

The Designated List of Archaeological Material from Mali covered by these import restrictions is set forth in CBP Dec. 07–77, see 72 FR 53414 dated September 19, 2007. More information on import restrictions can be obtained from the Mali country section of the International Cultural Property Protection Web site (<http://exchanges.state.gov/heritage/culprop/mlfact.html>).

The restrictions on the importation of these archaeological materials from Mali are to continue in effect through September 19, 2017. Importation of such materials 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 reasons, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

#### **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;

\* \* \* \* \*

#### **§ 12.104g [Amended]**

■ 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 Mali by removing the reference to “CBP Dec. 07–77” and adding in its place “CBP Dec. 12–14” in the column headed “Decision No.”.

**David V. Aguilar,**

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

Approved: September 13, 2012.

**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 Parts 520 and 558**

**[Docket No. FDA–2012–N–0002]**

#### **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 remove a warning for growing cattle on pasture or in dry lot and to codify all monensin free-choice Type C medicated feeds in 21 CFR part 558. This action is being taken to improve the accuracy of the regulations.

**DATES:** This rule is effective September 19, 2012.

**FOR FURTHER INFORMATION CONTACT:** Christina C. Edwards, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8228, Email: [christina.edwards@fda.hhs.gov](mailto:christina.edwards@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** FDA has noticed that the animal drug regulations for certain monensin free-choice Type C medicated feeds for growing cattle on pasture or in dry lot (slaughter, stocker, and feeder cattle; and dairy and beef replacement heifers) reflect a warning statement regarding the overdosing risk posed by uneaten free-choice feeds

(refusals) that is unnecessary and not required on product labeling.

Refusals of free-choice cattle feeds, including compressed blocks, granules, and liquids, are unlikely in practice to be fed to another group of cattle. These products are used almost exclusively in pasture-based systems where the product is placed in the pasture with the animals and is left until consumed. In addition, it is extremely unlikely that these free-choice cattle feeds would be fed to another production class because these products generally are not appropriate for the nutritional needs of another production class.

For these reasons, FDA is revising the regulations to exclude monensin free-choice Type C medicated feeds for growing cattle on pasture or in dry lot from the requirement to include a warning statement. This action is being taken to improve the accuracy of the regulations.

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 520*

Animal drugs.

*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 parts 520 and 558 are 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.

**§§ 520.1448 and 520.1448a [Removed]**

■ 2. Remove §§ 520.1448 and 520.1448a.

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

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

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

■ 4. In § 558.355, revise paragraphs (d)(7)(vii), (d)(10)(i), and (d)(10)(ii); remove and reserve paragraph (f)(3)(v); redesignate paragraph (f)(7) as paragraph (f)(8); and add new paragraph (f)(7) to read as follows:

**§ 558.355 Monensin.**

\* \* \* \* \*

(d) \* \* \*  
(7) \* \* \*

(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 (see paragraphs (d)(10)(i) and (d)(10)(ii) of this section).

\* \* \* \* \*

(10) \* \* \*

(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. Paragraph (d)(7)(vii) of this section does not apply to free-choice Type C medicated feeds as defined in § 510.455 of this chapter.

(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. Paragraph (d)(7)(vii) of this section does not apply to free-choice Type C medicated feeds as defined in § 510.455 of this chapter.

\* \* \* \* \*

(f) \* \* \*

(7) *Free-choice feeds*—(i) *Amount*. 150 milligrams per pound of protein-mineral block (0.033 percent).

(a) [Reserved]

(b) *Conditions of use*—(1) *Indications for use*. For increased rate of weight gain; and for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii* in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) which may require supplemental feed.

(2) *Limitations*. Provide 50 to 200 milligrams of monensin (0.34 to 1.33 pounds of block) per head per day, at least 1 block per 10 to 12 head of cattle. Roughage must be available at all times. Do not allow animals access to other protein blocks, salt or mineral, while being fed this product. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(ii) *Amount*. 400 milligrams per pound of protein-mineral block (0.088 percent).

(a) *Sponsor*. See No. 067949 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Indications for use*. For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

(2) *Limitations*. Provide 80 to 200 milligrams of monensin (0.2 to 0.5 pounds of block) per head per day, at

least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or minerals containing salt. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(iii) *Amount*. 175 milligrams per pound of protein-mineral block (0.038 percent).

(a) *Sponsor*. See No. 066071 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Indications for use*. For increased rate of weight gain in pasture cattle (slaughter, stocker, and feeder).

(2) *Limitations*. Provide 40 to 200 milligrams of monensin (0.25 to 1.13 pounds or 4 to 18 ounces of block) per head per day, at least 1 block per 4 head of cattle. Do not allow cattle access to salt or mineral while being fed this product. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

(iv) *Amount*. 400 milligrams per pound of block (0.088 percent).

(a) *Sponsor*. See No. 051267 in § 510.600(c) of this chapter.

(b) *Conditions of use*—(1) *Indications for use*. For increased rate of weight gain in pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers).

(2) *Limitations*. Provide 50 to 200 milligrams of monensin (2 to 8 ounces of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 milligrams per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.

\* \* \* \* \*

Dated: September 13, 2012.

**Bernadette Dunham,**

*Director, Center for Veterinary Medicine.*

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 926

[SATS No. MT-034-FOR; Docket ID No. OSM-2011-0018]

#### Montana Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We are approving an amendment to the Montana regulatory program (the “Montana program”) under the Surface Mining Control and Reclamation Act of 1977 (“SMCRA” or “the Act”). Montana proposed revisions to and additions of statutory definitions of approximate original contour, in situ coal gasification, and recovery fluid. Montana revised its program to clarify ambiguities and improve operational efficiency. Montana intends to promulgate regulations pertaining to in situ coal gasification within one year. The statutory revisions discussed here will support that future rulemaking effort.

**DATES:** *Effective Date:* September 19, 2012.

**FOR FURTHER INFORMATION CONTACT:** Jeffrey Fleischman, Chief, Casper Field Office, Telephone: (307) 261-6550, email address: [jfleischman@osmre.gov](mailto:jfleischman@osmre.gov).

#### SUPPLEMENTARY INFORMATION:

- I. Background on the Montana Program
- II. Submission of the Proposed Amendment
- III. Office of Surface Mining Reclamation and Enforcement’s (OSM’s) Findings
- IV. Summary and Disposition of Comments
- V. OSM’s Decision
- VI. Procedural Determinations

#### I. Background on the Montana Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act \* \* \*; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Montana program on April 1, 1980. You can find background information on the Montana program, including the Secretary’s findings, the disposition of comments, and conditions of approval in the April 1, 1980, **Federal Register** (45 FR 21560). You can also find later actions concerning Montana’s program and program amendments at 30 CFR 926.15 and 926.30.

#### II. Submission of the Proposed Amendment

By letter dated August 19, 2011, Montana sent us an amendment to its