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.

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 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*.

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: