

approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, Division of Eli Lilly and Co. The supplemental NADA provides for use of monensin Type A medicated articles to make a revised formulation of a free-choice Type C medicated feed for pastured cattle for increased rate of weight gain.

EFFECTIVE DATE: March 26, 1997.

ADDRESSES: Data and information filed to support previous approvals may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Russell G. Arnold, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1674.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, is the sponsor of NADA 95-735, which provides for use of a monensin Type A medicated article to make a monensin Type C medicated feed/free-choice mineral granule containing 1,620 grams monensin per ton to be fed at 50 to 200 milligrams per head per day free-choice to pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers) for increased rate of weight gain.

Elanco Animal Health, Division of Eli Lilly and Co. filed a supplemental NADA that provides for a revised formulation of the Type C medicated feed/free-choice granule to properly reflect the salt and mineral content of the product. The supplemental NADA is approved as of March 26, 1997, and the regulations are amended in 21 CFR 558.355(f)(3)(x)(b) to reflect the approval.

In addition, § 558.355(f)(3)(x)(b) is amended in the table to correct some editorial and typographical errors in the entry for "Ground limestone (33% calcium)" and in the entries for "6-01-080" and "4-04-152," respectively.

Approval of this supplement does not require a freedom of information summary because the approval concerns a change in salt and mineral content of the product. This change does not affect the product's safety or effectiveness. Therefore, no additional data was required for this approval. Data and information filed to support previous approvals may be seen in the Dockets Management Branch (HFA-305) (address above) between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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 an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in the table in paragraph (f)(3)(x)(b), in the first column, in the entry for "Ground limestone (33% calcium)" by adding the phrase "or calcium carbonate (38% calcium)" and in the third column in the first and third entries by removing the numbers "6-01-080" and "4-04-152" and adding in their place the numbers "6-01-082" and "4-04-695", respectively.

Dated: March 13, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 97-7551 Filed 3-25-97; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Change of Scientific Nomenclature

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of scientific nomenclature from *Corynebacterium* to *Actinomyces* (*Corynebacterium*). This change of nomenclature is necessary due to the scientific reclassification of the organism.

EFFECTIVE DATE: March 26, 1997.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1659.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., 2001 West Main St., P.O. Box 708, Greenfield, IN 46140, has informed FDA that the scientific nomenclature for the bacterial organism *Corynebacterium pyogenes* has been changed to *Actinomyces* (*Corynebacterium*) *pyogenes*. This change of nomenclature is necessary due to scientific reclassification of the organism. The organism causes liver abscesses in cattle. Accordingly, the agency is amending the regulations in 21 CFR 558.355(f)(3)(ii)(a) and (f)(3)(ix)(a) and 558.625(f)(1)(i)(b) to reflect this change.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.355 [Amended]

2. Section 558.355 *Monensin* is amended in paragraphs (f)(3)(ii)(a) and (f)(3)(ix)(a) by removing the word "*Corynebacterium*" and adding in its place the words "*Actinomyces* (*Corynebacterium*)".

§ 558.625 [Amended]

3. Section 558.625 *Tylosin* is amended in paragraph (f)(1)(i)(b) by removing the word "*Corynebacterius*" and adding in its place the words "*Actinomyces* (*Corynebacterium*)".

Dated: March 13, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 97-7603 Filed 3-25-97; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 920

[MD-040-FOR]

Maryland Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Maryland regulatory program (hereinafter referred to as the "Maryland program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Maryland proposed revisions and additions to its statutes pertaining to permit revocation, reinstatement, and reissuance. The amendment is intended to revise the Maryland program to be consistent with the corresponding Federal regulations and SMCRA.

EFFECTIVE DATE: March 26, 1997.

FOR FURTHER INFORMATION CONTACT: George Rieger, Program Manager, OSM, Appalachian Regional Coordinating Center, 3 Parkway Center, Pittsburgh, PA 15220. Telephone: (412) 937-2153.

SUPPLEMENTARY INFORMATION:

- I. Background on the Maryland Program
- II. Submission of the Proposed Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

I. Background on the Maryland Program

On December 1, 1980, the Secretary of the Interior conditionally approved the Maryland program. Background information on the Maryland program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the December 1, 1980, **Federal Register** (45 FR 79449). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 920.12, 920.15, and 920.16.

II. Submission of the Proposed Amendment

By letter dated August 5, 1996, (Administrative Record No. MD-575.00) Maryland submitted a proposed amendment to its program pursuant to SMCRA at its own initiative. House Bill 1124, enacted on May 14, 1996, revises the provisions of Chapter 522 of the Annotated Code of Maryland (Code) that pertain to surface coal mining. By letter dated November 26, 1996, (Administrative Record No. MD-575.03), Maryland clarified certain provisions of the proposed amendment. Because the information was explanatory in nature and did not constitute a major revision of the original submission, OSM did not reopen the comment period.

OSM announced receipt of the proposed amendment in the August 28, 1996, **Federal Register** (61 FR 44258),

and in the same document opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on September 27, 1996.

III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment. Revisions not specifically discussed below concern nonsubstantive wording changes and paragraph notations to reflect organizational changes resulting from this amendment.

Annotated Code of Maryland—Chapter 0522—Surface Coal Mining—Permit Revocation—Reinstatement

At section 15-514(a)(4), Maryland provides that if the Director revokes a permit and forfeits a bond, the operator of the permit forfeits: all rights and claims to the permit, all materials furnished with the permit application, and any subsequent amendments to the permit. The Director finds that the proposed revisions are not inconsistent with the general Federal requirements for permits at 30 CFR Part 773.

