

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 Parts 522 and 524

Animal drugs.

■ 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 522 and 524 are amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1662a [Amended]

■ 2. Section 522.1662a *Oxytetracycline hydrochloride injection* is amended in paragraph (k)(2) by removing "000864" and by adding in its place "061623".

■ 3. Section 522.1680 is amended in paragraph (b) by removing "000864" and by numerically adding "061623"; in paragraph (c) by removing the footnote; in paragraphs (c)(1)(i) and (c)(1)(ii) in the table headings by removing "ml" and by adding in its place "mL"; and by revising paragraphs (a) and (c)(3) to read as follows:

§ 522.1680 Oxytocin injection.

(a) *Specifications.* Each milliliter (mL) of solution contains 20 USP units oxytocin.

* * * * *

(c) * * *

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 4. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 524.1580b [Amended]

■ 5. Section 524.1580b *Nitrofurazone ointment* is amended in paragraph (b) by removing "000864".

Dated: June 3, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 03–15618 Filed 6–19–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF LABOR

Mine Safety and Health Administration

30 CFR Parts 56 and 57

RIN 1219–AA98 (Phase 6)

Seat Belts for Off-Road Work Machines and Wheeled Agricultural Tractors at Metal and Nonmetal Mines

AGENCY: Mine Safety and Health Administration (MSHA), Labor.

ACTION: Direct final rule; confirmation of effective date.

SUMMARY: MSHA issued a direct final rule to update its requirements for operator restraint systems (seat belts) for off-road work machines and wheeled agricultural tractors at metal and nonmetal mines. Two interested parties submitted comments raising issues outside the scope of the rulemaking. MSHA has determined that the comments submitted are not "significant adverse comments" and do not support withdrawal of the direct final rule. This document confirms the effective date for MSHA's direct final rule.

EFFECTIVE DATE: June 20, 2003.

The incorporation by reference of certain publications in this rule is approved by the Director of the Federal Register as of June 20, 2003.

FOR FURTHER INFORMATION CONTACT:

Marvin W. Nichols, Director; Office of Standards, Regulations, and Variances, MSHA; Phone: 202–693–9442; FAX: 202–693–9441; E-mail: nichols-marvin@msha.gov.

SUPPLEMENTARY INFORMATION:

I. Summary of Direct Final Rule

On April 21, 2003, MSHA issued a direct final rule (68 FR 19344) to update the Agency's requirements for operator restraint systems (seat belts) for off-road work machines and wheeled agricultural tractors at metal and nonmetal mines. The final rule requires seat belts for off-road work machines to meet the requirements of the Society of Automotive Engineers' (SAE) consensus standard SAE J386, *Operator Restraint System for Off-Road Work Machines* (1985, 1993, or 1997), as applicable. It also requires seat belts for wheeled agricultural tractors to meet the requirements of SAE J1194, *Roll-Over Protective Structures (ROPS) for Wheeled Agricultural Tractors* (1983, 1989, 1994, or 1999), as applicable. The direct final rule makes compliance easier and reduces burden for mine operators by allowing them to use the operator restraint systems provided by

manufacturers on new equipment, when they comply with more recent revisions of the incorporated SAE standards. These more recent revisions reflect advances in seat belt design and materials. The direct final rule does not reduce protection for miners.

MSHA determined that this rulemaking was suitable for a direct final rule because we did not expect that updating the metal and nonmetal seat belt standards, to include the revised SAE consensus standards, would elicit any significant adverse comments. The preamble to the direct final rule explained that—

A significant adverse comment is one that explains (1) why the direct final rule is inappropriate, including challenges to the rule's underlying premise or approach, or (2) why the direct final rule will be ineffective or unacceptable without a change.

II. Discussion of Comments on Seat Belt Requirements

MSHA received two comments on its direct final rule. Both comments suggest other seat belt standards for MSHA's consideration. MSHA fully considered both comments and determined that they were not "significant adverse comments." These comments can be viewed on MSHA's Web site at <http://www.msha.gov/regs/comments>.

One comment suggests that the direct final rule incorporate SAE J2292, *Combination Pelvic/Upper Torso (Type 2) Operator Restraint Systems for Off-Road Work Machines*. SAE J2292 is an Information Report, not a consensus standard. It provides guidance on three and four-point pelvic and upper torso operator restraint systems. MSHA does not require combination pelvic/upper torso operator restraint systems. SAE J2292 testing and performance criteria for the pelvic restraint portion of the operator restraint system, however, relies on SAE J386, the industry consensus standard incorporated into the direct final rule. MSHA determined that the comment is not a significant adverse comment because SAE J2292 relies on the same testing and performance criteria used in SAE J386 and requires seat belt assemblies to be labeled to indicate compliance with J386/J2292. This comment does not challenge the underlying premise of the direct final rule and there is no indication in the comment that the direct final rule would be ineffective or unacceptable without the change.

A second comment suggests that MSHA standards incorporate the Department of Transportation (DOT), National Highway Traffic Safety Administration's (NHTSA) performance specifications for seat belts. MSHA