

# Rules and Regulations

Federal Register

Vol. 68, No. 34

Thursday, February 20, 2003

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline 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 a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for the administration of an oxytetracycline injectable solution to lactating dairy cattle.

**DATES:** This rule is effective February 20, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Phoenix Scientific, Inc., 3915 South 48th Street Terr., St. Joseph, MO 64506-0457, filed a supplement to approved ANADA 200-123 that provides for the use of MAXIM-200 (oxytetracycline) Injection as a treatment for various bacterial diseases in cattle and swine. The supplemental ANADA provides for the administration of this oxytetracycline injectable solution to lactating dairy cattle. The supplemental ANADA is approved as of November 19, 2002, and the regulations are amended in 21 CFR 522.1660 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 supplemental application may be seen in the Dockets Management Branch (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)(1) 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 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:** 21 U.S.C. 360b.

#### § 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in paragraph (d)(1)(iii) in the eighth sentence by removing "sponsors 059130 and 061623"; and adding in its place "sponsor 061623"; and in the ninth sentence by removing "and 055529" and adding in its place "055529, and 059130".

Dated: January 21, 2003.

**Steven F. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*  
[FR Doc. 03-3434 Filed 2-19-03; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 021212307-2307-01; I.D. 021303C]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Groundfish by Vessels Using Non-Pelagic Trawl Gear in the Red King Crab Savings Subarea

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

**ACTION:** Closure.

**SUMMARY:** NMFS is closing directed fishing for groundfish with non-pelagic trawl gear in the red king crab savings subarea (RKCSS) of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the interim 2003 red king crab prohibited species catch (PSC) limit that is specified for the RKCSS of the BSAI.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), February 14, 2003, until superseded by the notice of Final 2003 Harvest Specifications of Groundfish for the BSAI, which will be published in the **Federal Register**.

#### FOR FURTHER INFORMATION CONTACT:

Mary Furuness, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the BSAI exclusive economic zone according to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and CFR part 679.

The interim 2003 red king crab PSC limit that is specified for the RKCSS of the BSAI is 5,231 animals as established by the interim 2003 harvest specifications for Groundfish of the BSAI (67 FR 78739, December 26, 2002).

In accordance with § 679.21(e)(7)(ii)(B), the Administrator, Alaska Region, NMFS, has determined that the amount of the interim 2003 red

king crab PSC limit specified for the RKCSS will be caught. Consequently, NMFS is closing the RKCSS to directed fishing for groundfish with non-pelagic trawl gear.

#### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is contrary to the public interest. This requirement is contrary to the public interest as it would delay the closure of the fishery, lead to exceeding the interim 2003 red king crab PSC limit, and therefore reduce the public's ability to use and enjoy the fishery resource.

The Assistant Administrator for Fisheries, NOAA, also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.21 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: February 14, 2003.

**Richard W. Surdi,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 03-4103 Filed 2-14-03; 2:17 pm]

**BILLING CODE 3510-12-S**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

#### 50 CFR Part 679

[Docket No. 021212306-2306-01; I.D. 021403C]

#### Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Vessels Catching Pacific Cod for Processing by the Inshore Component in the Western Regulatory Area of the Gulf of Alaska

**AGENCY:** National Marine Fisheries Service (NMFS), National Oceanic and

Atmospheric Administration (NOAA), Commerce.

**ACTION:** Closure.

**SUMMARY:** NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Western Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the interim 2003 total allowable catch (TAC) of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component of the Western Regulatory Area of the GOA.

**DATES:** Effective 1200 hrs, Alaska local time (A.l.t.), February 17, 2003, until superseded by the notice of Final 2003 Harvest Specifications of Groundfish for the GOA, which will be published in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Mary Furuness, 907-586-7228.

**SUPPLEMENTARY INFORMATION:** NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The interim 2003 TAC of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component in the Western Regulatory Area of the GOA is 7,979 metric tons (mt) as established by the interim 2003 harvest specifications of groundfish for the GOA (67 FR 78733, December 26, 2002).

In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the interim 2003 TAC of Pacific cod apportioned to vessels catching Pacific cod for processing by the inshore component of the Western Regulatory Area of the GOA will be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 7,929 mt, and is setting aside the remaining 50 mt as bycatch to support other anticipated groundfish fisheries. In accordance with

§ 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance will soon be reached. Consequently, NMFS is prohibiting directed fishing for Pacific cod by vessels catching Pacific cod for processing by the inshore component in the Western Regulatory Area of the GOA.

Maximum retainable bycatch amounts may be found in the regulations at § 679.20(e) and (f).

#### Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA, finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is contrary to the public interest. This requirement is contrary to the public interest as it would delay the closure of the fishery, lead to exceeding the interim TAC, and therefore reduce the public's ability to use and enjoy the fishery resource.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

**Authority:** 16 U.S.C. 1801 *et seq.*

Dated: February 14, 2003.

**Richard W. Surdi,**

*Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.*

[FR Doc. 03-4104 Filed 2-14-03; 2:17 pm]

**BILLING CODE 3510-22-S**