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.

(4) *Conditions of use in cattle*—(i) *Amount.* 10,000 USP units as a single, deep intramuscular injection; 500 to 2,500 USP units for intrafollicular injection; 2,500 to 5,000 USP units intravenously.

* * * * *

(5) *Conditions of use in finfish*—(i) *Amount.* 50 to 510 I.U. per pound of body weight for males, 67 to 1816 I.U. per pound of body weight for females, by intramuscular injection.

(ii) *Indications for use.* An aid in improving spawning function in male and female brood finfish.

(iii) *Limitations.* May administer up to three doses. The total dose administered per fish (all injections combined) should not exceed 25,000 I.U. chorionic gonadotropin (25 milliliters) in fish intended for human consumption. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(b) * * *

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

(4) *Conditions of use in heifers* * * * * * * * * *

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.304 is added to subpart B to read as follows:

§ 556.304 Gonadotropin.

(a) *Acceptable daily intake (ADI).* The ADI for residues of total gonadotropins (human chorionic gonadotropin and pregnant mare serum gonadotropin) is 42.25 I.U. per kilogram of body weight per day.

(b) *Tolerances.* A tolerance for residues of gonadotropin in uncooked edible tissues of cattle or of fish is not required.

Dated: August 24, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–23132 Filed 9–3–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8838]

RIN 1545–AU45

Inflation-Indexed Debt Instruments

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the federal income tax treatment of inflation-indexed debt instruments, including Treasury Inflation-Indexed Securities. The regulations in this document provide needed guidance to holders and issuers of inflation-indexed debt instruments.

EFFECTIVE DATE: The regulations are effective September 7, 1999.

FOR FURTHER INFORMATION CONTACT: Helen Vanek-Bigelow or William E. Blanchard, (202) 622–3950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On January 6, 1997, temporary regulations (TD 8709 [1997–1 C.B. 167]) relating to the federal income tax treatment of inflation-indexed debt instruments under sections 1275 and 1286 of the Internal Revenue Code (Code) were published in the **Federal Register** (62 FR 615). A notice of proposed rulemaking (REG–242996–96 [1997–1 C.B. 784]) cross-referencing the temporary regulations was published in the **Federal Register** for the same day (62 FR 694). A public hearing was held on April 30, 1997. However, no one requested to speak at the hearing.

No written comments responding to the notice were received. Therefore, the proposed regulations under sections 1275 and 1286 are adopted by this Treasury decision with no changes, and the corresponding temporary regulations are redesignated as final regulations.

Explanation of Provisions

The following is a general explanation of the provisions in the final regulations, which are the same as the provisions in the temporary regulations.

A. In General

The final regulations provide rules for the treatment of certain debt instruments that are indexed for inflation and deflation, including Treasury Inflation-Indexed Securities. The final regulations generally require holders and issuers of inflation-indexed debt instruments to account for interest and original issue discount (OID) using constant yield principles. In addition, the final regulations generally require holders and issuers of inflation-indexed debt instruments to account for inflation and deflation by making current adjustments to their OID accruals.

B. Applicability

The final regulations apply to inflation-indexed debt instruments. In general, an inflation-indexed debt instrument is a debt instrument that (1) is issued for cash, (2) is indexed for inflation and deflation (as described below), and (3) is not otherwise a contingent payment debt instrument. The final regulations do not apply, however, to certain debt instruments, such as debt instruments issued by qualified state tuition programs.

C. Indexing Methodology

A debt instrument is considered indexed for inflation and deflation if the payments on the instrument are indexed by reference to the changes in the values of a general price or wage index over the term of the instrument. Specifically, the amount of each payment on an inflation-indexed debt instrument must equal the product of (1) the amount of the payment that would be payable on the instrument (determined as if there were no inflation or deflation over the term of the instrument) and (2) the ratio of the value of the reference index for the payment date to the value of the reference index for the issue date.

The reference index for a debt instrument is the mechanism for measuring inflation and deflation over the term of the instrument. This mechanism associates the value of a single qualified inflation index for a particular month with a specified day of a succeeding month. For example, under the terms of the Treasury Inflation-Indexed Securities, the reference index for the first day of a month is the value of a qualified inflation index for the third preceding month. The reference index must be reset once a month to the current value of a qualified inflation index. Between reset dates, the value of the reference index is determined through straight-line interpolation.

A qualified inflation index is a general price or wage index that is updated and published at least monthly by an agency of the United States Government. A general price or wage index is an index that measures price or wage changes in the economy as a whole. An index is not general if it only