(B) *Notice of adverse determination.* A notice of adverse determination will state the action being taken, specific grounds for the determination, and advise the gauger that it may administratively appeal the adverse determination to the Assistant Commissioner, in accordance with paragraph (i)(3) of this section. The gauger may not continue to perform any Customs-approved functions upon receiving a notice of adverse determination that its approval has been suspended or revoked.

(3) *Appeal.* A Customs-approved gauger receiving an adverse determination from the Executive Director that its approval has been suspended or revoked, and/or that it has been assessed a monetary penalty may file an administrative appeal to the Assistant Commissioner within 30 calendar days of the notice of determination. If the gauger does not file an administrative appeal, the determination made by the Executive Director in paragraph (i)(2) of this section will become a final agency decision which will be communicated to the gauger by a notice of final action issued 30 days after the notice of determination. If the gauger does file a timely appeal, then the Assistant Commissioner, within 30 calendar days of receipt of the appeal, will make a final agency decision regarding the gauger's suspension or revocation of approval, and/or assessment of a monetary penalty. If the final agency decision is adverse to the gauger, the decision will be communicated to the gauger by a notice of final action. Any adverse final agency decision will be communicated to the public by a publication in the **Federal Register** and Customs Bulletin, giving the effective date, duration, and scope of the decision. Any notice of adverse final action communicated to a gauger will state the action taken, the specific grounds for the action, and advise the gauger that it may choose to:

(i) If suspended or revoked, submit a new application to the Executive Director after waiting 90 days from the date of the Executive Director's notice of final action; or

(ii) File an action with the Court of International Trade, pursuant to chapter 169 of title 28, United States Code, within 60 days after issuance of the Executive Director's notice of final action.

§ 151.14 [Amended]

4. In § 151.14, the first sentence is amended by removing the words ''`sediment and water' characteristic as set out in § 151.13(a)(2)'' and adding, in its place, the words ''analysis method for crude petroleum contained in ASTM D96 or other approved analysis method''.

PART 178—APPROVAL OF INFORMATION COLLECTION REQUIREMENTS

1. The authority citation for part 178 continues to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 1624; 44 U.S.C. 3501 *et seq.*

2. Section 178.2 is amended by removing the entry for § 151.13(i), and adding, in its place, separate listings for §§ 151.12(f) and 151.13(d) to read as follows:

§ 178.2 Listing of OMB control numbers.

19 CFR section	Description	OMB control no.
*	* * * * * *	*
§ 151.12(f)	Application and other documents pertaining to accreditation of commercial laboratories.	1515–0155
§ 151.13(d)	Application and other documents pertaining to approval of commercial gaugers	1515–0155

Raymond W. Kelly,

Commissioner of Customs.

Approved: July 30, 1999

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 99–23033 Filed 9–3–99; 8:45 am]

BILLING CODE 4820–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

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 an additional package size of oxytetracycline hydrochloride soluble powder to be used to make a medicated drinking water for chickens, turkeys, cattle, swine, and sheep for control and/or treatment of various bacterial diseases.

EFFECTIVE DATE: September 7, 1999.

FOR FURTHER INFORMATION CONTACT: William G. Marnane, Center for Veterinary Medicine (HFV–140), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6966.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed supplemental ANADA 200–146 that provides for use of 6.4 ounce (181.5 gram (g)) packet of oxytetracycline hydrochloride soluble powder (10 g oxytetracycline hydrochloride per packet) for use in making medicated drinking water for chickens, turkeys, cattle, swine, and sheep for treatment and/or control of various bacterial diseases. The supplemental ANADA is approved as of July 26, 1999, and the regulations are amended in 21 CFR 520.1660d(a)(7) to reflect the approval.

This supplemental ANADA concerns an additional packet size of product to be used as currently approved. The safety and effectiveness of the product does not change. A freedom of information summary as described in 21 CFR part 20 and 514.11(e)(2)(ii) is not required.

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 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: 21 U.S.C. 360b.

§ 520.1660d [Amended]

2. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraphs (a)(1) and (a)(2) by removing the semicolons at the end of the paragraphs and by adding periods in their places, and in paragraph (a)(7) by adding at the beginning of the first parenthetical phrase the words ''packet: 6.4 oz.;''.

Dated: August 24, 1999.

Claire M. Lathers,

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

[FR Doc. 99–23131 Filed 9–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Chorionic Gonadotropin

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 Intervet, Inc. The supplemental NADA provides for intramuscular use of chorionic gonadotropin, a freeze-dried powder reconstituted for intramuscular injection in male and female brood finfish as an aid in improving spawning function. The regulations are also amended to establish an acceptable daily intake (ADI) for total gonadotropins.

EFFECTIVE DATE: September 7, 1999.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7571.

SUPPLEMENTARY INFORMATION: Intervet, Inc., 405 State St., P.O. Box 318, Millsboro, DE 19966–0318, filed supplemental NADA 140–927 that provides for use of Chorulon® (chorionic gonadotropin) freeze-dried powder, reconstituted for intramuscular injection in male and female brood finfish as an aid in improving spawning function. The supplemental NADA is approved as of August 6, 1999, and § 522.1081 (21 CFR 522.1081) is amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In addition, data in the supplemental NADA were evaluated to establish an ADI for total gonadotropins. The regulations are amended in part 556 (21 CFR part 556) by adding § 556.304 to provide an ADI for total gonadotropins and to provide that a tolerance for residues of gonadotropins in edible tissues of treated animals is not required. Also, § 522.1081 is amended to add paragraphs referencing related tolerances.

In addition, FDA is removing the footnote in § 522.1081(a)(3). This regulation was footnoted to reflect those conditions of use that were subject to review under the National Academy of Sciences/National Research Council (NAS/NRC) Drug Efficacy Study Implementation (DESI) program and FDA's conclusions based on that review. With the enactment of the Generic Animal Drug and Patent Term Restoration Act of 1986, use of NAS/NRC DESI reviews to support approval of new animal drugs became obsolete.

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, 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(c) 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.

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 for food-producing animals qualifies for 3 years of marketing exclusivity beginning August 6, 1999, because the supplement contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies to use of chorionic gonadotropin freeze-dried powder, reconstituted for intramuscular injection in male and female brood finfish as an aid in improving spawning function.

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

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 522 and 556 are 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.

2. Section 522.1081 is amended by adding after the word ''intrafollicularly'' the phrase ''in cattle'' in paragraphs (a)(2)(i) and (a)(2)(ii), by adding after the word ''intramuscularly'' the phrase ''in cattle and finfish'' in paragraph (a)(2)(iii), by redesignating paragraph (a)(3) as paragraph (a)(4), by adding new paragraph (a)(3), by revising the heading and by removing the footnote of newly redesignated paragraph (a)(4), by revising newly redesignated paragraph (a)(4)(i), by adding paragraph (a)(5), by redesignating paragraph (b)(3) as paragraph (b)(4), by adding new paragraph (b)(3), by revising the heading of newly redesignated paragraph (b)(4), by removing ''ovualtions'' and adding in its place ''ovulations'' in newly redesignated paragraph (b)(4)(iii) to read as follows:

§ 522.1081 Chorionic gonadotropin for injection; chorionic gonadotropin suspension.

(a) * * *

(3) *Related tolerances.* See § 556.304 of this chapter.