(g) Replacing the fin spar, P/N’s 205–032–899-all dash numbers, 205–030–846-all dash numbers, or 205–032–851-all dash numbers, with an airworthy fin spar that has been demonstrated to the FAA to satisfy the structural fatigue requirements of repeated high torque events and approved by the Manager, FAA, Rotorcraft Standards Staff, constitutes a terminating action for the requirements of this AD.

(h) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, FAA, Regulations Group, Rotorcraft Standards Staff. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, FAA, Regulations Group.

Note 4: Information concerning the existence of approved fin spar configurations and alternative methods of compliance with this AD, if any, may be obtained from the Regulations Group.

(i) Special flight permits may be issued in accordance with §§21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the helicopter to a location where the requirements of this AD can be accomplished.

(j) This amendment becomes effective on January 11, 2000.

Issued in Fort Worth, Texas, on November 30, 1999.

Mark R. Schilling, Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 99–31675 Filed 12–6–99; 8:45 am]
BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Trimethoprim and Sulfadiazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Pharmacia & Upjohn Co. The ANADA provides for use of Trimoprim® (trimethoprim and sulfadiazine) powder for control of bacterial infections of horses during treatment of acute strangles, respiratory tract infections, acute urological infections, wound infections, and abscesses. ANADA 200–244 is approved as a generic copy of Macleod Pharmaceuticals, Inc.’s ANADA 200–033 Uniprim™ (trimethoprim and sulfadiazine) powder for horses. The ANADA is approved as of October 22, 1999, and the regulations in 21 CFR 520.2613 are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(o)(2)(i), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) 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.

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 Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegate to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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


§520.2613 [Amended]

2. Section 520.2613 Trimethoprim and sulfadiazine powder is amended in paragraph (b) by adding the phrase “000009 and” before “058711”.


Stephen F. Sundlof, Director, Center for Veterinary Medicine.

[FR Doc. 99–31571 Filed 12–6–99; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 918

[SPATS No. LA–018–FOR]

Louisiana Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is approving an amendment to the Louisiana program (Louisiana program) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Louisiana proposed revisions to and additions of statutes concerning requirements for permit applications, eligibility requirements for the Small Operator Assistance Program (SOAP), and permit exemptions. Louisiana intends to revise the Louisiana program to be consistent with SMCRA and the Louisiana Surface Mining Regulations.

EFFECTIVE DATE: December 7, 1999.


SUPPLEMENTARY INFORMATION:

I. Background on the Louisiana 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 Louisiana Program

On October 10, 1980, the Secretary of the Interior approved the Louisiana program. You can find background information on the Louisiana program, including the Secretary’s findings and the disposition of comments in the October 10, 1980, Federal Register (45 FR 67340). You can find later actions concerning the Louisiana program at 30 CFR 918.15 and 918.16.
II. Submission of the Proposed Amendment

By letter dated August 23, 1999 (Administrative Record No. LA-364), Louisiana sent us an amendment to its program under SMCRA. Louisiana sent the amendment, which amends the Louisiana Revised Statutes (R.S.) 30:907 and 927, at its own initiative.

We announced receipt of the amendment in the September 10, 1999, Federal Register (64 FR 49118). In the same document, we opened the public comment period and provided an opportunity for a public hearing or meeting on the adequacy of the amendment. The public comment period closed on October 12, 1999. Because no one requested a public hearing or meeting, we did not hold one.

III. Director's Findings

Following, under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are our findings concerning the amendment.

<table>
<thead>
<tr>
<th>Topic</th>
<th>State statute</th>
<th>Federal counterpart regulation and/or statute</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application requirements: description of the nature of cultural, historical, and archaeological resources.</td>
<td>R.S. 30:907(B)(18) .......... Sec. 507(b)(13) of SMCRA; 30 CFR 779.12(b) and 780.31.</td>
<td></td>
</tr>
<tr>
<td>Application requirements: description of fish and wildlife resources.</td>
<td>R.S. 30:907(B)(19) .......... Sec. 515(b)(24) of SMCRA; 30 CFR 780.16(a).</td>
<td></td>
</tr>
<tr>
<td>Application requirements: description of how the operator will minimize disturbances.</td>
<td>R.S. 30:907(B)(20) .......... Sec. 515(b)(24) of SMCRA; 30 CFR 780.16(b).</td>
<td></td>
</tr>
<tr>
<td>Eligibility requirements for the Small Operator Assistance Program (SOAP).</td>
<td>R.S. 30:907(C) ............... Sec. 507(c)(1) of SMCRA.</td>
<td></td>
</tr>
</tbody>
</table>

Because the above State statutes have the same meaning as the corresponding Federal statutes and/or regulations, we find that they are no less stringent than SMCRA and no less effective than the Federal regulations.

B. R.S. 30:907(B)(16) and (17)

Louisiana proposes to remove the provision at paragraph B(16) that requires an applicant to make information about coal seams, test borings, core samplings, or soil samples available to any person with an interest which is or may be adversely affected. Louisiana relocated the provision to new paragraph B(17).

We find that Louisiana's relocation of this provision does not render the Louisiana statutes any less stringent than SMCRA. Therefore, we are approving the modification.

