

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Crystalline Free Acid

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 new animal drug application (NADA) filed by Pharmacia & Upjohn Co. The NADA provides for the veterinary prescription use of ceftiofur crystalline free acid suspension in beef and nonlactating dairy cattle, by subcutaneous injection in the ear, for the treatment and control of bovine respiratory disease (BRD).

DATES: This rule is effective October 22, 2003.

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, e-mail: jgotthar@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199, filed NADA 141-209 for NAXCEL XT (ceftiofur crystalline free acid) Sterile Suspension. The NADA provides for the veterinary prescription use of ceftiofur crystalline free acid suspension in beef and nonlactating dairy cattle, by subcutaneous injection in the ear, for the treatment of BRD (shipping fever, pneumonia) associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus* and for the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somnus*. The application is approved as of September 5, 2003, and the regulations are amended in 21 CFR part 522 by adding new § 522.315 to reflect the approval. In addition, 21 CFR 556.113 is being amended to add an acceptable single-dose intake for residues of ceftiofur at the injection site and a tolerance for residues at the injection site. 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 application may be seen in the Division of Dockets Management (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.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning September 5, 2003.

The agency has determined under 21 CFR 25.33(d)(5) 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

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 522.315 is added to read as follows:

§ 522.315 Ceftiofur crystalline free acid.

(a) *Specifications.* Each milliliter of suspension contains 200 milligrams (mg) ceftiofur equivalents (CE).

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.113 of this chapter.

(d) *Conditions of use in cattle—(1) Amount.* 6.6 mg CE per kilogram of body weight by a single, subcutaneous injection in the middle third of the posterior aspect of the ear.

(2) *Indications for use.* For the treatment of bovine respiratory disease (BRD, shipping fever, pneumonia)

associated with *Mannheimia haemolytica*, *Pasteurella multocida*, and *Haemophilus somnus*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *M. haemolytica*, *P. multocida*, and *H. somnus*.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. A withdrawal period has not been established in preruminating calves. Do not use in calves to be processed for veal.

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 556.113 is amended by redesignating paragraph (a) as paragraph (a)(1); by adding a new header to paragraph (a); by adding new paragraph (a)(2); and by adding a new sentence to the end of paragraph (b)(2) to read as follows:

§ 556.113 Ceftiofur.

(a) *Acceptable daily intake and acceptable single-dose intake—(1) Acceptable daily intake (ADI).* * * *

(2) *Acceptable single-dose intake (ASDI).* The ASDI total residues of ceftiofur is 0.830 milligrams per kilogram of body weight. The ASDI is the amount of total residues of ceftiofur that may safely be consumed in a single meal. The ASDI is used to derive the tolerance for residues of desfuroylceftiofur at the injection site.

(b) * * *

(1) * * *

(2) * * * The tolerance for residues of desfuroylceftiofur in injection site muscle is 166 parts per million.

Dated: October 2, 2003.

Andrew J. Beaulieu,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 03-26569 Filed 10-21-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9093]

RIN 1545-AX39

Special Rules for Certain Foreign Business Entities

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations providing rules regarding the application of the general entity classification rules to certain foreign business entities, in particular providing a rule that terminates the grandfathered status of certain foreign business entities upon a 50 percent change of ownership and a special rule that clarifies and further modifies the rules relating to whether the classification of certain foreign eligible entities is relevant for Federal tax purposes.

EFFECTIVE DATES: These regulations are effective as of October 22, 2003.

FOR FURTHER INFORMATION CONTACT: Ronald M. Gootzeit, (202) 622-3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 18, 1996, Treasury and IRS published in the **Federal Register** (61 FR 66584) final regulations relating to the classification of business entities under section 7701 (check-the-box regulations). On November 29, 1999, Treasury and the IRS published in the **Federal Register** (64 FR 66591) a notice of proposed rulemaking (REG-110385-99) proposing to amend §§ 301.7701-2 and 301.7701-3 of the current check-the-box regulations (proposed regulations). A public hearing on the proposed regulations was held on January 31, 2000. In addition, written comments were received. Most of the written and oral comments related to proposed § 301.7701-3(h), which provided a rule that would have operated to change the classification of a foreign disregarded entity if a so-called "extraordinary transaction" occurred one day before or within one year after the election to treat the entity as disregarded. On June 26, 2003, Treasury and the IRS issued Notice 2003-46 (2003-28 IRB 53) announcing the intention to withdraw this extraordinary transaction rule of proposed § 301.7701-3(h) and to finalize the remaining provisions of the proposed regulations.

