

withdrawal time for new animal drugs to be used in sheep. The proposed rule is therefore expected to lower research expenses and provide an impetus for sponsors to submit supplemental NADA's for sheep. More specifically, it would eliminate the need for a total residue metabolism study that can be costly and prohibitive for sponsors of new animal drugs for small markets such as sheep. FDA believes this study is unnecessary in this instance due to the similarities in the metabolism of most drugs in cattle and sheep. Adopting the approach that allows for interspecies data extrapolation, along with the tissue residue depletion studies, would encourage NADA submissions by decreasing research costs while continuing to protect human food safety. Apart from these cost savings, FDA does not expect this proposal to impose any other compliance burdens on sponsors of new animal drugs.

#### IX. Regulatory Flexibility Analysis

The proposed rule is intended to reduce research costs for sponsors of NADA's for animal drugs used in sheep while maintaining the necessary safeguards concerning animal drug residues in human food. FDA estimates that this rule will not result in any compliance costs on the affected industry, regardless of the size of the companies involved. Further, FDA estimates that the rule will result in cost savings to sponsors of NADA's for animal drugs for use in sheep. In addition, most NADA sponsors would not be considered small businesses according to the standards of the Small Business Administration. Thus, in accordance with the Regulatory Flexibility Act, FDA certifies that this proposed rule would not have a significant economic effect on a substantial number of small entities.

#### X. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any expenditure by State, local, and tribal governments, in the aggregate, or by the private sector of \$100 million (adjusted annually for inflation) in any one year. The publication of the proposal to reclassify sheep as a minor species for all data collection purposes is not expected to result in expenditures of funds by State, local, and tribal governments or the private sector in excess of \$100 million in any one year. Because the agency estimates no compliance costs and

modest cost savings due to the proposed rule, FDA is not required to perform a cost/benefit analysis according to the Unfunded Mandates Reform Act.

#### XI. The Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### XII. Comments

Interested persons may, on or before October 25, 1999, submit to the Dockets Management Branch (address above), written comments regarding this proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

#### XIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Food and Drug Administration, "Guidance for Industry: FDA Approval of New Animal Drugs for Minor Uses and for Minor Species," Guidance No. 61, January 1999.
2. Short, C. R., "Consideration of Sheep as a Minor Species: Comparison of Drug Metabolism and Disposition with Other Domestic Ruminants," *Veterinary and Human Toxicology*, vol. 36, No. 1, pp. 24-40, February 1994.

#### List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 514 be amended as follows:

#### PART 514—NEW ANIMAL DRUG APPLICATIONS

1. The authority citation for 21 CFR part 514 continues to read as follows:

**Authority:** 21 U.S.C. 351, 352, 360b, 371, 379e, 381.

2. Revise § 514.1 in paragraph (d)(1)(ii) to read as follows:

#### § 514.1 Applications.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(ii) *Minor species* means animals other than cattle, horses, swine, chickens, turkeys, dogs, and cats.

\* \* \* \* \*

Dated: July 15, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

[FR Doc. 99-18926 Filed 7-23-99; 8:45 am]

BILLING CODE 4160-01-F

#### DEPARTMENT OF THE INTERIOR

#### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 916

[SPATS No. KS-021-FOR]

#### Kansas Regulatory Program

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing.

**SUMMARY:** The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of an amendment to the Kansas regulatory program (Kansas program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Kansas is proposing to condense and revise its previously approved revegetation success guidelines. The amendment is intended to revise the Kansas program to be consistent with the corresponding Federal regulations and to improve operational efficiency.

This document gives the times and locations that the Kansas program and the amendment to that program are available for public inspection, the comment period during which you may submit written comments on the proposed amendment, and the procedures that will be followed for the public hearing, if one is requested.

**DATES:** We will accept written comments until 4:00 p.m., c.d.t., August 25, 1999. If requested, we will hold a public hearing on the amendment on August 20, 1999. We will accept requests to speak at the hearing until 4:00 p.m., c.d.t. on August 10, 1999.

