

Issued in Kansas City, MO, on November 8, 2004.

**Anthony D. Roetzel,**  
Acting Area Director, Western Flight Services Operations.

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 71

[Docket No. FAA-2004-18825; Airspace Docket No. 04-ACE-51]

#### Modification of Class E Airspace; Harrisonville, MO

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** This document confirms the effective date of the direct final rule which revises Class E airspace at Harrisonville, MO.

**EFFECTIVE DATE:** 0901 UTC, January 20, 2005.

**FOR FURTHER INFORMATION CONTACT:** Brenda Mumper, Air Traffic Division, Airspace Branch, ACE-520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329-2524.

**SUPPLEMENTARY INFORMATION:** The FAA published this direct final rule with a request for comments in the **Federal Register** on October 8, 2004 (69 FR 60285). The FAA uses the direct final rulemaking procedure for a non-controversial rule where the FAA believes that there will be no adverse public comment. This direct final rule advised the public that no adverse comments were anticipated, and that unless a written adverse comment, or a written notice of intent to submit such an adverse comment, were received within the comment period, the regulation would become effective on January 20, 2005. No adverse comments were received, and thus this notice confirms that this direct final rule will become effective on that date.

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**Anthony D. Roetzel,**  
Acting Area Director, Western Flight Services Operations.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Parts 556 and 558

#### New Animal Drugs; Monensin

**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 Elanco Animal Health. The supplemental NADA provides for use of monensin Type A medicated articles to formulate Type B and Type C medicated feeds used for increased milk production efficiency in dairy cows.

**DATES:** This rule is effective November 26, 2004.

**FOR FURTHER INFORMATION CONTACT:** Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; 301-827-0232; e-mail: [edubbin@cvm.fda.gov](mailto:edubbin@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95 735 that provides for the use of RUMENSIN 80 (monensin sodium) Type A medicated article to formulate Type B and Type C medicated feeds used for increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows. The supplemental NADA is approved as of October 28, 2004, and the regulations in 21 CFR 556.420 and 558.355 are 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 carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that

finding, contained in an environmental assessment, may be seen in the Division of Dockets Management (see previous paragraph).

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 October 28, 2004.

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 556

Animal drugs, Foods.

##### 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 parts 556 and 558 are amended as follows:

#### PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 1. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

■ 2. Section 556.420 is amended by revising paragraph (b) and by adding paragraph (c) to read as follows:

##### § 556.420 Monensin.

\* \* \* \* \*

(b) *Tolerances.* The tolerances for residues of monensin are:

(1) *Cattle*—(i) *Edible tissues.* 0.05 part per million (ppm).

(ii) *Milk.* Not required.

(2) *Goats*—(i) *Edible tissues.* 0.05 ppm.

(ii) [Reserved]

(3) *Chickens, turkeys, and quail.* A tolerance for residues of monensin in chickens, turkeys, and quail is not required.

(c) *Related conditions of use.* See §§ 520.1448 and 558.355 of this chapter.

#### 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. Section 558.355 is amended by revising paragraph (d)(7)(vi); and by adding paragraphs (d)(13) and (f)(3)(xiii) to read as follows:

§ 558.355 Monensin.

\* \* \* \* \*

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

(vi) A withdrawal time has not been established for prerinuating calves. Do not use in calves to be processed for veal.

\* \* \* \* \*

(13) The labeling of Type B and Type C (liquid and dry) medicated feeds intended for use in dairy cows shall bear the following caution statements: You may notice: 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.

\* \* \* \* \*

- (f) \* \* \*
- (3) \* \* \*

(xiii) Amount per ton. Monensin, 11 to 22 grams.

(A) *Indications for use.* For increased milk production efficiency (production of marketable solids-corrected milk per unit of feed intake) in dairy cows.

(B) *Limitations.* Feed continuously to dry and lactating dairy cows in a total mixed ration ("complete feed"). See paragraphs (d)(2), (d)(5), (d)(6), (d)(7)(i), (d)(7)(ii), (d)(7)(iii), (d)(7)(vi), (d)(8), and (d)(12) of this section.

\* \* \* \* \*

Dated: November 10, 2004.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 04-26091 Filed 11-24-04; 8:45 am]

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**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**24 CFR Part 203**

[Docket No. FR-4835-F-03]

RIN 2502-A100

**FHA TOTAL Mortgage Scorecard**

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Final rule.

**SUMMARY:** On November 21, 2003, HUD published an interim rule to codify the procedures that mortgagees and automated underwriting system vendors must follow if they opt to use the "Technology Open to Approved Lenders" (TOTAL) Mortgage Scorecard offered by the Federal Housing Administration (FHA). The interim rule did not alter the underwriting requirements applicable to FHA mortgagees. Rather, the interim rule defined the acronym TOTAL and provided the requirements and procedures for use of the TOTAL Mortgage Scorecard. This final rule follows publication of the November 21, 2003, interim rule. HUD did not receive any public comments on the interim rule. Accordingly, HUD is adopting the interim rule, as corrected by a technical correction published on January 2, 2004, without change.

**DATES:** *Effective date:* December 27, 2004.

**FOR FURTHER INFORMATION CONTACT:** Vance T. Morris, Director, Office of Single Family Program Development, Room 9278, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410-8000; telephone (202) 708-2121. (This is not a toll-free number.) Hearing- or speech-impaired persons may access this number by calling the toll-free Federal Information Relay Service number at 1-800-877-8339.

**SUPPLEMENTARY INFORMATION:**

**I. Background—HUD's November 21, 2003, Interim Rule**

On November 21, 2003 (68 FR 65824), HUD published an interim rule codifying the procedures that mortgagees and automated underwriting system vendors must follow if they opt to use the "Technology Open to Approved Lenders" (TOTAL) Mortgage Scorecard offered by the Federal Housing Administration (FHA). The TOTAL Mortgage Scorecard (or Scorecard) developed by HUD assesses the credit worthiness of FHA mortgagees by evaluating certain mortgage application and mortgagor credit information that has been statistically proven to accurately predict the likelihood of mortgagor default. The TOTAL Mortgage Scorecard is not an automated underwriting system (AUS); rather, it is a mathematical equation intended for use within an AUS.

The November 21, 2003, interim rule followed a December 6, 2000 (65 FR 76273) **Federal Register** notice announcing HUD's intention to deploy the FHA TOTAL Mortgage Scorecard. The objectives for use of the TOTAL

Mortgage Scorecard, which were first stated in the Notice are (1) to provide an improved credit evaluation system for FHA loans that has been statistically proven to accurately predict the likelihood of mortgagor default while providing a uniform system protective of borrowers; (2) to expand access to mortgage credit for low- and moderate-income mortgagors and discourage unlawful discrimination against mortgagors protected by the Fair Housing Act and the Equal Credit Opportunity Act; (3) to facilitate access to, and reduce the cost and time associated with, originating HUD/FHA-insured mortgages; and (4) to encourage a standardized, industry-wide capability for communication and exchange of information among members of the mortgage lending community.

The December 6, 2000, Notice also advised that after deployment of the TOTAL Mortgage Scorecard, HUD would require use of the Scorecard in any AUS. The Notice also indicated that users of the TOTAL Mortgage Scorecard would receive documentation relief and credit policy waivers provided by HUD. Further, the Notice advised that HUD also had developed a Use Agreement that established the requirements and responsibilities for implementation and use of the TOTAL Mortgage Scorecard by qualified mortgagees and others that purchase, sell, underwrite, or document HUD mortgage loans for mortgagees under HUD's Direct Endorsement program.

While HUD could have continued, through individual approvals, to authorize organizations to use the TOTAL Mortgage Scorecard, HUD decided that a more efficient course of action would be to promulgate regulations for the use of the Scorecard consistent with the purpose and objectives described above instead of executing individual approvals that establish the requirements and responsibilities for use of the Scorecard. Accordingly, HUD issued the November 21, 2003, interim rule.

The interim rule revised HUD's regulation at 24 CFR 203.251 to define the acronym "TOTAL" and revised § 203.255 to establish specific requirements that mortgagees and vendors must abide by when using the TOTAL Mortgage Scorecard. The interim rule described the Scorecard requirements in order to assist the mortgagor in expediting the endorsement process. While the Scorecard is a valuable tool, its value depends on approved lenders properly using the Scorecard in accordance with HUD requirements and procedures. The preamble to the November 21, 2003,