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 determined under 21 CFR 25.33(a)(2) 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 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 (f)(3)(ii) and (f)(3)(xii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(ii) *Amount per ton*. Monensin, 5 to 40 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use*. Cattle fed in confinement for slaughter: For improved feed efficiency; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

(*b*) *Limitations*. Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 480 milligrams of monensin and 60 to 90 milligrams of tylosin per head per day. Combination drug liquid Type B medicated feeds may be used to manufacture dry Type C medicated feeds and shall conform to mixing instructions as in § 558.625(c) of this chapter.

* * * * *

(xii) *Amount per ton*. Monensin, 10 to 40 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use*. Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

(*b*) *Limitations*. Feed only to cattle being fed in confinement for slaughter. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligrams monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day; and 60 to 90 milligrams of tylosin per head per day.

* * * * *

Dated: November 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–23519 Filed 12–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Monensin USP

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 removes the requirement for 30-day expiration on labeling of monensin Type C medicated feeds for several classes of cattle and goats.

DATES: This rule is effective December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@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 95–735 that provides for use of RUMENSIN 80 (monensin) Type A medicated articles. The supplement removes the requirement for 30-day expiration on labeling of monensin Type C medicated feeds for several classes of cattle and goats. The supplemental NADA is approved as of November 9, 2007, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

In addition, the regulations are being amended to remove a redundant entry for combination use of monensin USP and melengestrol acetate, with or without tylosin phosphate, in medicated feed for heifers fed in confinement for slaughter. 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.

The agency 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 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, remove and reserve paragraphs (d)(2), (d)(3), and (f)(3)(viii); and revise paragraph (f)(6)(i)(*b*)(*1*) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(6) * * *

(i) * * *

(*b*) * * *

(*1*) *Feed continuously*. Feed only to goats being fed in confinement. Do not

feed to lactating goats. Type C feeds may be manufactured from monensin liquid Type B feeds. The liquid Type B feeds have a pH of 4.3 to 7.1 and their labels must bear appropriate mixing directions, as defined in paragraph (d)(12) of this section. See special labeling considerations in paragraph (d) of this section.

* * * * *

Dated: November 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–23517 Filed 12–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF TRANSPORTATION

Federal Highway Administration

23 CFR Part 630

[FHWA Docket No. FHWA–2006–25203]

RIN 2125–AF10

Temporary Traffic Control Devices

AGENCY: Federal Highway Administration (FHWA), DOT.

ACTION: Final rule.

SUMMARY: The FHWA is adding a new Subpart K to 23 CFR part 630 to supplement existing regulations that govern work zone safety and mobility in highway and street work zones to include conditions for the appropriate use of, and expenditure of funds for, uniformed law enforcement officers, positive protective measures between workers and motorized traffic, and installation and maintenance of temporary traffic control devices during construction, utility, and maintenance operations. These regulations are intended to decrease the likelihood of fatalities and injuries to road users, and to workers who are exposed to motorized traffic (vehicles using the highway for purposes of travel) while working on Federal-aid highway projects. The regulations are issued in accordance with section 1110 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), Public Law 109–59, 119 Stat. 1227, codified at 23 U.S.C. 109(e) and 112(g).

DATES: *Effective Date:* December 4, 2008.

The incorporation by reference of certain publications listed in this rule is approved by the Director of the Federal Register as of December 4, 2008.

FOR FURTHER INFORMATION CONTACT: Mr. Chung Eng, Office of Transportation Operations, HOTO–1, (202) 366–8043; or Mr. Raymond W. Cuprill, Office of the Chief Counsel, HCC–30, (202) 366–0791, U.S. Department of Transportation, Federal Highway Administration, 1200 New Jersey Avenue, SE., Washington, DC 20590. Office hours are from 7:45 a.m. to 4:15 p.m., e.t., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Electronic Access

This document, the notice of proposed rulemaking (NPRM), and all comments received may be viewed online through the Federal eRulemaking portal at: *http://www.regulations.gov.* The Web site is available 24 hours each day, 365 days each year. Electronic submission and retrieval help and guidelines are available under the help section of the Web site.

An electronic copy of this document may also be downloaded from the Office of the **Federal Register**'s home page at: *http://www.archives.gov* and the Government Printing Office's Web page at: *http://www.access.gpo.gov/nara.*

Background

History

In 2004, the FHWA published a final rule updating its regulations on Work Zone Safety and Mobility (23 CFR 630, subpart J). Section 630.1006 of subpart J (Work Zone Safety and Mobility Policy) stated that ''Each State shall implement a policy for the systematic consideration and management of work zone impacts on all Federal-aid highway projects. This policy shall address work zone impacts throughout the various stages of the project development and implementation process. This policy may take the form of processes, procedures, and/or guidance, and may vary based on the characteristics and expected work zone impacts of individual projects or classes of projects. The States should institute this policy using a multidisciplinary team and in partnership with the FHWA. The States are encouraged to implement this policy for non-Federal-aid projects as well.'' This final rule on Temporary Traffic Control Devices provides additional guidance on the development of such Work Zone Safety and Mobility Policies, and specifically addresses the requirements of section 1110 of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users (SAFETEA–LU), Public Law 109–59, 119 Stat. 1227, which have been codified at 23 U.S.C. 109(e) and 112(g).

Section 109(e)(2) of title 23, United States Code, states that no funds shall be approved for expenditure on any Federal-aid highway ''unless proper temporary traffic control devices to improve safety in work zones will be installed and maintained during construction, utility, and maintenance operations on that portion of the highway with respect to which such expenditures are to be made. Installation and maintenance of the devices shall be in accordance with the Manual on Uniform Traffic Control Devices.'' Additionally, section 112(g)(1) requires that ''[t]he Secretary, after consultation with appropriate Federal and State officials, shall issue regulations establishing the conditions for the appropriate use of, and expenditure of funds for, uniformed law enforcement officers, positive protective measures between workers and motorized traffic, and installation and maintenance of temporary traffic control devices during construction, utility, and maintenance operations.''

A NPRM proposing the creation of a new Subpart K of 23 CFR part 630 was published on November 1, 2006, at 71 FR 64173. The purpose was to emphasize the need to appropriately consider and manage worker safety as part of the project development process by providing guidance on key factors to consider in reducing worker exposure and risk from motorized traffic. The FHWA proposed to require that each agency's policy for the systematic consideration and management of work zone impacts be established in accordance with the recently updated 23 CFR part 630 subpart J (effective October 12, 2007), and address the consideration and management of worker safety as follows:

1. Avoid or minimize worker exposure to motorized traffic through the application of appropriate positive protective strategies including, but not limited to, full road closures; ramp closures; crossovers; detours; and rolling road blocks during work zone setup and removal;

2. Where exposure cannot be adequately managed through the application of the above strategies, reduce risk to workers from being struck by motorized traffic through the use of appropriate positive protective devices;

3. Where exposure and risk reduction is not adequate, possible, or practical, manage risk through the application of appropriate intrusion countermeasures including, but not limited to, the use of uniformed law enforcement officers; and

4. Assure that the quality and adequacy of deployed temporary traffic control devices are maintained for the project duration.