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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 558

#### New Animal Drugs for Use in Animal Feeds; Monensin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to simplify the organization of special labeling requirements for formulations (Type A medicated articles, Type B and Type C medicated feeds) containing monensin sodium. This action is being taken to improve the clarity of the regulations.

**DATES:** This rule is effective November 14, 2006.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:** On

October 28, 2004, FDA approved a supplemental new animal drug application (sNADA 95-735) filed by Elanco Animal Health for RUMENSIN (monensin sodium) Type A medicated article adding use in a new class of cattle (dairy cows) for increased milk production efficiency (69 FR 68783, November 26, 2004). On December 15, 2005, FDA approved another supplement to NADA 95-735 for use in dairy cow component feeding systems (71 FR 1689, January 11, 2006). The approval of each of these new conditions of use resulted in the amendment of the animal drug

regulations for monensin in § 558.355 (21 CFR 558.355).

Since these approvals for use of monensin in dairy cow feeds as well as beef cattle feeds, FDA has become aware of confusion regarding which statements on the approved Type A medicated article labeling also appear on the approved representative labeling (Blue Bird labeling) for Type B and Type C medicated feeds for each class of cattle. At this time, the regulations are being amended in § 558.355 to simplify the organization of special labeling requirements for formulations (Type A medicated articles, Type B and Type C medicated feeds) containing monensin sodium. This action is being taken to improve the clarity of the regulations.

Publication of this document constitutes final action on this change under the Administrative Procedures Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

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 558

Animal drugs, Animal feeds.

■ 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 558 is amended as follows:

#### PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

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

■ 2. Amend § 558.355 as follows:

a. Revise paragraphs (d)(6) through (d)(11);

b. Remove paragraph (d)(13); and

c. Revise the second sentence of paragraph (f)(3)(xiii)(B), the third sentence of paragraph (f)(3)(xiv)(B), and the sixth sentence of paragraph (f)(6)(i)(b)(1).

The revisions read as follows:

#### § 558.355 Monensin.

\* \* \* \* \*

(d) \* \* \*

(6) All formulations containing monensin shall bear the following caution statement: Do not allow horses or other equines access to feed

containing monensin. Ingestion of monensin by horses has been fatal.

(7) Type A medicated articles containing monensin intended for use in cattle and goats shall bear, in addition to the caution statement in paragraph (d)(6) of this section, the following statements:

(i) Monensin medicated cattle and goat feeds are safe for use in cattle and goats only. Consumption by unapproved species may result in toxic reactions.

(ii) Feeding undiluted or mixing errors resulting in high concentrations of monensin has been fatal to cattle and could be fatal to goats.

(iii) Must be thoroughly mixed in feeds before use.

(iv) Do not feed undiluted.

(v) Do not exceed the levels of monensin recommended in the feeding directions, as reduced average daily gains may result.

(vi) Do not feed to lactating goats.

(vii) If feed refusals containing monensin are fed to other groups of cattle, the concentration of monensin in the refusals and amount of refusals fed should be taken into consideration to prevent monensin overdosing.

(viii) A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

(ix) You may notice the following: Reduced voluntary feed intake in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Rule out monensin as the cause of reduced feed intake before attributing to other causes such as illness, feed management, or the environment. Reduced milk fat percentage in dairy cows fed monensin. This reduction increases with higher doses of monensin fed. Increased incidence of cystic ovaries and metritis in dairy cows fed monensin. Reduced conception rates, increased services per animal, and extended days open and corresponding calving intervals in dairy cows fed monensin. Have a comprehensive and ongoing nutritional, reproductive, and herd health program in place when feeding monensin to dairy cows.

(x) Inadequate mixing (recirculation or agitation) of monensin liquid Type B or Type C medicated feeds has resulted in increased monensin concentration which has been fatal to cattle and could be fatal to goats.

(8) Type A medicated articles containing monensin intended for use in chickens shall bear the caution statements specified in paragraphs (d)(6), (d)(7)(iii), and (d)(7)(iv) of this section.

(9) Type B feeds containing monensin shall bear the statements specified in the following paragraphs of this section when intended for use in:

(i) *Cattle (as described in paragraphs (f)(3)(i) through (f)(3)(xii) of this section)*: See paragraphs (d)(6), (d)(7)(i) through (d)(7)(v), (d)(7)(vii), and (d)(7)(viii) of this section.

(ii) *Dairy cows (as described in paragraphs (f)(3)(xiii) and (f)(3)(xiv) of this section)*: See paragraphs (d)(6), (d)(7)(i) through (d)(7)(iv), (d)(7)(vii), (d)(7)(viii), and (d)(7)(ix) of this section.

(iii) *Goats*: See paragraphs (d)(6) and (d)(7)(i) through (d)(7)(vi) of this section.

(10) Type C feeds containing monensin shall bear the statements specified in the following paragraphs of this section when intended for use in:

(i) *Cattle (as described in paragraphs (f)(3)(i) through (f)(3)(xii) of this section)*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(v), (d)(7)(vii), and (d)(7)(viii) of this section.

(ii) *Dairy cows (as described in paragraphs (f)(3)(xiii) and (f)(3)(xiv) of this section)*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(vii), (d)(7)(viii), and (d)(7)(ix) of this section.

(iii) *Goats*: See paragraphs (d)(6), (d)(7)(i), (d)(7)(v), and (d)(7)(vi) of this section.

(11) Type B and Type C liquid feeds requiring recirculation or agitation that contain monensin and are intended for use in cattle (including dairy cows) and goats shall bear the caution statement specified in paragraph (d)(7)(x) of this section.

\* \* \* \* \*

(f) \* \* \*

(3) \* \* \*

(xiii) \* \* \*

(B) \* \* \* See special labeling considerations in paragraph (d) of this section.

(xiv) \* \* \*

(B) \* \* \* See special labeling considerations in paragraph (d) of this section.

\* \* \* \* \*

(6) \* \* \*

(i) \* \* \*

(b) \* \* \*

(1) \* \* \* See special labeling considerations in paragraph (d) of this section.

\* \* \* \* \*

Dated: October 31, 2006.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

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**DEPARTMENT OF THE TREASURY**

**Internal Revenue Service**

**26 CFR Part 1**

[TD 9297]

RIN 1545-BG02

**Residence Rules Involving U.S. Possessions**

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

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations that provide rules for determining bona fide residency in the following U.S. territories: American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the United States Virgin Islands under section 937(a) of the Internal Revenue Code.

**DATES:** *Effective Date:* These regulations are effective November 14, 2006.

*Applicability Dates:* For dates of applicability, see § 1.937-1(i).

**FOR FURTHER INFORMATION CONTACT:** J. David Varley, (202) 435-5262 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:**

**Background**

On April 11, 2005, the IRS and Treasury Department published in the **Federal Register** temporary regulations (TD 9194, 70 FR 18920, as corrected at 70 FR 32589-01), which provided rules to implement section 937 of the Internal Revenue Code (Code) dealing with U.S. possessions or territories specified in that section (territories) and to conform existing regulations to other legislative changes with respect to the territories. A notice of proposed rulemaking (REG-159243-03, 70 FR 18949) cross-referencing the temporary regulations was published in the **Federal Register** on the same day. Written comments were received in response to the notice of proposed rulemaking and a public hearing on the proposed regulations was held on July 21, 2005. After consideration of the comments, the IRS and Treasury Department on January 31, 2006 published in the **Federal Register** final regulations (TD 9248, 71 FR 4996, as corrected at 71 FR 14099) under section 937(a) dealing with determining residency in a territory, adopting with amendments the proposed regulations (specifically, §§ 1.937-1 and 1.881-5T(f)(4)).

Section 937(a) provides that an individual is a bona fide resident of a territory if the individual meets a presence test, a tax home test and a closer connection test. In order to satisfy

the presence test, a person must be present in the territory for at least 183 days during the taxable year (the 183-day rule), unless otherwise provided in regulations. The final section 937(a) regulations provide several alternatives to the 183-day rule in the statute.

Treasury Reg. § 1.937-1 provides that an individual who does not satisfy the 183-day rule nevertheless meets the presence test if the individual satisfies one of three alternative tests: (1) The individual spends no more than 90 days in the United States during the taxable year; (2) the individual has no more than \$3,000 of earned income from U.S. sources and is present for more days in the territory than in the United States during the taxable year; or (3) the individual has no significant connection to the United States during the tax year. The term “significant connection” is generally defined as a permanent home, voter registration, spouse, or minor child in the United States. The final regulations also provide that certain days count as days of presence in the relevant territory for the purposes of the presence test, even if the person was not physically present in the territory. Similarly, certain days that an individual spends in the United States do not count as days of presence in the United States for purposes of the presence test.

Before finalizing the regulations, the IRS and Treasury Department received comments suggesting that days spent outside of a territory for nonmedical family emergencies, charitable pursuits or business travel should count as days spent in the territory and outside the United States. The IRS and Treasury Department were sympathetic to the concern that the realities of life in the territories might require periodic temporary absences from the territories, but found that the particular suggestions would have been very difficult to implement and monitor administratively. Further, the IRS and Treasury Department declined to adopt the commentators’ suggestion to import a simple mirroring of the substantial presence test of section 7701(b) on the ground that Congress had considered but rejected this approach for determining residency in a territory. See H.R. Conf. Rep. No. 108-755, at 791-795 (2004). Nonetheless, the IRS and Treasury Department believed that final regulations provided meaningful advantages to taxpayers over the proposed and temporary regulations.

**Explanation of Provisions**

Following publication of the final regulations, additional comments were made requesting that the IRS and