

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

Sub

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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 reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for minor revisions to labeling of monensin Type A medicated articles for chickens. FDA is also amending the regulations to simplify the organization of special labeling requirements for formulations (Type A medicated articles, Type B and Type C medicated feeds) containing monensin for poultry and game birds. This action is being taken to improve the clarity of the regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

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.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 38-878 that provides for use of COBAN 60 and COBAN 90 (monensin, USP) Type A medicated articles in feed of chickens. The supplement provides for minor revisions to labeling. The supplemental NADA is approved as of

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February 7, 2007, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

In addition, FDA is taking this opportunity to amend the regulations to simplify the organization of special labeling requirements for formulations (Type A medicated articles, Type B and Type C medicated feeds) containing monensin for poultry and game birds. Similar restructuring was done recently for monensin formulations used in ruminants (71 FR 66231, November 14, 2006). This action is being taken to improve the clarity of the regulations.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

FDA 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 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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. In § 558.355, revise paragraphs (a), (b)(1), (b)(4), (b)(6), (d)(4), (d)(5), and (d)(8); and add paragraphs (d)(9)(iv) through (d)(9)(vi), and (d)(10)(iv) through (d)(10)(vi) to read as follows:

§ 558.355 Monensin.

(a) *Specifications.* Type A medicated articles containing monensin, USP.

(b) * * *

(1) To No. 000986: 36.3 (for export only), 44, 45, 60, or 90.7 grams per pound for use as in paragraphs (f)(1)(i) and (f)(4) of this section.

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(4) To No. 000986: 45, 60, or 90.7 grams per pound for use as in paragraph (f)(2) of this section.

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(6) To No. 000986: 45, 60, or 90.7 grams per pound for use as in paragraph (f)(5) of this section.

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(d) * * *

(4) Liquid Type B feeds shall bear an expiration date of 8 weeks after its date of manufacture.

(5) All Type A medicated articles containing monensin shall bear the following warning statement: When mixing and handling monensin Type A medicated articles, use protective clothing, impervious gloves, and a dust mask. Operators should wash thoroughly with soap and water after handling. If accidental eye contact occurs, immediately rinse thoroughly with water.

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(8) Type A medicated articles containing monensin intended for use in chickens, turkeys, and quail shall bear the following statements:

(i) Do not allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal.

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

(iii) Do not feed undiluted.

(iv) Do not feed to laying chickens.

(v) Do not feed to chickens over 16 weeks of age.

(vi) For replacement chickens intended for use as cage layers only.

(vii) Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(viii) In the absence of coccidiosis in broiler chickens the use of monensin with no withdrawal period may limit feed intake resulting in reduced weight gain.

(9) * * *

(iv) *Chickens*: See paragraphs (d)(8)(i) through (d)(8)(vi), and (d)(8)(viii) of this section.

(v) *Turkeys*: See paragraphs (d)(8)(i), (d)(8)(ii), (d)(8)(iii), and (d)(8)(vii) of this section.

(vi) *Quail*: See paragraphs (d)(8)(i), (d)(8)(ii), and (d)(8)(iii) of this section.

(10) * * *

(iv) *Chickens*: See paragraphs (d)(8)(i), (d)(8)(iv), (d)(8)(v), (d)(8)(vi), and (d)(8)(viii) of this section.

(v) *Turkeys*: See paragraphs (d)(8)(i) and (d)(8)(vii) of this section.

(vi) *Quail*: See paragraph (d)(8)(i) of this section.

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Dated: February 21, 2007
February 12, 2007.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Joe

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