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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]

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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