

# Rules and Regulations

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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.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Sulfachlorpyridazine 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 new animal drug application (NADA) filed by Fort Dodge Animal Health, A Division of Wyeth Holdings Corp. The supplemental NADA provides for a revised food safety warning statement for oral use of sulfachlorpyridazine in the milk or milk replacer of ruminating calves.

**DATES:** This rule is effective June 24, 2008.

**FOR FURTHER INFORMATION CONTACT:** Cindy L. Burnsteel, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8341, e-mail: [cindy.burnsteel@fda.hhs.gov](mailto:cindy.burnsteel@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Fort Dodge Animal Health, A Division of Wyeth Holdings Corp., P.O. Box 1339, Fort Dodge, IA 50501, filed a supplement to NADA 33-373 for VETISULID (sulfachlorpyridazine sodium) Powder, approved for oral use in calves and swine for the treatment of diarrhea caused or complicated by *Escherichia coli* (colibacillosis). The supplemental NADA provides for a revised food safety warning statement for oral use of sulfachlorpyridazine in the milk or milk replacer of ruminating calves. The supplemental application is

approved as of May 19, 2008, and the regulations are amended in 21 CFR 520.2200b to reflect the approval and a current format.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary 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.

■ 2. Revise § 520.2200b to read as follows:

#### § 520.2200b Sulfachlorpyridazine powder.

(a) *Specifications.* Sodium sulfachlorpyridazine powder.

(b) *Sponsor.* See No. 053501 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.630 of this chapter.

(d) *Conditions of use.* It is used as follows:

(i) *Calves*—(i) *Amount.* Administer 30 to 45 milligrams per pound (mg/lb) body weight per day in milk or milk replacer for 1 to 5 days in 2 divided doses twice daily.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(iii) *Limitations.* Treated, ruminating calves must not be slaughtered for food during treatment or for 7 days after the

last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) *Swine*—(i) *Amount.* Administer 20 to 35 mg/lb body weight per day for 1 to 5 days in 2 divided doses twice daily:

(A) In drinking water; or

(B) For individual treatment, in an oral suspension containing approximately 42 mg sulfachlorpyridazine per milliliter in divided doses twice daily.

(ii) *Indications for use.* For the treatment of diarrhea caused or complicated by *E. coli* (colibacillosis).

(iii) *Limitations.* Treated swine must not be slaughtered for food during treatment or for 4 days after the last treatment.

Dated: June 9, 2008.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

[FR Doc. E8-14291 Filed 6-23-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### 25 CFR Part 292

RIN 1076-AE81

#### Gaming on Trust Lands Acquired After October 17, 1988; Correction

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Final rule; correction and stay of effective date.

**SUMMARY:** This document contains a correction to a final rule that was published May 20, 2008 (73 FR 29354). The regulation relates to gaming on trust lands acquired after October 17, 1988.

**DATES:** The effective date of this correction is June 24, 2008. In rule FR Document E8-11086 published on May 20, 2008 (73 FR 29353), the effective date of the rule is stayed until August 25, 2008.

**FOR FURTHER INFORMATION CONTACT:** Paula Hart, Acting Director, Office of Indian Gaming, (202) 219-4066.

**SUPPLEMENTARY INFORMATION:** The Bureau of Indian Affairs published on May 20, 2008, a final rule relating to gaming on trust lands acquired after October 17, 1988. The preamble to this

rule contained an incorrect effective date, contained an error in the Small Business Regulatory Enforcement and Fairness Act statement in the **SUPPLEMENTARY INFORMATION** section, and omitted a sentence.

In rule FR Document E8-11086 published on May 20, 2008 (73 FR 29353), make the following corrections:

1. On page 29354, in the first column, the effective date is listed as June 19, 2008. This is stayed until August 25, 2008.

2. On page 29358, in the second column, under the heading "Section 292.3 When can a tribe conduct gaming activities on trust lands?" a sentence was omitted after the sentence that ends, "concerns whether a specific area of land is a reservation." A new sentence should be added in this location to read, "Regardless of where the tribe sends its request for an Indian lands opinion, the Department will coordinate the completion of the request by the appropriate offices."

3. On page 29374, in the third column, under the heading "Small Business Regulatory Enforcement and Fairness Act (SBREFA)," the first sentence reads, "This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement and Fairness Act." This sentence should be corrected to read, "This rule is a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement and Fairness Act." In this same location, paragraph (a) incorrectly states that this rule, "Does not have an annual effect on the economy of \$100 million or more." This should be corrected to read, "Has an annual effect on the economy of \$100 million or more."