With the publication of a notice of withdrawal elsewhere in this issue of the **Federal Register**, proposed § 301.7701-3(h) is withdrawn. This Treasury decision adopts without substantive change the remaining provisions of the proposed regulations. The final regulations thus adopt the following provisions from the proposed regulations: (1) The rule that terminates the grandfathered status of certain foreign business entities when there has been a 50 percent change of ownership

of such entity; (2) the provision clarifying that a foreign eligible entity with respect to which an entity classification election is made and which is not otherwise relevant for Federal tax purposes is deemed so relevant only on the effective date specified on a Form 8832, "Entity Classification Election"; and (3) the modifications to the classification rules for certain foreign eligible entities that have never been relevant or are no longer relevant for Federal tax purposes.

Explanation of Provisions

A. Grandfathered Foreign Per Se Entities

The check-the-box regulations allow certain foreign business entities that were in existence and treated as partnerships prior to the date the check-the-box regulations were proposed (PS-43-95, 61 FR 21989) and that would otherwise be classified as per se corporations under § 301.7701-2(b)(8)(i) to remain classified as partnerships if the conditions enumerated in § 301.7701-2(d)(1) are satisfied. These rules also provide that the occurrence of certain events results in a termination of this grandfathered status. See § 301.7701-2(d)(3)(i). The final regulations adopt the rule in the proposed regulations at § 301.7701-2(d)(3)(i) that provides an additional event resulting in the termination of an entity's grandfathered status. Under this rule, an entity's grandfathered status is terminated on the date when one or more persons who were not owners of the entity as of November 29, 1999, own in the aggregate a 50 percent or greater interest in the entity. Consistent with the proposed regulations, the final regulations provide that this rule will apply as of the date the final regulations are published in the **Federal Register**; therefore, if persons that were not owners of a grandfathered entity on November 29, 1999, obtain a greater than 50 percent ownership interest between November 29, 1999, and October 22, 2003, the grandfathered entity will cease to have that status on October 22, 2003.

Several commentators requested clarification as to whether this rule takes into account changes in direct ownership only or also changes in indirect ownership, and they suggested that the rule should take into account only changes in direct ownership. Treasury and the IRS believe that for purposes of grandfathered foreign per se entities a rule that took only direct changes of ownership into account could be easily circumvented in inappropriate cases. Therefore, this rule has not been modified in these final

regulations. Some commentators requested that the rule be limited to significant changes in ownership within a specified period of time. For example, one commentator suggested that the rule be limited to situations where persons obtained a 50 percent or greater ownership interest within a 12-month period. The final regulations do not adopt this suggestion because Treasury and the IRS believe that an entity should retain grandfathered status only if there have been no significant changes in the ownership of that entity.

B. Relevance of Classification

The check-the-box regulations provide that if the classification of a foreign eligible entity that was previously relevant for Federal tax purposes ceases to be relevant for 60 consecutive months and then subsequently becomes relevant again, the entity's classification at the start of the subsequent period of relevance will be determined under the default classification rules (60-month rule).

These final regulations adopt the two rules in the proposed regulations that relate to the application of the 60-month rule. First, these final regulations adopt the rule providing that the classification of a foreign eligible entity that files an entity classification election is deemed to be relevant for Federal tax purposes on the effective date of the election for purposes of the 60-month rule. Second, these final regulations adopt the rule providing that the classification of a foreign eligible entity whose classification has never been relevant for Federal tax purposes will initially be determined pursuant to the default classification provisions of § 301.7701-3(b)(2) at the time the classification of the entity first becomes relevant.

