

the Center for Veterinary Medicine, 21 CFR parts 520 and 558 are amended as follows:

**PART 520—ORAL DOSAGE FORM
NEW ANIMAL DRUGS NOT SUBJECT
TO CERTIFICATION**

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.1448 is amended by adding text to read as follows:

§ 520.1448 Monensin oral dosage forms.

Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the R_f value must be comparable to a reference standard (the R_f value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line). The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

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

4. Section 558.355 is amended by revising paragraph (a) to read as follows:

§ 558.355 Monensin.

(a) *Specifications.* Monensin, as the base or the sodium salt, contains a minimum of 90 percent monensin activity derived from monensin A and a minimum of 95 percent derived from monensin A plus B. Using thin layer chromatography, the R_f value must be comparable to a reference standard (the R_f value is the distance the spots travel from the starting line divided by the distance the solvent front travels from the starting line). The loss on drying is not more than 10 percent when dried in vacuum at 60 °C for 2 hours.

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Dated: January 29, 1990.

Robert C. Livingston,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 90-2433 Filed 2-1-90; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 522

**Implantation or Injectable Dosage
Form New Animal Drugs Not Subject
to Certification; Ivermectin Injection**

CFR Correction

In title 21 of the Code of Federal Regulations, parts 500 to 599, revised as of April 1, 1989, the revision of § 522.1192(d)(4)(ii) as published at 53 FR 27006, July 18, 1988, was incorrectly omitted. The correct text for this paragraph reads as follows:

§ 522.1192 [Corrected]

* * * * *

(d) * * *

(4) * * *

(ii) *Indications for use.* It is used in swine for treatment and control of gastrointestinal roundworms (adults and fourth-stage larvae) (large roundworm, *Ascaris suum*; red stomach worm, *Hyostrogylus rubidus*; nodular worm, *Oesophagostomum* spp.; threadworm, *Strongyloides ransomi* (adults only)); somatic roundworm larvae (threadworm, *Strongyloides ransomi* (somatic larvae)); lungworms (*Metastrongylus* spp. (adults only)); lice (*Haematopinus suis*); and mites (*Sarcoptes scabiei* var. *suis*).

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BILLING CODE 1505-01-D

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

**Schedules of Controlled Substances;
Placement of N,N-Dimethylamphetamine into Schedule I**

AGENCY: Drug Enforcement Administration, Justice.

ACTION: Final rule.

SUMMARY: This final rule is issued by the Administrator of the Drug Enforcement Administration (DEA) to place *N,N*-dimethylamphetamine into Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 801 *et seq.*). This action is based on findings made by the DEA Administrator, after review and evaluation of the relevant data by both DEA and the Assistant Secretary for Health, Department of Health and Human Services, that *N,N*-dimethylamphetamine meets the statutory criteria for inclusion in Schedule I of the CSA. Since this substance has been temporarily scheduled in Schedule I, the regulatory control mechanisms and criminal sanctions of Schedule I continue to be

applicable to the manufacture, distribution, importation and exportation and possession of this substance.

EFFECTIVE DATE: February 2, 1990.

FOR FURTHER INFORMATION CONTACT: Howard McClain, Jr., Chief, Drug Control Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307-7183.

SUPPLEMENTARY INFORMATION: On August 2, 1989, in a notice of proposed rulemaking published in the Federal Register (54 FR 31855) and after a review of relevant data, the Administrator of the Drug Enforcement Administration (DEA) proposed to place *N,N*-dimethylamphetamine into Schedule I of the CSA pursuant to 21 U.S.C. 811(a). At that time, the DEA Administrator submitted data which DEA gathered regarding *N,N*-dimethylamphetamine to the Assistant Secretary for Health, delegate of the Secretary of the Department of Health and Human Services. In accordance with 21 U.S.C. 811(b), the DEA Administrator also requested a scientific and medical evaluation and a scheduling recommendation for *N,N*-dimethylamphetamine from the Assistant Secretary for Health.

