

Convention, codified into U.S. law as the Convention on Cultural Property Implementation Act (Pub. L. 97-446, 19 U.S.C. 2601 *et seq.*), the United States entered into a bilateral agreement with Guatemala on September 29, 1997, concerning the imposition of import restrictions on archaeological objects and materials from the pre-Columbian cultures of Guatemala. On October 3, 1997, the former United States Customs Service published T.D. 97-81 in the **Federal Register** (62 FR 51771), which amended 19 CFR 12.104g(a) to reflect the imposition of these restrictions, and included a list designating the types of archaeological objects and materials covered by the restrictions. The restrictions cover Maya material from the Peten Lowlands and related pre-Columbian material from the Highlands and the Southern Coast of Guatemala.

Prior to the issuance of T.D. 97-81, on April 15, 1991, the former United States Customs Service published T.D. 91-34 in the **Federal Register** (56 FR 15181), which imposed emergency import restrictions on certain archaeological material from the Peten Region of Guatemala. Under T.D. 91-34, § 12.104g(b) (19 CFR 12.104g(b)) of the regulations pertaining to emergency restrictions was amended accordingly. These emergency restrictions were extended for a period of three years on November 7, 1994, under T.D. 94-84 (59 FR 55528). Subsequently, the same archaeological material covered by T.D. 91-34 (and the extension of T.D. 94-84) was subsumed in T.D. 97-81 when it was published in 1997, at which time the emergency restrictions of T.D. 91-34 (and T.D. 94-84) were removed from § 12.104g(b).

Import restrictions listed in 19 CFR 12.104g(a) are “effective for no more than five years beginning on the date on which the agreement enters into force with respect to the United States. This period can be extended for additional periods not to exceed five years if it is determined that the factors which justified the initial agreement still pertain and no cause for suspension of the agreement exists” (19 CFR 12.104g(a)).

On September 30, 2002, the former United States Customs Service published T.D. 02-56 in the **Federal Register** (67 FR 61259), which amended 19 CFR 12.104g(a) to reflect the extension of these import restrictions for an additional period of five years until September 29, 2007.

After reviewing the findings and recommendations of the Cultural Property Advisory Committee, and in response to a request by the Government of Guatemala, the Acting Assistant

Secretary for Educational and Cultural Affairs, United States Department of State, concluding that the cultural heritage of Guatemala continues to be in jeopardy from pillage of archaeological materials, made the necessary determination to extend the import restrictions for an additional five years on July 18, 2007, and diplomatic notes have been exchanged, reflecting the extension of the restrictions.

Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of the import restrictions.

The Designated List of Archaeological Material from Guatemala covered by these import restrictions is set forth in T.D. 97-81. The Designated List and accompanying image database may also be found at the following internet Web site address: <http://exchanges.state.gov/culprop/gtimage.html>.

The restrictions on the importation of these archaeological materials from Guatemala are to continue in effect for an additional 5 years. Importation of such material continues to be restricted unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

#### **Inapplicability of Notice and Delayed Effective Date**

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure (5 U.S.C. 553(a)(1)). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

#### **Regulatory Flexibility Act**

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

#### **Executive Order 12866**

Because this rule involves a foreign affairs function of the United States, it is not subject to Executive Order 12866.

#### **Signing Authority**

This regulation is being issued in accordance with 19 CFR 0.1(a)(1).

#### **List of Subjects in 19 CFR Part 12**

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise.

#### **Amendment to CBP Regulations**

■ For the reasons set forth above, part 12 of Title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

## **PART 12—SPECIAL CLASSES OF MERCHANDISE**

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

\* \* \* \* \*

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

\* \* \* \* \*

■ 2. In § 12.104g(a), the table of the list of agreements imposing import restrictions on described articles of cultural property of State Parties is amended in the entry for Guatemala by removing the reference to “T.D. 02-56” and adding in its place “CBP Dec. 07-79” in the column headed “Decision No.”.

**W. Ralph Basham,**

*Commissioner, U.S. Customs and Border Protection.*

Approved: September 21, 2007.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

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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; Tulathromycin**

**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 Pfizer, Inc. The supplemental NADA provides for the addition of a pathogen to the indication for use of tulathromycin, by injection, for the control of respiratory disease in high-risk cattle.

**DATES:** This rule is effective September 26, 2007.

**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: [joan.gotthardt@fda.hhs.gov](mailto:joan.gotthardt@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed a supplement to NADA 141-244 for DRAXXIN (tulathromycin) Injectable Solution. The supplemental NADA provides for the addition of a pathogen, *Mycoplasma bovis*, to the indication for use of tulathromycin solution in cattle, by subcutaneous injection, for the control of respiratory disease in cattle at high risk of developing bovine respiratory disease. The application is approved as of September 4, 2007, and the regulations in 21 CFR 522.2630 are amended to reflect the approval.

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 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)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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.

#### **§ 522.2630 [Amended]**

■ 2. In § 522.2630, in paragraph (d)(1)(ii), remove "and *H. somni*" and

add in its place "*H. somni*, and *M. bovis*".

Dated: September 17, 2007.

**Bernadette Dunham,**

*Deputy Director, Center for Veterinary Medicine*

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## **DEPARTMENT OF THE TREASURY**

### **Office of the Secretary**

#### **31 CFR Part 10**

[TD 9359]

**RIN 1545-BA72**

#### **Regulations Governing Practice Before the Internal Revenue Service**

**AGENCY:** Office of the Secretary, Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations revising the regulations governing practice before the Internal Revenue Service (Circular 230). These regulations affect individuals who practice before the Internal Revenue Service (IRS). The amendments modify the general standards of practice before the IRS.

**DATES: Effective Date:** These regulations are effective September 26, 2007.

**Applicability Date:** For dates of applicability, see §§ 10.1(d), 10.2(b), 10.3(i), 10.4(e), 10.5(f), 10.6(p), 10.7(g), 10.22(c), 10.25(e), 10.27(d), 10.29(d), 10.30(e), 10.34(f), 10.50(e), 10.51(b), 10.52(b), 10.53(e), 10.60(d), 10.61(c), 10.62(d), 10.63(f), 10.65(c), 10.68(e), 10.70(c), 10.71(g), 10.72(g), 10.73(g), 10.76(e), 10.77(c), 10.78(d), 10.82(h), 10.90(b), and 10.91.

**FOR FURTHER INFORMATION CONTACT:** Matthew Cooper at (202) 622-4940.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

Section 330 of title 31 of the United States Code authorizes the Secretary of the Treasury to regulate the practice of representatives before the Treasury Department. The Secretary is authorized, after notice and an opportunity for a proceeding, to censure, suspend or disbar from practice before the Treasury Department those representatives who are incompetent, disreputable, or who violate regulations prescribed under section 330 of title 31. The Secretary also is authorized to impose a monetary penalty against these individuals or seek an injunction under section 7408 of the Internal Revenue Code.

The Secretary has published regulations governing the practice of representatives before the IRS in Circular 230 (31 CFR part 10). These regulations authorize the Director of the Office of Professional Responsibility to act upon applications for enrollment to practice before the IRS, to make inquiries with respect to matters under the Office of Professional Responsibility's jurisdiction, to institute proceedings to impose a monetary penalty or to censure, suspend or disbar a practitioner from practice before the IRS, to institute proceedings to disqualify appraisers, and to perform other duties necessary to carry out these functions.

On December 19, 2002 (67 FR 77724), the Treasury Department and the IRS issued an advance notice of proposed rulemaking (2002 ANPRM) requesting comments on amendments to the regulations relating to the Office of Professional Responsibility, unenrolled practice, eligibility for enrollment, sanctions and disciplinary proceedings, contingent fees and confidentiality agreements. On February 8, 2006, the Treasury Department and the IRS published in the **Federal Register** (71 FR 6421) proposed amendments to the regulations (REG-122380-02) reflecting consideration of the comments received in response to the 2002 ANPRM and reflecting amendments to section 330 of title 31 made by the American Jobs Creation Act of 2004, Public Law 108-357 (118 Stat. 1418) (the Jobs Act). A public hearing was held on these proposals on June 21, 2006. Written public comments responding to the proposed regulations were received. After consideration of the public comments, the proposed regulations are adopted as revised by this Treasury decision.

#### **Summary of Comments and Explanation of Revisions**

Over 30 written comments were received in response to the notice of proposed rulemaking. All comments were considered and are available for public inspection upon request. A number of these comments are summarized in this preamble. The scope of these regulations is limited to practice before the IRS. These regulations do not alter or supplant ethical standards that are otherwise applicable to practitioners.

#### **Definitions—Practice Before the Internal Revenue Service**

Section 10.2(a)(4) of the final regulations adopts the proposed change without modification. The final regulations provide that practice before