C. R.S. 30:927(2)

Louisiana proposed to revise paragraph (2) by removing the language that allowed surface mining operations that disturbed two acres or less to be exempt from the requirements of Chapter 9. Louisiana then added a provision to allow a person mining other minerals to be exempt from the requirements of Chapter 9 if the amount of coal extracted incidental to the extraction of other minerals does not exceed sixteen and two-thirds percent of the total tonnage of coal and other minerals removed for purposes of commercial use or sale.

Pub. L. 100-34, signed into law May 7, 1987, repealed section 528(2) of SMCRA, which allowed surface mining operations that disturbed two acres or less to be exempt from the requirements of SMCRA. As Federal law, Pub. L. 100–34 invalidates any applicable State laws or regulations that would authorize persons to conduct surface coal mining operations of two acres or less without complying with SMCRA and the approved regulatory program. Thus, Louisiana's removal of the provision that would allow surface mining operations that disturbed two acres or less to be exempt from the requirements of Chapter 9 has no effect on its program. We therefore approve the removal of this provision as it does not render the Louisiana statutes any less stringent than SMCRA.

We also approve the addition of the new language at this section, which allows a person mining other minerals to be exempt from the requirements of Chapter 9 if the amount of coal extracted incidental to the extraction of other minerals does not exceed sixteen and two-thirds percent of the total tonnage of coal and other minerals removed for purposes of commercial use or sale. This language is substantively identical to the language found at Section 701(28)(A) of SMCRA and 30 CFR Part 702.

IV. Summary and Disposition of Comments

Public Comments

We requested public comments on the amendment, but did not receive any.

Federal Agency Comments

Under 30 CFR 732.17(h)(11)(i), we requested comments on the amendment from various Federal agencies with an actual or potential interest in the Louisiana program (Administrative Record No. LA–364-03).

By letter dated September 8, 1999 (Administrative Record No. LA–364-04), the Natural Resources Conservation Service responded to our request by stating that it had no comment on Louisiana's amendment. Also, by letter dated September 30, 1999 (Administrative Record No. LA–364-06), the U.S. Army Corps of Engineers responded to our request by stating that it found Louisiana's proposed amendment satisfactory.

Environmental Protection Agency (EPA)

Under 30 CFR 732.17(h)(11)(i), we are required to get a written agreement from the EPA for those provisions of the program amendment that relate to air or water quality standards issued 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 Louisiana proposed to make in this amendment pertain to air or water quality standards. Therefore, we did not ask the EPA to agree on the amendment.

Under 30 CFR 732.17(h)(11)(i), we requested comments on the amendment from the EPA (Administrative Record No. LA–364-01). The EPA did not respond to our request.

State Historical Preservation Officer (SHPO) and the Advisory Council on Historic Preservation (ACHP)

Under 30 CFR 732.17(h)(4), we are required to request comments from the SHPO and ACHP on amendments that may have an effect on historic...
properties. On September 1, 1999, we requested comments on Louisiana’s amendment (Administrative Record No. LA–364.02), but neither responded to our request.

V. Director’s Decision

Based on the above findings, we approve the amendment as sent to us by Louisiana on August 23, 1999. We approve the statutes that Louisiana proposed with the provision that they be published in identical form to the statutes sent to and reviewed by OSM and the public.

To implement this decisions, we are amending the Federal regulations at 30 CFR Part 918, which codify decisions concerning the Louisiana program. We are making this final rule effective immediately to expedite the State program amendment process and to encourage Louisiana to bring its program into conformity with the Federal standards. SMCRA requires consistency of State and Federal standards.

VI. 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 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(b)(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 918

Intergovernmental relations, Surface mining, Underground mining.

Dated: November 19, 1999.

Charles E. Sandberg,
Acting Regional Director, Mid-Continent Regional Coordinating Center.

For the reasons set out in the preamble, 30 CFR Part 918 is amended as set forth below:

PART 918—LOUISIANA

1. The authority citation for Part 918 continues to read as follows:

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

2. Section 918.15 is amended in the table by adding a new entry in chronological order by “Date of final publication” to read as follows:

§ 918.15 Approval of Louisiana regulatory program amendments.

* * * * *

Original amendment submission date Date of final publication Citation/description

August 23, 1999 December 7, 1999 R.S. 30:907(B)(16) through (20); (C); and 927(2).

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD11–99–017]

Drawbridge Operation Regulations; China Basin, Mission Creek, CA

AGENCY: Coast Guard, DOT.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Coast Guard has issued a temporary deviation to the regulations governing operation of the City and County of San Francisco 3rd Street (Lefty O’Doul) bascule bridge which spans the China Basin portion of Mission Creek (also known as the Channel Street Waterway) mile 0.0, in San Francisco, San Francisco County, California. The deviation specifies that the bridge need not open for the passage of vessels from December 1, 1999 through January 31, 2000. Normally, the 3rd Street Bridge opens on one-hour advance notice. The deviation is needed to allow the City and County of San Francisco and its contractors to complete bridge seismic retrofit and rehabilitation. That work requires the bridge to remain in the closed to navigation position.

DATES: The deviation is effective from 8 a.m., December 1, 1999 through 5 p.m., January 31, 2000.

FOR FURTHER INFORMATION CONTACT: Mr. Jerry Olmes, Bridge Management Specialist, Eleventh Coast Guard