N,N-dimethylamphetamine had been temporarily placed into Schedule I of the CSA by the DEA Administrator on August 3, 1988 for a period of one year (53 FR 29232) using the temporary scheduling provisions of the CSA (21 U.S.C. 811(h)). The temporary scheduling of *N,N*-dimethylamphetamine subsequently was extended for six months until February 3, 1990 (54 FR 31815). The temporary scheduling of *N,N*-dimethylamphetamine was based on a finding by the DEA Administrator that such scheduling was necessary to avoid an imminent hazard to the public safety.

By letter dated January 19, 1990, the DEA Administrator received a scheduling recommendation for *N,N*-dimethylamphetamine from the Assistant Secretary for Health. The Assistant Secretary recommended that *N,N*-dimethylamphetamine be placed into Schedule I of the CSA based on a scientific and medical evaluation of the available data.

The notice of proposed rulemaking for *N,N*-dimethylamphetamine provided the opportunity for interested parties to submit comments, objections or requests for a hearing regarding the scheduling of *N,N*-dimethylamphetamine. No comments, objections or requests for a hearing were received.

N,N-dimethylamphetamine is *N,N*-alpha-trimethylbenzeneethanamine or *N,N*-alpha-trimethylphenethylamine. It is a close structural analogue of amphetamine, methamphetamine and *N*-ethylamphetamine, all psychomotor stimulants with demonstrated high abuse potentials.

Pharmacologically, *N,N*-dimethylamphetamine is a sympathomimetic amine which produces significant central nervous system stimulant effects. These effects are qualitatively similar to those produced by equipotent doses of amphetamine and methamphetamine. *N,N*-dimethylamphetamine is recognized as cocaine by rats trained to discriminate cocaine from saline and it is self-administered by monkeys trained to self-administer cocaine. *N,N*-dimethylamphetamine, similar to methamphetamine, produces neurotoxic effects on dopaminergic nerve terminals in rodents. In these tests, *N,N*-dimethylamphetamine is several times less potent than methamphetamine.

Since the summer of 1987, law enforcement agencies have seized at least 20 clandestine laboratories (18 in California and one each in Georgia and Iowa) which have produced *N,N*-dimethylamphetamine. Over 57 kg. of *N,N*-dimethylamphetamine and sufficient precursors to produce an additional 246 kg. were seized at these laboratories. Forensic chemists have identified *N,N*-dimethylamphetamine in drug evidence purchased or seized by law enforcement officials in California, Iowa, Alabama, Missouri, Colorado, Utah, Arizona, Kansas, Florida, Idaho and Georgia. *N,N*-dimethylamphetamine is currently a Schedule I controlled substance in California.

N,N-dimethylamphetamine is routinely sold on the street as methamphetamine or speed and individuals abusing it often do not know that they are taking *N,N*-dimethylamphetamine. Thus, injuries or adverse effects associated with the use of *N,N*-dimethylamphetamine are likely to be reported as methamphetamine or speed-related incidents. The pharmacological and toxicological profiles of *N,N*-dimethylamphetamine suggest that abuse of this substance will lead to health and safety problems similar to those produced by methamphetamine. Since *N,N*-dimethylamphetamine is produced in clandestine laboratories, additional health and safety risks are associated with this substance.

There are no commercial manufacturers or suppliers of *N,N*-dimethylamphetamine in the United States. The Food and Drug

Administration (FDA) has notified DEA that *N,N*-dimethylamphetamine is not approved for marketing in the United States and that there are no exemptions for investigational use of *N,N*-dimethylamphetamine in effect under the Federal Food, Drug and Cosmetic Act. A search of the scientific and medical literature uncovered no indications of current medical use of *N,N*-dimethylamphetamine in the United States.

Based on the investigation and review conducted by DEA and on the scientific and medical evaluation and recommendation of the Assistant Secretary for Health received in accordance with 21 U.S.C. 811(b) and after consideration of the factors listed in 21 U.S.C. 811(c) by DEA and the Assistant Secretary for Health, the DEA Administrator, pursuant to the provisions of 21 U.S.C. 811(a) and (b), finds that:

- (1) *N,N*-dimethylamphetamine has a high potential for abuse;
- (2) *N,N*-dimethylamphetamine has no currently accepted medical use in treatment in the United States; and
- (3) There is a lack of accepted safety for use of *N,N*-dimethylamphetamine under medical supervision.