Commentators generally agreed with and supported the approach taken in the proposed regulations with respect to the relevance issues, and several commentators requested that these provisions be retroactive when finalized. These final regulations do not adopt the suggestion that these provisions be applied retroactively because Treasury and the IRS believe that it is not in the interest of sound tax administration.

One commentator requested that the provisions be revised to clarify that it is the Federal tax classification of the foreign eligible entity, and not the entity itself, that is deemed to be relevant. Treasury and the IRS have adopted this clarifying change in these final regulations.

One commentator requested that the regulations clarify why the classification of a foreign eligible entity, not otherwise

relevant, that files Form 8832, "Entity Classification Election", is deemed relevant only on the date the entity classification election is effective. The commentator neither suggested what the period of deemed relevance should be if not limited to one day nor suggested a principle for when the deemed relevance should terminate such that the 60-month rule would be triggered. In the interest of certainty and administrability of the application of the 60-month rule, Treasury and the IRS have retained the limitation of deemed relevance to the day on which the entity's classification is effective.

One commentator requested further guidance on when and under what circumstances the classification of a foreign eligible entity that was previously relevant ceases to be relevant under the 60-month rule. Treasury and the IRS believe § 301.7701-3(d)(1) and (3) provide sufficient guidance on when an entity's classification becomes relevant and, accordingly, when an entity's classification ceases to be relevant.

One commentator suggested that the regulations be revised to provide that an election by a non-relevant foreign entity to continue its current classification may be filed at any time within the 60-month period starting on the day after the date of the most recent election for that entity, and that such election will start a new 60-month period. Section 301.7701-3(c) provides that an eligible entity may elect to be classified other than as provided under the default classification rules of § 301.7701-3(b), or to change its election. Allowing an eligible entity whose classification is not relevant to renew its election for purposes of the 60-month rule would frustrate the policies underlying that rule. Accordingly, the suggestion was not adopted.

One commentator requested clarification and examples regarding the determination of the classification of a foreign eligible entity whose classification was never relevant or whose classification has not been relevant for 60 months and therefore has lapsed under the 60-month rule. In either case (assuming in the latter case that no election is made following the lapse of the classification), the entity's classification initially will be determined under the default classification rules of § 301.7701-3(b)(2) when the classification of the entity becomes relevant. Under the general rules of § 301.7701-3(c), an eligible entity may elect at such time to be classified other than as provided under the default classification rules, and may elect at some later time to change its

classification. Treasury and the IRS do not believe at this time that further guidance or examples are needed to illustrate these general rules.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these final regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Therefore, a Regulatory Flexibility Analysis is not required.

Drafting Information

The principal authors of these regulations are Aaron A. Farmer and Ronald M. Gootzeit, Office of Associate Chief Counsel (International). However, other personnel from Treasury and the IRS participated in their development.

List of Subjects in 26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 301 is proposed to be amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 301 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 301.7701-2 is amended by:

- 1. Removing the language "or" at the end of paragraph (d)(3)(i)(B).
- 2. Removing the period at the end of paragraph (d)(3)(i)(C) and adding "; or" in its place.
- 3. Adding paragraph (d)(3)(i)(D).
- 4. Adding a sentence at the end of paragraph (e).

The additions read as follows:

§ 301.7701-2 Business entities; definitions.

- * * * * *
- (d) * * *
- (3) * * *
- (i) * * *

(D) The date any person or persons, who were not owners of the entity as of November 29, 1999, own in the

aggregate a 50 percent or greater interest in the entity.

* * * * *

(e) *Effective date.* * * * However, paragraph (d)(3)(i)(D) of this section applies on or after October 22, 2003.

■ **Par. 3.** Section 301.7701-3 is amended as follows:

- 1. The text of paragraph (d)(1) following the paragraph heading is redesignated as paragraph (d)(1)(i), and a paragraph heading is added for paragraph (d)(1)(i).
- 2. Paragraph (d)(1)(ii) is added.
- 3. Paragraph (d)(2) is revised.
- 4. Paragraphs (d)(3) and (d)(4) are added.

The revision and additions read as follows:

§ 301.7701-3 Classification of certain business entities.

* * * * *

(d) *Special rule for foreign eligible entities—(1) Definition of relevance—(i) General rule.* * * *

(ii) *Deemed relevance—(A) General rule.* For purposes of this section, except as provided in paragraph (d)(1)(ii)(B) of this section, the classification for Federal tax purposes of a foreign eligible entity that files Form 8832, "Entity Classification Election", shall be deemed to be relevant only on the date the entity classification election is effective.

(B) *Exception.* If the classification of a foreign eligible entity is relevant within the meaning of paragraph (d)(1)(i) of this section, then the rule in paragraph (d)(1)(ii)(A) of this section shall not apply.

(2) *Entities the classification of which has never been relevant.* If the classification of a foreign eligible entity has never been relevant (as defined in paragraph (d)(1) of this section), then the entity's classification will initially be determined pursuant to the provisions of paragraph (b)(2) of this section when the classification of the entity first becomes relevant (as defined in paragraph (d)(1)(i) of this section).

(3) *Special rule when classification is no longer relevant.* If the classification of a foreign eligible entity is not relevant (as defined in paragraph (d)(1) of this section) for 60 consecutive months, then the entity's classification will initially be determined pursuant to the provisions of paragraph (b)(2) of this section when the classification of the foreign eligible entity becomes relevant (as defined in paragraph (d)(1)(i) of this section). The date that the classification of a foreign entity is not relevant is the date an event occurs that causes the classification to no longer be relevant, or, if no event occurs in a taxable year

that causes the classification to be relevant, then the date is the first day of that taxable year.

(4) *Effective date.* Paragraphs (d)(1)(ii), (d)(2), and (d)(3) of this section apply on or after October 22, 2003.

* * * * *

Robert E. Wenzel,
Deputy Commissioner for Services and Enforcement.

Approved: October 8, 2003.

Pamela F. Olson,
Assistant Secretary of the Treasury.

[FR Doc. 03-26547 Filed 10-21-03; 8:45 am]

BILLING CODE 4830-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 03-3145, MB Docket No. 03-121, RM-10707]

Television Broadcast Service; Longview, TX

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission, at the request of Estes Broadcasting, Inc., substitutes channel 38 – for channel 54+ at Longview, Texas. See 68 FR 33431, June 4, 2003. TV channel 38 – can be allotted to Longview, Texas, in compliance with the minimum distance separation requirements of Sections 73.610 and 73.698 of the Commission’s Rules. The coordinates for channel 38 – at Longview are North Latitude 32–35–23 and West Longitude 95–23–27. With this action, this proceeding is terminated.

DATES: Effective December 1, 2003.

FOR FURTHER INFORMATION CONTACT: Pam Blumenthal, Media Bureau, (202) 418-1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission’s Report and Order, MB Docket No. 03-121, adopted October 9, 2003, and released October 16, 2003. The full text of this document is available for public inspection and copying during regular business hours in the FCC Reference Information Center, Portals II, 445 12th Street, SW., Room CY-A257, Washington, DC 20554. This document may also be purchased from the

Commission’s duplicating contractor, Qualex International, Portals II, 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone (202) 863-2893, facsimile (202) 863-2898, or via-e-mail *qualexint@aol.com*.

List of Subjects in 47 CFR Part 73

Television broadcasting.

■ Part 73 of Title 47 of the Code of Federal Regulations is amended as follows:

PART 73—[AMENDED]

■ 1. The authority citation for Part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334 and 336.

§ 73.606 [Amended]

■ 2. Section 73.606(b), the Table of Television Allotments under Texas, is amended by removing TV channel 54+ and adding TV channel 38 – at Longview.

Federal Communications Commission.

Barbara A. Kreisman,

Chief, Video Division, Media Bureau.

[FR Doc. 03-26681 Filed 10-21-03; 8:45 am]

BILLING CODE 6712-01-P