these body systems at the third step of our sequential evaluation process after the current expiration date of these listings. In order to ensure that we continue to have regulatory criteria for assessing impairments under these listings, we find that it is in the public interest to make this final rule effective on the date of publication.

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that this final rule does not meet the criteria for a significant regulatory action under Executive Order (E.O.) 12866, as amended by E.O. 13258. We have also determined that this final rule meets the plain language requirement of E.O. 12866, as amended by E.O. 13258.

Regulatory Flexibility Act

We certify that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, a regulatory flexibility analysis, as provided in the Regulatory Flexibility Act, as amended, is not required.

Paperwork Reduction Act

This final rule imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: June 4, 2003.

Jo Anne B. Barnhart,

Commissioner of Social Security.

■ For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—[Amended]

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)-(h), 216(i), 221(a) and (i), 222(c), 223,225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)-(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

■ 2. Appendix 1 to subpart P of part 404 is amended by revising items 1, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14 and 15 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P of Part 404—Listing of Impairments

1. Growth Impairment (100.00): July 1, 2005

* * * * *

3. Special Senses and Speech (2.00 and 102.00): July 1, 2005
4. Respiratory System (3.00 and 103.00): July 1, 2005
5. Cardiovascular System (4.00 and 104.00): July 1, 2005
6. Digestive System (5.00 and 105.00): July 1, 2005
7. Genito-Urinary System (6.00 and 106.00): July 1, 2005
8. Hemic and Lymphatic System (7.00 and 107.00): July 1, 2005
9. Skin (8.00): July 1, 2005
10. Endocrine System (9.00 and 109.00): July 1, 2005
11. Multiple Body Systems (10.00): June 19, 2008 and (110.00): July 1, 2005
12. Neurological (11.00 and 111.00): July 1, 2005
13. Mental Disorders (12.00 and 112.00): July 1, 2005
14. Neoplastic Diseases, Malignant (13.00 and 113.00): July 1, 2005
15. Immune System (14.00 and 114.00): July 1, 2005

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[FR Doc. 03–15599 Filed 6–19–03; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 524

Dosage Form New Animal Drugs; Change of Sponsor; Technical Amendment

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 a change of sponsor for four approved new animal drug applications (NADAs) from Anthony Products, Co. to Cross Vetpharm Group, Ltd.

DATES: This rule is effective June 20, 2003.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6967, e-mail: *dnewkirk@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Anthony Products, Co., 5600 Peck Rd., Arcadia, CA 91006, has informed FDA that it has transferred ownership of, and all rights and interest in, the following four approved NADAs to Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland.

NADA Number	Trade Name	21 CFR Section
049–187	PHEN–BUTA (phenylbutazone) Vet Tablets; Phenylbutazone Tablets (Dogs)	520.1720a
122–447	FURA–SEPTIN (nitrofurazone) Soluble Dressing	524.1580b
130–136	Oxytocin Injection	522.1680
140–582	BIOCYL 50; BIOCYL 100 (oxytetracycline)	522.1662a

Accordingly, the agency is amending the regulations in §§ 522.1662a, 522.1680, and 524.1580b (21 CFR 522.1662a, 522.1680, and 524.1580b) to reflect the transfer of ownership. No amendment of 21 CFR 520.1720a is necessary as each sponsor owns additional phenylbutazone products.

In addition, § 522.1662a is being revised to reflect current format. This action is being taken to improve consistency between sections of the regulations.

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 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