

CIVIL MONETARY PENALTIES AUTHORITIES ADMINISTERED BY FDA AND ADJUSTED MAXIMUM PENALTY AMOUNTS—
Continued

U.S.C. Section	Description of Violation	Former Maximum Penalty Amount (in dollars)	Assessment Method	Date of Last Penalty	Adjusted Maximum Penalty Amount (in dollars)
(9) 335b(a)	Violation of certain requirements of the Generic Drug Enforcement Act of 1992 (GDEA)	250,000	Per violation for an individual	2004	275,000
(10) 335b(a)	Violation of certain requirements of the GDEA	1,000,000	Per violation for "any other person"	2004	1,100,000
(11) 360pp(b)(1)	Violation of certain requirements of the Radiation Control for Health and Safety Act of 1968 (RCHSA)	1,000	Per violation per person	2004	1,100
(12) 360pp(b)(1)	Violation of certain requirements of the RCHSA	300,000	For any related series of violations	2004	330,000
(b) 42 U.S.C.					
(1) 263b(h)(3)	Violation of certain requirements of the Mammography Quality Standards Act of 1992 and the Mammography Quality Standards Act of 1998	10,000	Per violation	2004	11,000
(2) 300aa-28(b)(1)	Violation of certain requirements of the National Childhood Vaccine Injury Act of 1986	100,000	Per occurrence	2004	110,000

Dated: August 5, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-18407 Filed 8-11-04; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Ivermectin and Praziquantel Paste

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 Merial Ltd. The supplemental NADA provides revised labeling for ivermectin and praziquantel oral paste used in horses for the treatment and control of various internal parasites.

DATES: This rule is effective August 12, 2004.

FOR FURTHER INFORMATION CONTACT:

Martine Hartogensis, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7519 Standish

Pl., Rockville, MD 20855, 301-827-7815, e-mail: martine.hartogensis@fda.gov.

SUPPLEMENTARY INFORMATION: Merial Ltd., 3239 Satellite Blvd., Bldg. 500, Duluth, GA 30096-4640, filed a supplement to NADA 141-214 for ZIMECTERIN GOLD (ivermectin 1.55 percent/praziquantel 7.75 percent) Paste for horses. This supplement amends product labeling to separate parasite life stages in the indications section, to remove the 8-week retreatment interval from the dosage and administration section, and to add a new precaution statement. The supplemental NADA is approved as of July 13, 2004, and 21 CFR 520.1198 is amended to reflect the approval. 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.

The agency has determined under 21 CFR 25.33(d)(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. Section 520.1198 is amended by revising paragraphs (d)(2)(i) and (d)(3) to read as follows:

§ 520.1198 Ivermectin and praziquantel paste.

* * * * *

(d) * * *

(2) * * *

(i) For treatment and control of the following parasites in horses: Tapeworms—*Anoplocephala perfoliata*; Large strongyles (adults)—*Strongylus vulgaris* (also early forms in blood vessels), *S. edentatus* (also tissue stages), *S. equinus*, *Triodontophorus* spp. including *T. brevicauda* and *T. serratus*, and *Craterostomum acuticaudatum*; Small Strongyles (adults, including those resistant to some benzimidazole class compounds)—*Coronocyclus* spp. including *C. coronatus*, *C. labiatus*, and *C. labratus*, *Cyathostomum* spp. including *C. catinatum* and *C. pateratum*, *Cylicocyclus* spp. including *C. insigne*, *C. leptostomum*, *C. nassatus*, and *C. brevicapsulatus*, *Cylicodontophorus* spp., *Cylicostephanus* spp. including *C. calicatus*, *C. goldi*, *C. longibursatus*, and *C. minutus*, and *Petrovinema poculatum*; Small Strongyles—fourth-stage larvae; Pinworms (adults and fourth stage larvae)—*Oxyuris equi*; Ascarids (adults and third- and fourth-stage larvae)—*Parascaris equorum*; Hairworms (adults)—*Trichostrongylus axei*; Large-mouth Stomach Worms (adults)—*Habronema muscae*; Bots (oral and gastric stages)—*Gasterophilus* spp. including *G. intestinalis* and *G. nasalis*; Lungworms (adults and fourth-stage larvae)—*Dictyocaulus arnfieldi*; Intestinal Threadworms (adults)—*Strongyloides westeri*; Summer Sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; Dermatitis caused by neck threadworm microfilariae, *Onchocerca* sp.

* * * * *

(3) *Limitations*. For oral use only. Do not use in horses intended for human consumption.

Dated: July 27, 2004.

Daniel G. McChesney,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.
[FR Doc. 04-18406 Filed 8-11-04; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[TD 9153]

RIN 1545-BD43

Clarification of Definitions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains temporary regulations providing clarification of the definitions of a corporation and a domestic entity in circumstances where the business entity is considered to be created or organized in more than one jurisdiction. These regulations will affect business entities that are created or organized under the laws of more than one jurisdiction. The final regulations consist of technical revisions to reflect the issuance of the temporary regulations and to correct a cross-reference in § 301.7701-3. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective August 12, 2004.

Applicability Dates: For the dates of applicability of these regulations, see § 301.7701-2T(f) and § 301.7701-5T(c).

FOR FURTHER INFORMATION CONTACT:

Thomas Beem, (202) 622-3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Several jurisdictions have recently enacted provisions (generally referred to as either continuance or domestication statutes) that make it possible for a business entity to be treated as created or organized under the laws of more than one jurisdiction at the same time (a dually chartered entity). A dually chartered entity and the interest holders in the entity must determine for Federal tax purposes (1) the entity's classification (e.g., corporation or partnership) and (2) whether the entity is foreign or domestic. The regulations contained in this document are intended to clarify the rules for these determinations.

Section 7701(a)(3) of the Internal Revenue Code of 1986 (Code) provides that the term *corporation* includes associations, joint stock companies, and insurance companies. The definition of a corporation under the tax statutes has not changed since the Revenue Act of 1918, Public Law 65-254 (40 Stat. 1057, section 1). Final regulations (TD 8697) providing rules for the classification of business entities were published in the **Federal Register** on December 18, 1996 (61 FR 66584 (1996)). Those entity classification rules identify certain entities that are always treated as corporations and are not eligible to elect their entity classification.

Section 7701(a)(4) of the Code provides that the term *domestic* when applied to a corporation or partnership

means “created or organized in the United States or under the law of the United States or of any State unless, in the case of a partnership, the Secretary provides otherwise by regulations.” Section 7701(a)(5) of the Code provides that the term *foreign* when applied to a corporation or partnership means a “corporation or partnership that is not domestic.” This definition is significantly different than the definition of foreign entity that preceded it. The Revenue Act of 1918 used the term foreign to mean a corporation or partnership “created or organized outside the United States.” Thus, under that definition, a dually chartered entity that was organized in the United States and in a foreign jurisdiction would have met the definitions of both a domestic entity and a foreign entity, creating uncertainty as to the entity's status. The Revenue Act of 1924, Public Law 68-176 (43 Stat. 253) eliminated that potential for uncertainty by providing the definition of a foreign entity that is currently reflected in section 7701(a)(5). This definition of a foreign entity as “a corporation or partnership that is not domestic” makes it impossible for an entity to meet the definitions of both a domestic entity and a foreign entity for Federal tax purposes at the same time. As a result, a dually chartered entity that is organized both in the United States and in a foreign jurisdiction is a domestic entity.

Final regulations providing further guidance on the definitions of domestic and foreign business entities were published in the **Federal Register** on November 17, 1960 (25 FR 10928 (1960)).

Explanation of Provisions

Under the existing rules, the characterization of a business entity for Federal tax purposes is established in two separate and independent steps. The first involves a determination of whether the entity is a corporation or a non-corporate entity (e.g., a partnership). The second involves a determination of whether the entity is foreign or domestic.

The determination of whether a business entity is classified as a corporation is made by applying the definition in § 301.7701-2(b). If the entity is not a corporation under that definition, then it is a partnership if it has more than one owner and it is a disregarded entity if it has only a single owner. The temporary regulations in this document clarify that this same definition applies to dually chartered entities. Thus, to determine whether a dually chartered entity is a corporation,