**ADDRESSES:** You should mail or hand deliver written comments and requests to speak at the hearing to John Coleman, Mid-Century Regional Coordinating Center, at the address listed below.

You may review copies of the Kansas program, the amendment, a listing of any scheduled public hearings, and all written comments received in response

to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Mid-Continent Regional Coordinating Center.

John Coleman, Mid-Continent Regional Coordinating Center, Office of Surface Mining, Alton Federal Building, 501 Belle Street, Alton, Illinois, 62002, Telephone: (618) 463-6460.

Kansas Department of Health and Environment, Surface Mining Section, 4033 Parkview Drive, Frontenac, Kansas 66763, Telephone (316) 231-8540.

**FOR FURTHER INFORMATION CONTACT:** John Coleman, Mid-Continent Regional Coordinating Center. Telephone: (618) 463-6460. Internet: jcoleman@mcrgw.osmre.gov.

#### **SUPPLEMENTARY INFORMATION:**

### **I. Background on the Kansas Program**

On January 21, 1981, the Secretary of the Interior conditionally approved the Kansas program. You can find general background information on the Kansas program, including the Secretary's findings, the disposition of comments, and the conditions of approval in the January 21, 1981, **Federal Register** (46 FR 5892). You can find later actions concerning the Kansas program at 30 CFR 916.10, 916.12, 916.15, and 916.16.

### **II. Description of the Proposed Amendment**

By letter dated July 12, 1999 (Administrative Record No. KS-616), the Kansas Department of Health and Environment, Surface Mining Section (SMS) sent us an amendment to the Kansas program under SMCRA. The SMS sent the amendment in response to deficiencies that we identified in Kansas' revegetation success guidelines in a final rule decision on August 19, 1992 (57 FR 37430). The amendment also includes changes made at the SMS's own initiative. The SMS proposes to amend the Kansas revegetation success guidelines entitled "Revegetation Standards for Success and Statistically Valid Sampling Techniques for Measuring Revegetation Success." A brief summary of the changes are discussed below. The full text of the program amendment is available for your inspection at the locations listed above under **ADDRESSES**.

#### *1. Preface*

Kansas revised the preface to reflect the current revisions to its revegetation success guidelines. Kansas also removed language from the preface that was not approved by us in the August 19, 1992, final rule decision. The removed

language appeared to exempt specific permits from possible revisions to reflect the success standards and sampling techniques in Kansas' revegetation success guidelines.

#### *2. Introduction*

Kansas made minor revisions to the existing language and added the following new paragraph:

In adopting the aforementioned references, the operator is required to use a statistically valid sampling technique at a 90% or greater statistical confidence as approved by the SMS in consultation with the United States Department of Agriculture (USDA), Natural Resource Conservation Service (NRCS). Furthermore, success standards for each permit will be based on the most current county survey in place at the time of the permit's issuance.

#### *3. Definitions*

Kansas defined the following terms that are used throughout the Kansas revegetation success guidelines: A.U.M.; Cropland; Diverse; Effective; Forage; Historically Cropped; KDWP; KSU; NRCS; Permanent; Previously Mined; Prime Farmland; and SMS.

#### *4. Tables*

Kansas added four new tables. Table 1 contains productivity and ground cover vegetation requirements for Phase II and Phase III bond release of pasture land and grazing land; wildlife habitat, recreation, shelter belts, and forest products; and industrial, commercial, or residential land uses. Table 2 lists productivity and ground cover vegetation requirements for Phase II and Phase III bond release of prime farmland. Table 3 contains productivity and ground cover vegetation requirements for Phase II and Phase II bond release of cropland. Table 4 provides the suggested minimum number of samples by size of area being evaluated for corn, soybeans, wheat/oats, sorghum, and forage crops.

#### *5. Chapter I. Ground Cover Success*

Kansas consolidated the substantive provisions of its currently approved ground cover success standards for all land uses in this chapter. Section A covers the standard for ground cover on topsoiled areas. Section B discusses the standard for ground cover on previously mined areas. Section C provides the standard for ground cover on wildlife habitat areas. Section D contains standards for ground cover on industrial, commercial, or residential areas with topsoil. Sections E and F provide general information on ground cover sampling criteria and techniques. Section G contains specific pre-mining ground cover sampling techniques.

Section H provides specific post-mining ground cover sampling criteria. Finally, Section I covers specific post-mining ground cover sampling techniques.

#### *6. Chapter II. Forage Production Success Standard*

Kansas revised and consolidated the substantive provisions of its currently approved forage production success standards for all applicable land uses in this chapter. Kansas also added whole field harvest to the methods of data collection for forage. Section A discusses the use of the USDA-NRCS crop yield database that is listed by soil mapping units in the published county soil surveys for Kansas and the USDA-NRCS database in the Technical Guide Notice KS-145 (Appendix B). Section B contains information on methods of calculation using the Animal Unit Month (A.U.M.) values listed in the USDA-NRCS soil surveys for Kansas. Section C provides productivity standards for prime farmland forage crops. Section D covers the productivity standard for previously mined lands reconstructed to pasture and grazing land. Section E contains information on the productivity standard for pasture and grazing land. Section F discusses the use of representative areas, with test plots, or whole field harvesting as methods for data collection. Section G contains forage crop production sampling criteria. Finally, Section H provides forage crop production sampling techniques.

#### *7. Chapter III. Productivity Standard Databases for Row Crops*

Kansas revised and consolidated the substantive provisions of its currently approved row crop production success standards for prime and non-prime farmland in this chapter. Kansas also added corn as an acceptable row crop. Section A discusses the acceptable row crops for revegetation productivity. Section B contains information on the method of row crop production success standard calculations. Section C provides row crop sampling criteria. Section D contains methods for data collection involving representative areas, with test plots, and whole field harvesting. Section E provides productivity sampling criteria for prime farmland row crops. Section F discusses productivity sampling criteria for non-prime farmland cropland row crops. Finally, Section G contains row crop sampling techniques involving test plots and whole field harvest for grain sorghum (milo), wheat, soybeans, and corn. In response to deficiencies that we identified in the August 19, 1992, final rule decision on Kansas' current

revegetation success guidelines, Kansas revised its row crop sampling techniques for grain sorghum and wheat to require a determination of statistical sample adequacy based on sample weights corrected to a standard moisture content.

#### 8. Chapter IV. Stem Density

Kansas consolidated its productivity success standards for trees and shrubs in this chapter. Section A discusses the general success standards for fish and wildlife habitat, recreation, shelter belts, and forest products land uses. Section B contains the Phase II and Phase III productivity success standards for these land uses. Section C provides information on productivity sampling criteria. Section D contains stem density sampling techniques. Section E discusses previously mined areas that are reclaimed to fish and wildlife habitat, recreation, shelter belts, or forest products land uses.

#### 9. References

Kansas listed the technical reports, studies and other documents used in developing its revegetation success guidelines.

#### 10. Appendix A, Plant Species List

This appendix lists plant species, tree species, shrub and vine species, and legume species. It lists the plant species that are unacceptable for all land uses, with the following exception. All plant species listed are acceptable for the fish and wildlife habitat land use unless they are marked with an asterisk (\*). It lists the acceptable tree species for fish and wildlife habitat, recreation, shelter belts, and forest products land uses. It also lists the acceptable shrub and vine species for fish and wildlife habitat, recreation, and shelter belt land uses. Finally, Appendix A lists the acceptable legume species based on land use for revegetation productivity and ground cover.

#### 11. Appendix B, Methods of Production Success Standard Calculations

Kansas is proposing a new Animal Unit Month (A.U.M.) value for use in calculating forage production. Kansas defines the A.U.M. as the monthly average pounds of forage needed to support each 1,000 pounds of cattle. Kansas submitted calculations and documentation to support an A.U.M. equal to 760 pounds. The documentation included two methods of calculating forage production based on A.U.M. per soil type for cool season grass seed mixtures and warm season grass seed mixtures. Appendix B also contains tables showing two methods of

calculating the success standard for grain sorghum by soil type and soybeans by soil type.

#### 12. Appendix C, Planting Reports

This appendix contains the following reports: Mining Section Planting Report; Cropland Seeding Report; Forage/Pastureland Seeding Report; Woodland/Wildlife Seeding and Planting Report; Wildlife Seeding Mixture Report; and Annual Production and Ground Cover Survey.

#### 13. Appendix D, Reference Area Criteria

Kansas moved its previously approved provisions for reference areas to Appendix D.

#### 14. Appendix E, Representative Sample Field Area Definition and Test Plot Criteria

This appendix discusses the use of data from representative sample field areas to prove row crop production success. This data is obtained from individual row crop test plots.

### III. Public Comment Procedures

Under the provisions of 30 CFR 732.17(h), we are requesting comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If we approve the amendment, it will become part of the Kansas program.

#### Written Comments

Your written comments should be specific and pertain only to the issues proposed in this rulemaking. You should explain the reason for any recommended change. In the final rulemaking, we will not necessarily consider or include in the Administrative Record any comments received after the time indicated under DATES or at locations other than the Mid-Continent Regional Coordinating Center.

#### Public Hearing

If you wish to speak at the public hearing, contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., c.d.t. on August 10, 1999. We will arrange the location and time of the hearing with those persons requesting the hearing. If you are disabled and need special accommodation to attend a public hearing, contact the individual listed under **FOR FURTHER INFORMATION CONTACT**. The hearing will not be held if no one requests an opportunity to speak at the public hearing.

You should file a written statement at the time you request the hearing. This will allow us to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to speak have been heard. If you are in the audience and have not been scheduled to speak and wish to do so, you will be allowed to speak after those who have been scheduled. We will end the hearing after all persons scheduled to speak and persons present in the audience who wish to speak have been heard.

#### Public Meeting

If only one person requests an opportunity to speak at a hearing, a public meeting, rather than a public hearing, may be held. If you wish to meet with us to discuss the amendment, request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings are open to the public and, if possible, we will post notices of meetings at the locations listed under **ADDRESSES**. We also make a written summary of each meeting a part of the Administrative Record.

### IV. Procedural Determinations

#### Executive Order 12866

The Office of Management and Budget (OMB) exempts this rule from review under Executive Order 12866 (Regulatory Planning and Review).

#### Executive Order 12988

The Department of the Interior has conducted the reviews required by section 3 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 State regulatory programs and program amendments 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

This rule does not require an environmental impact statement since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on 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. Therefore, this rule will ensure that existing requirements previously published 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*

OSM has determined and certifies under the Unfunded Mandates Reform Act (2 U.S.C. 1502 *et seq.*) that this rule will not impose a cost of \$100 million or more in any given year on local, state, or tribal governments or private entities.

#### **List of Subjects in 30 CFR Part 916**

Intergovernmental relations, Surface mining, Underground mining.

Dated: July 19, 1999.

#### **Brent Wahlquist,**

*Regional Director, Mid-Continent Regional Coordinating Center.*

[FR Doc. 99-18946 Filed 7-23-99; 8:45 am]

BILLING CODE 4310-05-P

## **DEPARTMENT OF THE INTERIOR**

### **Office of Surface Mining Reclamation and Enforcement**

#### **30 CFR Part 924**

[SPATS No. MS-015-FOR]

#### **Mississippi Regulatory Program**

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Proposed rule; public comment period and opportunity for public hearing.

**SUMMARY:** The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of an amendment to the Mississippi regulatory program (Mississippi program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Mississippi proposes revisions to regulations concerning formal hearings; bond release; hydrologic balance; cessation orders; formal review of citations; definitions; areas where mining is prohibited or limited; performance bonds; pre-blasting surveys; permitting; inspections; coal exploration; qualified laboratories; disposal of excess spoil; coal mine waste impounding structures; backfilling and grading; roads; and coal preparation plant performance standards. The State also proposes to correct typographical errors and make other non-substantive revisions. Mississippi intends to revise its program to be consistent with the corresponding Federal regulations.

This document gives the times and locations that the Mississippi program and the amendment to that program are available for your inspection, the comment period during which you may submit written comments on the amendment, and the procedures that will be followed for the public hearing, if one is requested.

**DATES:** We will accept written comments until 4:00 p.m., c.d.t., August 25, 1999. If requested, we will hold a public hearing on the amendment on August 20, 1999. We will accept requests to speak at the hearing until 4:00 p.m., c.d.t. on August 10, 1999.

**ADDRESSES:** You should mail or hand deliver written comments and requests to speak at the hearing to Arthur W. Abbs, Director, Birmingham Field Office, at the address listed below.

You may review copies of the Mississippi program, the amendment, a listing of any scheduled public hearings, and all written comments received in response to this document at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. You may receive one free copy of the amendment by contacting OSM's Birmingham Field Office.

Arthur W. Abbs, Director, Birmingham Field Office, Office of Surface Mining, 135 Gemini Circle, Suite 215, Homewood, Alabama 35209, Telephone: (205) 290-7282.

Department of Environmental Quality, Office of Geology, 2380 Highway 80 West, P.O. Box 20307, Jackson, Mississippi 39289-1307, Telephone: (601) 961-5500.

**FOR FURTHER INFORMATION CONTACT:** Arthur W. Abbs, Director, Birmingham Field Office. Telephone: (205) 290-7282. Internet: aabbs@balgw.osmre.gov.

#### **SUPPLEMENTARY INFORMATION:**

#### **I. Background on the Mississippi Program**

On September 4, 1980, the Secretary of the Interior approved the Mississippi program. You can find background information on the Mississippi program, including the Secretary's findings and the disposition of comments, in the September 4, 1980, **Federal Register** (45 FR 58520). You can find later actions on the program at 30 CFR 924.10, 924.15, 924.16, and 924.17.

#### **II. Description of the Proposed Amendment**

By letter dated July 1, 1999 (Administrative Record No. MS-0373), Mississippi sent us an amendment to its program pursuant to SMCRA. Mississippi sent the amendment in response to required program amendments at 30 CFR 924.16(f)-(h), (j), (k), (m), and (n). The amendment also includes changes made at Mississippi's own initiative. Mississippi proposes to amend the Mississippi Surface Coal Mining Regulations. Below is a summary of the changes proposed by Mississippi. The full text of the program amendment is available for your inspection at the locations listed above under **ADDRESSES**.

##### *A. Revisions required by 30 CFR 924.16(f)-(n)*

##### **1. Section 3301. Formal Hearing**

Mississippi proposes to revise paragraph (b) to read as follows:

Any party may file a petition for temporary relief from the Permit Board's action in conjunction with the filing of the request for a formal hearing or at any time before a final decision is issued by the Permit Board after a formal hearing.

##### **2. Section 4501. Procedures for Seeking Release of Performance Bond**

Mississippi proposes to revise paragraph (c) to clarify that Federal, State, and local governmental agencies which have special expertise with respect to any environmental, social, or economic impact involved in the coal mining operation are allowed to file written objections to the proposed bond release and to request public hearings.

##### **3. Section 5333. Hydrologic Balance: Surface- and Ground-Water Monitoring**

Mississippi proposes to revise paragraph (b)(3)(A) to require the operator to demonstrate that the coal mining operation has minimized