These findings are consistent with the placement of *N,N*-dimethylamphetamine into Schedule I of the CSA.

All regulations applicable to Schedule I substances will continue to be effective as of February 2, 1990 with respect to *N,N*-dimethylamphetamine, which has been in Schedule I since August 3, 1988 pursuant to the temporary scheduling procedures of 21 U.S.C. 811(h). The current applicable regulations are as follows:

1. *Registration.* Any person who manufactures, distributes, delivers, imports or exports *N,N*-dimethylamphetamine or who engages in research or conducts instructional activities with respect to this substance, or who proposes to engage in such activities, must be registered to conduct such activities in accordance with parts 1301 and 1311 of title 21 of the Code of Federal Regulations.

2. *Security.* *N,N*-dimethylamphetamine must be manufactured, distributed and stored in accordance with §§ 1301.71-1301.76 of title 21 of the Code of Federal Regulations.

3. *Labeling and packaging.* All labels and labeling for commercial containers of *N,N*-dimethylamphetamine must comply with the requirements of §§ 1302.03-1302.05, 1302.07 and 1302.08 of title 21 of the Code of Federal Regulations.

4. *Quotas.* All persons required to obtain quotas for *N,N*-dimethylamphetamine shall submit applications pursuant to §§ 1303.12 and 1303.22 of title 21 of the Code of Federal Regulations.

5. *Inventory.* Every registrant required to keep records and who possesses any quantity of *N,N*-dimethylamphetamine shall take an inventory of all stocks of this substance on hand pursuant to §§ 1304.11-1304.19 of title 21 of the Code of Federal Regulations.

6. *Records.* All registrants required to keep records pursuant to §§ 1304.21-1304.27 of title 21 of the Code of Federal Regulations shall maintain such records on *N,N*-dimethylamphetamine.

7. *Reports.* All registrants required to submit reports pursuant to §§ 1304.34-1304.37 of title 21 of the Code of Federal Regulations shall do so regarding *N,N*-dimethylamphetamine.

8. *Order forms.* All registrants involved in the distribution of *N,N*-dimethylamphetamine shall comply with the order form requirements of §§ 1305.01-1305.16 of title 21 of the Code of Federal Regulations.

9. *Importation and exportation.* All importation and exportation of *N,N*-dimethylamphetamine shall be in compliance with part 1312 of title 21 of the Code of Federal Regulations.

10. *Criminal liability.* Any activity with respect to *N,N*-dimethylamphetamine not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act shall be unlawful.

Pursuant to title 5, United States Code, section 605(b), the Administrator of DEA certifies that the scheduling of *N,N*-dimethylamphetamine, as ordered herein, will not have a significant impact upon small businesses or other entities whose interests must be considered under the Regulatory Flexibility Act (Pub. L. 96-354). This action involves the control of a substance which has no legitimate medical use or manufacturer in the United States.

In accordance with the provisions of 21 U.S.C. 811(a), this scheduling action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, have been exempted from the consultation requirements of Executive Order 12612. It has been determined that this matter does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), the Administrator hereby orders that 21 CFR part 1308 be amended as follows:

PART 1308—[AMENDED]

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b).

2. Section 1308.11 is amended by adding paragraph (f)(3) as follows:

§ 1308.11 Schedule I.

(f) * * *
(3) *N,N*-dimethylamphetamine (also known as *N,N*, α -trimethylbenzeneethanamine; *N,N*, α -trimethylphenethylamine)—1480

§ 1308.11 [Amended]

3. Section 1308.11 is further amended by removing paragraph (g)(3).

Dated: January 29, 1990.

John C. Lawn,
Administrator Drug Enforcement Administration.

[FR Doc. 90-2392 Filed 2-1-90; 8:45 am]

BILLING CODE 4410-09-M

DEPARTMENT OF THE INTERIOR**Office of Surface Mining Reclamation and Enforcement****30 CFR Part 935****Ohio Permanent Regulatory Program; Revegetation; Correction**

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

ACTION: Final rule; correction.

SUMMARY: This document corrects the final rule notice published on December 15, 1989 (54 FR 51395) concerning an amendment to the Ohio regulatory program approved under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment (Program Amendment Number 25 Revised) concerned Ohio's use of average county yields for demonstrating cropland yield restoration and also

concerned information on Ohio's method of evaluating revegetation success.

FOR FURTHER INFORMATION CONTACT: Ms. Nina Rose Hatfield, Director, Columbus Field Office (614) 866-0578.

SUPPLEMENTARY INFORMATION:

I. Corrections

1. Reference to Ohio Administrative Code (OAC) section 1501:13-9-15(F)(12) in the first sentence of the second paragraph of Section II (Submission of Amendment) should be deleted. Ohio Program Amendment Number 25 Revised did not propose any changes to this rule concerning non-augmentative practices.

2. The last paragraph on page 51395 which continues on page 51396 should read as follows:

By letter dated May 24, 1988, Ohio submitted Program Amendment Number 34 (Administrative Record No. OH-1033). This amendment reiterated the changes first proposed in Program Amendment Number 25 Revised to OAC 1501:13-9-09 (A)(4) and (E)(3) and to OAC 1501:13-9-15(B), (F)(4)(b), (F)(5)(e)(i). Further, Program Amendment Number 34 revised OAC 1501:13-9-15(F)(5) (f) and (g) beyond the revisions earlier proposed in Program Amendment Number 25 Revised. Finally, Program Amendment Number 34 reiterated the administrative record information previously provided by Ohio in Program Amendment Number 25 revised in response to the required amendment at 30 CFR 935.16(h). OSM approved Program Amendment Number 34 on December 22, 1988 (53 FR 51543).

Therefore, the proposed revisions presented in Program Amendment Number 25 Revised concerning OAC 1501:13-9-09, OAC 1501:13-9-15, and the administrative record information regarding 30 CFR 935.16(h) will not be considered part of this rulemaking. As a result, the only proposed amendments which remain from the original submittal of proposed Program Amendment Number 25 Revised involve narrative information submitted in response to the required program amendments at 30 CFR 935.16 (f) and (g).

3. The first full paragraph on page 51396, which begins with the words "By letter dated April 17, 1987 . . .", should be deleted.

Dated: January 25, 1990.

Alfred E. Whitehouse,
Acting Assistant Director, Eastern Field Operations.

[FR Doc. 90-2426 Filed 2-1-90; 8:45 am]

BILLING CODE 4310-05-M

30 CFR Part 946**Virginia Regulatory Program—Bonding**

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is announcing approval of a proposed amendment to the Virginia regulatory program (hereinafter referred to as the Virginia program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The amendment pertains to changes in Virginia's Coal Surface Mining Reclamation Fund (hereinafter, Pool Bond Fund). The amendment is intended to improve the Pool Bond Fund's financial status and limit its liability by stiffening admission criteria, authorizing increased entrance fees under certain conditions, imposing renewal fees, and restricting highwall length and pit width. The changes will establish new requirements for Pool Bond Fund applicants to meet.

EFFECTIVE DATE: February 2, 1990.

FOR FURTHER INFORMATION CONTACT: Mr. W. Russell Campbell, Acting Director, Big Stone Gap Field Office, Office of Surface Mining Reclamation and Enforcement, P.O. Box 628, room 220, Powell Valley Square Shopping Center, Route 23, Big Stone Gap, Virginia 24219; telephone (703) 523-4303.

SUPPLEMENTARY INFORMATION:

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

I. Background on the Virginia Program

The Secretary of the Interior conditionally approved the Virginia program on December 15, 1981. Information pertinent to the general background and revisions to the Virginia program submission, as well as the Secretary's findings, the disposition of comments and a detailed explanation of the conditions of approval, can be found in the December 15, 1981, *Federal Register* (46 FR 61088-61115). Subsequent actions concerning the conditions of approval and proposed amendments are identified at 30 CFR 946.12, 946.13, 946.15, and 946.16.

II. Submission of Amendment

By letter dated July 5, 1989 (Administrative Record No. VA-729), Virginia submitted a proposed amendment consisting of amended