Dated: June 19, 2008.

**George Skibine,**

*Acting Deputy Assistant Secretary for Policy and Economic Development—Indian Affairs.*  
[FR Doc. E8-14211 Filed 6-23-08; 8:45 am]

**BILLING CODE 4310-4N-P**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9402]

RIN 1545-BH58

#### **Guidance Under Section 956 for Determining the Basis of Property Acquired in Certain Nonrecognition Transactions**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final and temporary regulations.

**SUMMARY:** This document contains final and temporary regulations under section 956 of the Internal Revenue Code (Code) regarding the determination of basis in certain United States property (within the meaning of section 956(c) of the Code) acquired by a controlled foreign corporation in certain nonrecognition transactions that are intended to repatriate earnings and profits of the controlled foreign corporation without United States income taxation. The final regulation adds a cross reference to the temporary regulations. These regulations affect United States shareholders of a controlled foreign corporation that acquires United States property in certain nonrecognition transactions. The text of the temporary regulations serves as the text of the proposed regulations (REG-102122-08) set forth in the notice of proposed rulemaking published in the Proposed Rules section in this issue of the **Federal Register**.

**DATES:** *Effective Date:* These regulations are effective on June 24, 2008.

*Applicability Date:* These regulations apply to property acquired in exchanges occurring on or after June 24, 2008.

**FOR FURTHER INFORMATION CONTACT:** John H. Seibert at (202) 622-3860 (not a toll-free number).

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

This document contains amendments to 26 CFR part 1 under section 956, which was added to the Code by the Revenue Act of 1962, Public Law 87-834 (76 Stat. 960 (1962)). The temporary regulations in this document are issued under the authority of sections 367(b) and 956(e). Section 367(b) was added to the Code by section 1042(a) of the Tax Reform Act of 1976, Public Law 94-455 (90 Stat. 1520 (1976)). Section 956(e) was added to the Code by section 13232(b) of the Omnibus Budget Reconciliation Act of 1993, Public Law 103-66, (107 Stat 312 (1993)).

The temporary regulations in this document apply to determine the basis of certain United States property (as defined in section 956(c) of the Code) acquired by a controlled foreign corporation in certain nonrecognition transactions that are intended to repatriate earnings and profits of the controlled foreign corporation without an income inclusion by the United States shareholders of the controlled foreign corporation under section 951(a)(1)(B).

#### **Explanation of Provisions**

##### *A. Transactions at Issue*

The IRS and the Treasury Department are aware that certain taxpayers are engaging in certain nonrecognition transactions in which a controlled foreign corporation (CFC) acquires certain United States property (within the meaning of section 956(c)) without resulting in an income inclusion to the United States shareholders of the CFC under section 951(a)(1)(B).

In one such transaction, for example, USP, a domestic corporation and the common parent of an affiliated group that files a consolidated tax return, owns 100-percent of the outstanding stock of US1 and US2, both domestic corporations that join USP in the filing of a consolidated tax return. US1 owns 100 percent of the stock of CFC, a controlled foreign corporation. US2 issues \$100x of its stock to CFC in exchange for \$10x of CFC stock and \$90x cash.

USP takes the position that: (i) US2's transfer of its stock to CFC in exchange for \$10x of CFC stock and \$90x cash is an exchange to which section 351 applies; (ii) US2 recognizes no gain on the receipt of \$10x of CFC stock and \$90x cash in exchange for its stock pursuant to section 1032(a); (iii) CFC recognizes no gain on the issuance of its stock to US2 under section 1032(a); (iv) CFC's basis in the US2 stock is zero pursuant to section 362(a); and (v) US1 and US2 do not and will not have an income inclusion under section 951(a)(1)(B) as a result of CFC holding the US2 stock (which constitutes United States property under section 956(c)).

The IRS and the Treasury Department believe these transactions raise significant policy concerns because the transactions may have the effect of repatriating earnings and profits of a CFC without a corresponding dividend inclusion, or an income inclusion under section 951(a)(1)(B) by reason of the CFC's investment in United States property.

##### *B. Section 956—In General*

Section 956 was enacted to require an income inclusion by United States shareholders of a CFC that invests certain earnings and profits in United States property "on the grounds that [the investment] is substantially the equivalent of a dividend being paid to them." S. Rep. No. 87-1881, 1962-3 CB 703, 794 (1962). (See § 601.601(d)(2)(ii)(b)).

Under Section 951(a)(1)(B) each United States shareholder (as defined in section 951(b)) of a CFC (as defined in section 957(a)) must include in its gross