DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Agri Laboratorics, Ltd. The supplemental ANADA provides for a new packet size and strength of oxytetracycline hydrochloride soluble powder used to make medicated drinking water.

DATES: This rule is effective August 11, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine, 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (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 Subject 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 redelegated 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:


§ 520.1660d [Amended]

2. Section 520.1660d is amended in paragraph (a)(6) by adding “Each 2.73 grams of powder contains 1 gram of OTC HCl (packet: 9.87 oz.)” after the last sentence.


Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY–216–FOR]

Kentucky Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: We are approving, with certain exceptions, an amendment to the Kentucky regulatory program (the “Kentucky program”) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Kentucky proposed revisions to the Kentucky Administrative Regulations (KAR) pertaining to water replacement, subsidence, bonding, definitions, hydrology, and permits. Kentucky revised its program to be consistent with the corresponding Federal regulations.


FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Telephone: (859) 260–8400. Internet address: bkovacic@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Kentucky Program

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, “a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of the Act” and rules and regulations consistent with regulations issued by the Secretary pursuant to the Act.” See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Kentucky program on May 18, 1982. You can find background information on the Kentucky program, including the Secretary’s findings, the disposition of comments, and conditions of approval in the May 18, 1982, Federal Register (47 FR 21404). You can also find later actions concerning Kentucky’s program and program amendments at 30 CFR 917.11, 917.12, 917.13, 917.15, 917.16 and 917.17.

II. Submission of the Proposed Amendment

By letter dated July 30, 1997 (administrative record no. KY–1410), Kentucky sent us, the Office of Surface Mining Reclamation and Enforcement (OSM), a proposed amendment to its program under SMCRA (30 U.S.C. 1201 et seq.). The amendment revises 405 KAR at Sections 8:001, 8:030, 8:040, 16:001, 16:060, 16:090, 16:100, 16:160,
We identified concerns relating to the proposed amendment in the September 5, 1997, Federal Register (62 FR 46933), and in the same document invited public comment and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on October 6, 1997. On November 14, 1997, a Statement of Consideration of public comments was filed with the Kentucky Legislative Research Committee. As a result of the comments and by letter dated March 4, 1998, Kentucky made changes to the original submission (administrative record no. KY–1422). The revisions were made at 405 KAR 8:040, 16:090, 18:060, and 18:210. By letter dated March 16, 1998, Kentucky made additional changes to the original submission (administrative record no. KY–1423). The revisions were made at 8:001, 8:030, 8:040, 16:001, 16:060, 16:090, 16:100, 16:160, 18:001, 18:060, 18:090, 18:100, 18:160, and 18:210. By letter dated July 14, 1998, Kentucky submitted a revised version of the proposed amendments (administrative record no. KY–1431). All the revisions, except for a portion of those submitted March 16, 1998, were announced in the August 26, 1998, Federal Register (63 FR 45430).

During our review of the amendment, we identified concerns relating to the provisions at 405 KAR 8:001, 8:030, 8:040, 16:001, 16:060, 16:090, 16:100, 16:160, 18:001, 18:060, 18:090, 18:100, 18:160, and 18:210. We notified Kentucky of the concerns by letter dated May 26, 2000 (administrative record no. KY–1479). Kentucky responded in a letter dated August 10, 2000, and submitted additional explanatory information (administrative record no. KY–1489). The explanatory information and those revisions not included in previous notices were announced in the June 5, 2002, Federal Register (67 FR 38621). On October 29, 2003, we asked Kentucky to clarify its notification procedures pertaining to water loss. Kentucky responded with an electronic message on the same day (administrative record no. KY–1604) with the requested information. Because the information clarified existing procedures and did not constitute a revision of the regulations or add new provisions, we did not reopen the comment period.

We addressed a portion of Kentucky’s revisions to the subsidence control regulations at 405 KAR 18:210 in a Federal Register final rule notice published on May 7, 2002 (67 FR 30549). The remaining subsidence issues will be discussed in this notice. We addressed a portion of Kentucky’s revisions at 405 KAR 16/18:090 Sections 1, 4 and 5 and added Section 6 pertaining to sedimentation ponds and “other treatment facilities” in a Federal Register final rule notice published on May 8, 2003 (68 FR 24644). Lastly, we addressed Kentucky’s revisions to its definitions of “impounding structure,” “impoundment,” and “other treatment facilities” at 405 KAR 8/16/18:001 and its impoundment and sedimentation pond regulations at 405 KAR 16/18:090 Sections 1 through 5, 16/18:100, and 16/18:160 in a Federal Register final rule notice published on July 17, 2003 (68 FR 42266).

III. OSM’s Findings

Following are the findings we made concerning the amendment under SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17. We are approving the amendment, with exceptions as described below. Any revisions that we do not specifically discuss below concern nonsubstantive wording or editorial changes.

[a] Revisions To Kentucky’s Rules That Have the Same Meaning as the Corresponding Provisions of the Federal Regulations

Kentucky proposed revisions to the following rules containing language that is the same as or similar to the corresponding sections of the Federal regulations.

<table>
<thead>
<tr>
<th>State rule</th>
<th>Subject</th>
<th>Federal counterpart</th>
</tr>
</thead>
<tbody>
<tr>
<td>405 KAR 8/18:001 Section 1(60) and (61)</td>
<td>Material Damage</td>
<td>30 CFR 701.5.</td>
</tr>
<tr>
<td>405 KAR 8/18:001 Section 1(65) and (67)</td>
<td>Noncommercial Building</td>
<td>30 CFR 701.5.</td>
</tr>
<tr>
<td>405 KAR 8/18:001 Section 1(69) and (68)</td>
<td>Occupied Residential Dwelling and Structures Related Thereto</td>
<td>30 CFR 701.5.</td>
</tr>
<tr>
<td>405 KAR 8/16/18:001 Section 1(86), (81) and (84).</td>
<td>Previously Mined Area</td>
<td>30 CFR 701.5.</td>
</tr>
<tr>
<td>405 KAR 8:040 Section 261(a) and (b)</td>
<td>Subsidence Control</td>
<td>30 CFR 784.20(a)(1) and (2).</td>
</tr>
<tr>
<td>405 KAR 8:040 Section 262(3a–d) and (l–l)</td>
<td>Subsidence Control</td>
<td>30 CFR 784.20(b), (b)(1–4) and (6–9).</td>
</tr>
<tr>
<td>405 KAR 18:210 Section 1(1–3)</td>
<td>Subsidence Control</td>
<td>30 CFR 817.121(a)(1), (2), (3) and (b).</td>
</tr>
<tr>
<td>405 KAR 18:210 Section 3(1–3)</td>
<td>Subsidence Control</td>
<td>30 CFR 817.121(c)(1–3).</td>
</tr>
<tr>
<td>405 KAR 18:210 Section 4(1–3)</td>
<td>Subsidence Control</td>
<td>30 CFR 817.121(d), (e) and (f).</td>
</tr>
</tbody>
</table>

Because these proposed rules contain language that is the same as or similar to the corresponding Federal regulations, we find that they are no less effective than the corresponding Federal regulations and can be approved.

[b] Revisions To Kentucky’s Rules That Are Not the Same as the Corresponding Provisions of the Federal Regulations

1. In the following sections, and their Federal counterparts, each rule contains a descriptive phrase followed by “including, but not limited to,” or a derivative of such language and then a list of examples. Kentucky proposes to delete the phrase “but not limited to” which follows “including” from each of these rules. Kentucky is not proposing to substantively revise the descriptive phrases in any of these rules, nor is it proposing any changes to the specific examples that should be considered as included within those descriptive phrases. The intent of the Federal rules, in each case, is to clarify the reach of the descriptive phrase and specify that certain items should be included while providing the authority to reach other unspecified terms if they also fall within the descriptive phrase of the rule. The word “including” is, by its very nature, not limiting; nor does it restrict the descriptive phrase of each rule. Therefore, having the phrase “but not limited to” in each of these rules could be considered redundant; although it does clarify that the listed examples are not all inclusive.

Kentucky, in its letter dated August 10, 2000, expresses concern that having the phrase “but not limited to” after the word “including” makes its rules too vague and open ended. Kentucky goes on to indicate that it believes the deletion of “but not limited to” in each of these rules significantly restricts its discretion, but does not necessarily eliminate it. We do not concur that the
phrase “but not limited to” makes these rules too vague and open ended because the reach of each rule is still proscribed by the descriptive phrase that precedes the list of examples. However, we do concur that Kentucky would still have the authority and discretion, under the proposed changes, to reach items not listed in the examples, when necessary. In fact, Kentucky would still have the obligation to do so when such items fall within the descriptive phrase of each rule. That is because the word “including” is not limiting nor has the descriptive phrase of each rule, which proscribes its reach, been revised. Based upon that understanding, we find these changes do not render the Kentucky program less effective than the Federal rules and can be approved. Should we, through future oversight, find that Kentucky is no longer, in fact, reaching items that should have been addressed by these regulations because they are not contained in the lists of examples, we will revisit the issue and may require an amendment to the Kentucky program to reinstate this phrase.

<table>
<thead>
<tr>
<th>State rule</th>
<th>Federal counterpart</th>
</tr>
</thead>
<tbody>
<tr>
<td>405 KAR 8/18:001 Section 1(20)—Definition of Coal Processing Plant</td>
<td>30 CFR 701.5.</td>
</tr>
<tr>
<td>405 KAR 8/18:001 Section 1(24)—Definition of Community or Institutional Building</td>
<td>30 CFR 761.5.</td>
</tr>
<tr>
<td>405 KAR 8:030/8:040 Section 11(2)(a)</td>
<td>30 CFR 779.12(b)(1)/783.12(b)(1).</td>
</tr>
<tr>
<td>405 KAR 8:030 Section 23(1)(g)</td>
<td>30 CFR 779.24(e).</td>
</tr>
<tr>
<td>405 KAR 8:030/8:040 Section 24(4)(e)</td>
<td>30 CFR 780.18(b)(5)/784.13(b)(5).</td>
</tr>
<tr>
<td>405 KAR 8:030 Section 27(2)(e)</td>
<td>30 CFR 780.35(b)(5).</td>
</tr>
<tr>
<td>405 KAR 8:040 Section 26(3)(e)</td>
<td>30 CFR 784.20(b)(5).</td>
</tr>
<tr>
<td>405 KAR 16/18:001 Section 1(53) and (55)—Definition of In Situ Process</td>
<td>30 CFR 701.5.</td>
</tr>
<tr>
<td>405 KAR 16:001 Section 1(99)—Definition of Significant, Imminent Environmental Harm</td>
<td>30 CFR 701.5.</td>
</tr>
<tr>
<td>405 KAR 16/18:060 Section 2(2)</td>
<td>30 CFR 816.45(b)/817.45(b).</td>
</tr>
</tbody>
</table>

2. In the following sections, Kentucky proposes to delete the phrase “but not limited to.” The Federal rules listed below do not include the phrase “but not limited to” or otherwise state that the requirements are not inclusive. Therefore, we find that the deletion of the phrase “but not limited to” does not render the Kentucky regulations listed below, less effective than the corresponding Federal regulations and can be approved.

<table>
<thead>
<tr>
<th>State rule</th>
<th>Federal counterpart</th>
</tr>
</thead>
<tbody>
<tr>
<td>405 KAR 8/16/18:001 Section 1(108), (98) and (100)—Definition of Sedimentation Pond</td>
<td>30 CFR 701.5.</td>
</tr>
<tr>
<td>405 KAR 8:030/040 Section 3(3)(d)(1)</td>
<td>30 CFR 778.14(c)(6).</td>
</tr>
<tr>
<td>405 KAR 8:030/040 Section 13(1)(b) and (3)</td>
<td>30 CFR 780.22(b)/784.22(b).</td>
</tr>
<tr>
<td>405 KAR 8:030/040 Section 14(5) and 15(5)</td>
<td>30 CFR 780.21(b)/784.14(b).</td>
</tr>
<tr>
<td>405 KAR 8:030/040 Section 37(1)(b)</td>
<td>30 CFR 780.23(b)/784.15(b).</td>
</tr>
<tr>
<td>405 KAR 16/18:060 Section 1(4)(b)</td>
<td>30 CFR 816.41(a)/817.41(a).</td>
</tr>
</tbody>
</table>

3. 405 KAR 8/16/18:001 Section 1(46) and (49)—Kentucky proposes revisions to its definition of “historically used for cropland,” by deleting the description of the term “acquisition” and reorganizing the remainder of the definition to provide a more straightforward reading. OSM approved the 1 definition of “historically used for cropland” in 1982. (47 FR 21409 (May 18, 1982)). Because Kentucky is adding the definition of “acquisition” to include the old description, we find that Kentucky’s proposed changes to its definition are no less effective than the Federal definition of “historically used for cropland” at 30 CFR 701.5 and can be approved.

4. 405 KAR 8:030/8:040 Section 4(3)—Kentucky proposes to delete these sections which read, “Nothing in this section shall be construed to afford the cabinet the authority to adjudicate property title disputes.” Kentucky stated in its August 10, 2000, response that the deletion of this subsection does not render Kentucky’s program less effective because there is nothing in the Kentucky statutes that gives Kentucky the authority to adjudicate property title disputes. Because Kentucky lacks the authority to decide property disputes and the Federal regulations at 30 CFR 778.15(c) do not provide the regulatory authority with the authority to adjudicate property rights disputes, we find that Kentucky’s proposed revisions are no less effective than the Federal regulations and can be approved.

5. 405 KAR 8:030 Section 12(4)—Kentucky revises this subsection to require that water quality analysis and sampling shall be conducted according to the 14th edition of Standard Methods for the Examination of Water and Wastewater or 40 CFR Parts 136 and 434. Kentucky’s regulations are substantively identical to the Federal regulations at 30 CFR 780.21(a), except the Federal regulation refers to the 15th edition of the publication. Because the 15th edition is not substantially different from the 14th edition, we find that Kentucky’s proposed revision is no less effective than the Federal regulation and can be approved.

6. 405 KAR 8:030/8:040 Section 16—Kentucky proposes to require that if the determination of probable hydrologic consequences (PHC) (required in Section 32) indicates that proposed surface or underground mining activities may proximately result in contamination, diminution, or interruption of a protected water source within the proposed permit area or adjacent area which is used for domestic, agricultural, industrial, or other legitimate use, then the application will identify and describe the adequacy and suitability of the alternative sources of water supply that could be developed for existing premining and approved postmining land uses. The Federal regulation at 30 CFR 780.21(e) also requires that if the PHC determination indicates that the surface coal mining operation results in contamination, diminution or interruption of a protected water source then the permit application must contain information on water availability and water sources. The Federal regulation at 30 CFR 784.14(e)(3)(iv) requires a PHC finding on whether or not underground mining activities conducted after October 24, 1992, may result in contamination, diminution or interruption of a well or spring that is used for protected water
supplies. Even though the Federal regulation for underground mining activities and section 720 of SMCRA do not explicitly include the terms “proximately result” we find the use of Kentucky’s term for both surface and underground mining activities is consistent with SMCRA.

Legislative history to a predecessor of Section 720 of SMCRA indicates that Congress believed Section 717(b) of SMCRA, which delineates water rights and replacement requirements for surface mining activities, would apply to underground mining. See H.R. Rep. No. 102-474 at 132 (1992). Section 717(b) uses the term “proximately resulting.” Thus, absent explicit Congressional intent to the contrary, we find that the most reasonable construction is to use “proximate result.” Accordingly, we find the proposed Kentucky regulations are no less effective than the Federal regulations at 30 CFR 784.14(e)(3)(iv) and can be approved. 7. 405 KAR 8:040 Section 32(3)(e)—Kentucky proposes to require that the determination of PHC in the permit application include a finding on whether the proposed mining activities may proximately result in contamination, diminution, or interruption of an underground or surface source of water within the permit or adjacent area that is used for domestic, agricultural, industrial, or other legitimate use at the time the application is submitted. Section 405 KAR 8:040 also requires that the finding should include underground mining activities after July 16, 1994. Even though the Federal regulation for underground mining activities does not explicitly include the terms “proximately result” we find the use of Kentucky’s term for both surface and underground mining activities is consistent with SMCRA. As discussed in the previous finding, we find that Kentucky’s proposed regulations are no less effective than the Federal regulations at 30 CFR 784.14(e)(3)(iii) and 784.14(e)(3)(iv) and can be approved.

Kentucky has stated to OSM that it does not have the statutory authority to enforce water replacement requirements prior to July 16, 1994. In implementing 30 CFR 843.25 [Energy Policy Act enforcement in States with approved State programs], OSM has previously found for the Kentucky regulatory program that “[f]or those underground mining activities conducted after October 24, 1992, and before July 16, 1994, and the provisions of 30 CFR 817.41(j).” 60 FR 38682, 38685 (July 28, 1995). Thus, where Kentucky cannot enforce the provisions of 30 CFR 817.41(j), OSM will continue to enforce the provisions of 30 CFR 817.41(j) for underground mining activities conducted after October 24, 1992, and before July 16, 1994. 8. 405 KAR 8:030/8:040 Section 34(1) and(4)—Kentucky proposes to change the term “coal processing waste” to “coal mine waste.” Kentucky’s regulations are nearly identical to the Federal regulations at 30 CFR 780.25(a) and (d) and 784.16(a) and (d). The Federal rules use the term “coal processing waste.” However, the Federal regulations at 30 CFR 701.5 define “coal mine waste,” in part, as “coal processing waste.” We, therefore, find that Kentucky’s proposed revisions are no less effective than the corresponding Federal regulation at 30 CFR 780.25(a) and (d), and 784.16(a) and (d) and can be approved. 9. 405 KAR 8:030/8:040 Section 34(2)—Kentucky proposes to delete subsection (b) and revise subsection (a) to require that temporary and permanent sedimentation ponds be designed to comply with the requirements of 405 KAR 16:090 and 16:100. The deleted requirement that mine reclamation plans comply with the requirements of the Mine Safety and Health Administration (MSHA) is added at subsection (3). We find that Kentucky’s proposed revisions are no less effective than the corresponding Federal regulations at 30 CFR 780.25(b) and 784.16(b) which also requires compliance with the applicable performance standards and can be approved.

10. 405 KAR 8:030/8:040 Section 34(3)—Kentucky proposes to require that the plans for permanent and temporary impoundments that are required to be submitted to MSHA also be submitted to Kentucky as part of the permit application. After the plan has been approved by MSHA, the permit applicant must submit a notarized copy of the final approved plan and any other MSHA-related correspondence or documents. The Federal regulations at 30 CFR 780.25(c)(2) and 784.16(c)(2) require the submission of the plans as part of the permit application. The regulations do not, however, specify that the final MSHA-approved plans be submitted. We find that this additional requirement does not render Kentucky’s program less effective than the corresponding Federal regulations and can be approved.

11. 405 KAR 8:030/8:040 Section 34(5)—Kentucky proposes to require the same as the proposed mine waste dams and embankments as those described above for impoundments. The Federal regulations at 30 CFR 780.25(e) and 784.16(e) require the submission of plans as part of the permit application. The regulations do not, however, specify that the final MSHA-approved plans be submitted. We find that Kentucky’s proposed requirements do not render the Kentucky program less effective than the corresponding Federal regulations and can be approved.

12. 405 KAR 8:030/8:040 Section 34(6)—Kentucky proposes to require that, if an impoundment or embankment structure is classified as Class B or C, or if it meets the size or other criteria of MSHA, the corresponding plan must include a stability analysis of each structure. The Federal regulations at 30 CFR 780.25(f) and 784.16(f) refer to the B or C dam classification criteria as specified in the Soil Conservation Service (currently the Natural Resource Conservation Service—NRCS) Technical Release No 60, Earth Dams and Reservoirs, 1985 (TR–60). Kentucky includes a reference to its counterpart criteria to TR–60: 405 KAR 7:09 and Section 5 and 4:030. Additionally, Kentucky proposes to delete the phrase “but not limited to” in reference to what a stability analysis must contain. We refer to our discussion at finding b–1 above in which we approved the deletion of the phrase. Accordingly, we find Kentucky’s proposed regulations are no less effective than the corresponding Federal regulations and can be approved.

13. 405 KAR 8:040 Sections 26(1)(c) and (1)(d)—Kentucky proposes to require that a permit application include an example of a letter by which the applicant proposes to notify owners of all structures for which a presubsidence survey is required under 405 KAR 18:210 Section 1(4). The application must also include a survey of the quantity and quality of each protected water supply within the permit and adjacent areas. The applicant must pay for the technical assessment or engineering evaluation used to determine the quantity and quality of a water supply and must provide copies of the survey and assessment or evaluation to the property owner and to Kentucky. If the owner disagrees with the survey results, he or she may submit any concerns in writing to the regulatory authority.

The Federal regulations at 30 CFR 784.20(a)(3) require the completion of a presubsidence survey prior to permit approval. The survey should include the condition of all non-commercial buildings or occupied residential dwellings that may be materially damaged as well as a survey of drinking, domestic and residential water supplies.
within the permit and adjacent areas. The Federal rules also require the applicant to supply copies to the property owner and the regulatory authority and to pay the costs of the assessment, etc. It should be noted, however, that the Federal regulations at 30 CFR 784.20(a)(3), as they pertain to the requirements to perform a survey of the condition of all noncommercial buildings or occupied residential structures that may be materially damaged within the areas encompassed by the applicable angle of draw, were suspended by OSM pursuant to an earlier court order. 64 FR 71653 (December 22, 1999).

Kentucky subsequently deleted 405 KAR 18:210 Section 1(4) because it was substantively identical to the suspended portion of the corresponding Federal regulation. OSM approved the deletion on May 7, 2002 (67 FR 30549). However, Kentucky is retaining its requirements with regard to a presubmission survey for water supplies. Therefore, we find 405 KAR 8:040 Section 26(1)(d) no less effective than the Federal rule because its requirements are the same as the Federal rule and can be approved. Because 405 KAR 8:040 Section 26(1)(c) relates to the presubmission structure survey requirement of 405 KAR 18:210, which was proposed as an amendment but then deleted, 8:040 Section 26(1)(c) has no effect and is not considered part of Kentucky’s proposed program.

14. 405 KAR 8:040 Section 32(1)(b)5—Kentucky proposes to require that each underground coal mining permit application include a description that identifies the protective measures to be taken to protect or replace the water supply of present users as required by 405 KAR 18:060 Section 12. Section 12 requires the permittee to provide a replacement water supply that is equivalent to the premining quantity and quality with an equivalent water delivery system. The Federal definition of “replacement of water supply” requires that the replaced water supply must be equivalent to premining quantity and quality with an equivalent delivery system. The replaced water supply is not subject to the current use, but to the premining supplies. 60 FR 16722, 16726 (March 31, 1995).

Kentucky acknowledged in its Statement of Consideration that the Kentucky statute (KRS 350.421) does not limit the replacement of water supplies to the uses in existence at the time of the permit issuance. Accordingly, Section 32(1)(b)5, when read together with 405 KAR 18:060 Section 12, is consistent with the Federal rules and can be approved.

15. 405 KAR 16:001 Section 1(63)/18:001 Section 1(62)—Kentucky proposes to delete the definition of “noxious plants.” Kentucky stated in its August 10, 2000, response that there is no official list of noxious plants for the State of Kentucky. The Federal regulations at 30 CFR 701.5 define “noxious plants” to mean “species included on official State lists of noxious plants for the State.” Because Kentucky has no official State list of noxious plants, and Kentucky still requires at 405 KAR 16/18:200 Section 1(5)(a) that plant species for revegetation must meet the applicable Federal laws for noxious plants, we find that Kentucky’s proposed deletion is not inconsistent with the Federal regulations which also require that a vegetative cover meet Federal noxious plant laws and regulations and can be approved.

16. 405 KAR 16/18:060 Section 4(1)—Kentucky proposes to revise its general hydrologic provisions to require “identifying, burying, and treating” materials in accordance with 405 KAR 16:18:190 Section 3. The Federal regulations at 30 CFR 816/817.41(f)(1)(i) require “identifying and burying and/or treating, when necessary, materials * * *” When we asked if this meant all three procedures would be required, Kentucky indicated in a letter dated August 10, 2000, that the Federal rules do not require all three actions and that section 3 prescribes the appropriate cover and treatment as necessary (administrative record no. KY–1489). As with the Federal rules, Kentucky’s proposed regulations do not require all three actions. Accordingly, we find that the revisions are no less effective than the Federal regulations and can be approved.

17. 405 KAR 16:060 Section 8 and 18:060 Section 12—Kentucky proposes to revise Section 8 and add Section 12 to establish requirements for the replacement of water supplies. At subsection (1)(a), Kentucky is required to promptly notify the permittee if the Natural Resources and Environmental Protection Cabinet (the Cabinet) receives a complaint alleging the permittee’s activities have adversely affected the complainant’s water supply. At subsection (1)(b), Kentucky is requiring the operator or permittee to promptly replace a water supply that has been adversely affected by the contamination, diminution or interruption proximately resulting from the mining operation. For underground mines, the replacement requirement is applicable to underground mining activities conducted after July 16, 1994. The Federal regulation at 30 CFR 816.41(h) requires the replacement of certain affected water supplies proximately resulting from surface mining activities. The Federal regulation at 30 CFR 817.41(j) requires prompt replacement of a more limited range of water supplies adversely affected by underground mining activities. As discussed in earlier findings, even though the Federal regulation for underground mining activities does not explicitly include the term “proximately resulting” we find that Kentucky’s use of that term for both surface and underground mining activities is not inconsistent with SMCRA. Accordingly, we find the proposed Kentucky regulations at subsections (1)(a) and (b) no less effective than the Federal regulations and can be approved. We would also note that SMCRA requires the enforcement of Section 720(a) as soon as it was enacted, which was October 24, 1992. Kentucky has stated to OSM that it does not have the statutory authority to enforce water replacement requirements prior to July 16, 1994. Thus, as we also stated earlier, “[for those underground mining activities conducted after October 24, 1992, and before July 16, 1994, OSM will enforce the provisions of 30 CFR 817.41(j).” 60 FR 38682, 38685 (July 28, 1995).

Kentucky also proposes to delete the existing requirement that the Cabinet shall issue a notice of noncompliance—Kentucky’s equivalent to a federal notice of violation—to the permittee or operator and order the replacement of the water supply if it determines that a protected water supply has been contaminated, diminished, or interrupted by the mining operation. Just because the water supply has been contaminated, diminished or interrupted by a mining operation, it is not a violation of SMCRA. A violation occurs under SMCRA when a permittee fails to replace the protected water supply. Kentucky must still issue, and still has the authority to issue, an NOV when a permittee does not timely replace a protected water supply. Thus, we are approving Kentucky’s deletion.

At subsection (2)(a), Kentucky establishes timetables for the replacement of a domestic water supply; within 48 hours for an emergency water supply, within two weeks for a temporary water supply and within two years for a permanent supply. The timetables are triggered by a notice from the Cabinet that the water supply was adversely impacted by mining. In an e-mail notification to OSM on October 29, 2003, (administrative record no. KY–1604), Kentucky clarified its citizen complaint process by stating that it sends an initial letter to provide notice
to the permittee that a complaint has been received. A second letter to the permittee follows Kentucky’s investigation and gives notice of the obligation to replace the water supply and provides the regulatory timeframes for replacement. If the permittee fails to replace the supply in accordance with the regulatory timeframes, an NOV is issued.

Section 720(a)(2) of SMCRE and 30 CFR 817.41(j) require the permittee to promptly replace any drinking, domestic, or residential water supply from a well or spring that was in existence at the time of permit application and that has been adversely affected by underground mining operations.

Additionally, the definition of “replacement of water supply” at 30 CFR 701.5 requires a permittee to replace water on a temporary and permanent basis and “is intended to apply to replacement of water supply under both Sections 717(b) and 720(c)(3)” (60 FR 16721, 16726 March 31, 1995). As discussed above in this finding, Kentucky’s proposed revisions specify timeframes for emergency, temporary, and permanent replacement of domestic water supplies. Because the proposed regulations include surface (16:060) and underground (18:060) mining operations, we find that these specific timeframes are sufficient to meet the requirement for replacement of water supplies on a temporary and permanent basis as mandated by the Federal rules. These revisions are sufficient to resolve the required amendment found at 30 CFR 917.16(m). We make this finding with the understanding that any drinking or residential water supply from a spring or well impacted by underground mining is considered a domestic water supply and is covered by the timeframes contained in 2(a). We are therefore removing the existing requirement at 30 CFR 917.16(m) that required Kentucky to amend its program to provide for the prompt replacement of water supplies.

At subsection 2(b), Kentucky is required to establish the replacement timetable on a case-by-case basis for water supplies other than domestic supplies. The Federal regulations at 30 CFR 816.41(h) and 817.41(j) do not specify a timetable for the replacement of these water supplies. Again, OSM finds that this subsection is not inconsistent with the Federal regulations and is approving it with the understanding that Kentucky does consider domestic water supplies covered by 2(a) to include any drinking or residential water supply from a well or spring in existence at the time of the permit application and that is adversely affected by underground mining operations.

At subsections 2(c) and (d), the replacement water supply must be of quantity and quality equivalent to the premining water supply and an equivalent water delivery system must be provided. At subsection 2(e), the permittee is required to pay, for a period of 20 years or other period agreed to by the permittee and owner, any operation and maintenance costs in excess of customary and reasonable operation and maintenance costs for the premining supply. Several alternative methods of payment are proposed. The Federal regulation at 30 CFR 701.5 defines “replacement of water supply” as “provision of water supply on both a temporary and permanent basis equivalent to premining quality and quantity * * * and payment of operation and maintenance costs in excess of customary and reasonable delivery costs for premining water supplies.” The maintenance costs may be paid “for a period agreed to by the permittee and the water supply owner.”

In the Federal rule preamble, we gave as an example, that in determining the useful life of a delivery system, 20 years may be a reasonable amount of time to calculate the lump sum payment by a permittee (60 FR at 16726). Kentucky has incorporated that 20-year timeframe directly into its regulations. However, the regulation also includes authority to modify that period when agreed to by the permittee and the owner. Accordingly, we find these subsections are no less effective than the Federal rule and can be approved.

At subsection (3), Kentucky establishes certain conditions under which it may not actually be necessary to replace a damaged water supply. If the affected water supply was not needed for the land use in existence at the time of loss, contamination, or diminution, and if the supply is not needed to achieve the postmining land use, replacement requirements may be satisfied by demonstrating that a suitable alternative water source is available and could feasibly be developed. With this approach, written concurrence from the owner of interest is required. The Federal definition of “replacement of water supply” also provides that a delivery system does not need to be replaced as long as it is demonstrated that a suitable alternative water source is available for future development. Accordingly, we find that Kentucky’s proposed regulations at subsection (3) are no less effective than the Federal regulation at 30 CFR 701.5 and can be approved.

At subsection (4)(a), Kentucky requires that if the permittee does not complete the water replacement within 90 days, he/she must post an additional performance bond to cover the replacement. Under certain conditions, the 90-day period may be extended up to one year. The Federal rule at 30 CFR 817.121(c)(5), which is applicable to underground mining operations, requires an adjustment to the bond amount for water supplies protected under 30 CFR 817.41(j), if water supplies are not replaced within 90 days of the occurrence, with an extension of the grace period for up to one year. The Federal regulations do not specify a timeframe for adjusting a bond when water supplies are affected by surface coal mining operations. Nonetheless, we find Kentucky’s provision for surface coal mining operations not inconsistent with the Federal requirements and we find that Kentucky’s surface and underground mining provisions for bonding of affected water supplies are no less effective than the Federal rule at 30 CFR 817.121(c)(5) and are approving the revisions.

At subsection (4)(b), