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 depletions 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

FDIA 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.


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) to read as follows:

§514.1 Applications.

(d)(1) * * *

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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 SM CRA. 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 included 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 is 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; KDWHP; 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 III bond release of prime farmland. 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 success guidelines and techniques. Section G contains specific pre-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 harvesting to the methods for 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 calculating 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 and 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...
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

The 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 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.


Brent Wahlquist,
Regional Director, Mid-Continet Regional Coordinating Center.

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

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 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.

FOR FURTHER INFORMATION CONTACT: Arthur W. Abbs, Director, Birmingham Field Office. Telephone: (205) 290-7282. Internet: abbsb@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.


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