combination feed use of MGA 500, OPTAFLEXX, and RUMENSIN. The application is approved as of January 29, 2007, and the regulations are amended in 21 CFR 558.500 to 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 21 CFR 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 Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ 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 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: 21 U.S.C. 360b, 371.

§ 558.500 [Amended]

■ 2. In the table in paragraph (e)(2)(viii) of § 558.500, in the "Limitations" column remove "No. 000009" and add in its place "Nos. 000009 or 021641", and in the "Sponsor" column add in numerical sequence "021641".

Dated: February 20, 2007.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. E7-4100 Filed 3-7-07; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD01-07-014]

Drawbridge Operation Regulations; Connecticut River, East Haddam, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Route 82 Bridge across the Connecticut River, mile 16.8, at East Haddam, Connecticut. Under this temporary deviation, the bridge may remain in the closed position for two nights from 8:30 p.m. to 4:30 a.m. between March 19, 2007 and March 23, 2007. The exact two closure dates will be determined based upon favorable weather necessary to perform the scheduled repairs. This deviation is necessary to facilitate scheduled bridge maintenance.

DATES: This deviation is effective from March 19, 2007 through March 23, 2007.

ADDRESSES: Materials referred to in this document are available for inspection or copying at the First Coast Guard District, Bridge Branch Office, One South Street, New York, New York 10004, between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays. The telephone number is (212) 668-7165. The First Coast Guard District Bridge Branch Office maintains the public docket for this temporary deviation.

FOR FURTHER INFORMATION CONTACT: Judy Leung-Yee, Project Officer, First Coast Guard District, at (212) 668-7195.

SUPPLEMENTARY INFORMATION: The Route 82 Bridge, across the Connecticut River, mile 16.8, at East Haddam, Connecticut, has a vertical clearance in the closed position of 22 feet at mean high water and 25 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.205(c).

The owner of the bridge, Connecticut Department of Transportation, requested a temporary deviation to facilitate scheduled bridge maintenance, drive gear repairs. The bridge will not be able to open while the bridge maintenance is underway.

Under this temporary deviation the Route 82 Bridge may remain in the closed position between 8:30 p.m. and 4:30 a.m., for two nights, between

March 19, 2007 and March 23, 2007. The exact two closure dates will be selected depending upon favorable weather necessary to perform the required repairs.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible.

This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: February 26, 2007.

Gary Kassof,

Bridge Program Manager, First Coast Guard District.

[FR Doc. E7-4112 Filed 3-7-07; 8:45 am]

BILLING CODE 4910-15-U

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD09-07-002]

RIN 1625-AA00

Safety Zones; Annual Fireworks Events in the Captain of the Port Milwaukee Zone

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the Manitowoc St. Patrick's Day Fireworks safety zone on the Manitowoc River on March 17, 2007 from 5:30 p.m. through 7 p.m. This action is necessary to protect the public from the hazards associated with fireworks displays. During the enforcement period no person or vessel may enter the safety zone without the permission of the Captain of the Port or his designated representative.

DATES: Effective from 5:30 p.m. (local) through 7 p.m. (local) on March 17, 2007.

FOR FURTHER INFORMATION CONTACT: CWO Brad Hinken, Prevention Department, Coast Guard Sector Lake Michigan, 2420 South Lincoln Memorial Drive, Milwaukee, WI at (414) 747-7154.

SUPPLEMENTARY INFORMATION: We are publishing this document to provide notice that under the provisions of 33 CFR 165.909(a)(11), the St. Patrick's Day Fireworks safety zone on the Manitowoc River will be enforced on March 17, 2007 from 5:30 p.m. through 7 p.m. The safety zone consists of all waters and adjacent shoreline across from the