At new section 15-514.1, Maryland provides for the reinstatement and reissuance of revoked permits. At subsection (A), "permit" is defined to include all areas approved in the mining application. At subsection (B), a permit that has been revoked may be reinstated for the sole purpose of reissuing all or part of the permit to another qualified operator in accordance with subsection (C). At subsection (C), in order to qualify for a reissued permit, the operator shall: provide proof of the right to mine; enter into an agreement with the State to assume the duties and responsibilities of the permit and conduct mining operations in accordance with applicable requirements, regulations, and permit conditions; file the required performance bond; and provide any other required information to reissue the permit.

In its letter dated November 26, 1996, Maryland stated that its procedures for processing and reissuing a revoked permit will track the procedures for the transfer, sale, or assignment of permit rights specified in the Code of Maryland Administrative Regulations (COMAR) at 26.20.07.04. The applicant will be required to: submit an application for reissuance of a permit; comply with public notice requirements; and post a performance bond. Approval of the permit will be in accordance with the provisions of COMAR 26.20.07.04D.

The Director finds that the proposed revisions, when read with the corresponding regulations at COMAR 26.20.07.04, are not inconsistent with the general Federal provisions for the transfer, assignment, or sale of permits at 30 CFR 774.17.

IV. Summary and Disposition of Comments

Public Comments

The Director solicited public comments and provided an opportunity for a public hearing on the proposed amendment. No comments were received and because no one requested an opportunity to speak at a public hearing, no hearing was held.

Federal Agency Comments

Pursuant to 30 CFR 732.17(h)(11)(I), the Director solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the Maryland program. None were received.

Environmental Protection Agency (EPA)

Pursuant to 30 CFR 732.17(h)(11)(ii), OSM is required to obtain the written concurrence of the EPA with respect to those provisions of the proposed program amendment that relate to air or water quality standards promulgated under the authority of the Clean Water Act (33 U.S.C. 1251 *et seq.*) or the Clean Air Act (42 U.S.C. 7401 *et seq.*). None of the revisions that Maryland proposed to make in this amendment pertain to air or water quality standards. Therefore, OSM did not request EPA's concurrence.

The Federal regulations at 30 CFR Part 920, codifying decisions concerning the Maryland program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

V. Director's Decision

Based on the above findings, the Director approves Maryland's proposed amendment as submitted on August 5, 1996, and supplemented with additional explanatory information on November 26, 1996.

The Federal regulations at 30 CFR Part 920, codifying decisions concerning the Maryland program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to

encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

VI. Procedural Determinations

Executive Order 12866

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

Executive Order 12988

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12988 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory program provisions do not constitute major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. Accordingly, this rule will ensure that existing requirements previously promulgated by OSM will be implemented by the State. In making the determination as to whether this rule would have a significant economic

impact, the Department relied upon the data and assumptions for the corresponding Federal regulations.

Unfunded Mandates

This rule will not impose a cost of \$100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 Part CFR 920

Intergovernmental relations, Surface mining, Underground mining.

Dated: March 5, 1997.

Allen D. Klein,

Regional Director, Appalachian Regional Coordinating Center.

For the reasons set out in the preamble, Title 30, chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

PART 920—MARYLAND

1. The authority citation for Part 920 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

2. Section 920.15 is amended in the table by adding a new entry in chronological order by "Date of Final Publication" to read as follows:

§ 920.15 Approval of Maryland regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
August 5, 1996	March 26, 1997	M.C.A. §§ 15-514(a)(4), 15-514.1.

[FR Doc. 97-7535 Filed 3-25-97; 8:45 am]
BILLING CODE 4310-05-M

30 CFR Part 935

[OH-236-FOR]

Ohio Abandoned Mine Land Reclamation Plan

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving, with certain exceptions, a proposed amendment to the Ohio abandoned mine land reclamation plan (hereinafter referred to as the "Ohio plan") under the Surface mining Control and

Reclamation Act of 1977 (SMCRA). Ohio proposed revisions and additions to its plan pertaining to acid mine drainage set aside program, water quality improvement, project eligibility, and remining incentives. The amendment is intended to revise the Ohio plan to be consistent with SMCRA, as amended.

EFFECTIVE DATE: March 26, 1997.

FOR FURTHER INFORMATION CONTACT: George Rieger, Field Branch Chief, Appalachian Regional Coordinating Center, OSM, 3 Parkway Center, Pittsburgh, PA 15220, Telephone: (412) 937-2153.

SUPPLEMENTARY INFORMATION:

- I. Background on the Ohio Plan
- II. Submission of the Proposed Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments

V. Director's Decision
VI. Procedural Determinations

I. Background on the Ohio Plan

On August 10, 1982, the Secretary of the Interior approved the Ohio plan. Background information on the Ohio plan, including the Secretary's findings, the disposition of comments, and the approval of the plan can be found in the April 15, 1994, **Federal Register** (59 FR 17930). Subsequent actions concerning the conditions of approval and amendments to the plan can be found at 30 CFR 935.25.

II. Submission of the Proposed Amendment

By letter dated March 19, 1996, (Administrative Record No. OH-2163) Ohio submitted a proposed amendment to its plan pursuant to SMCRA at its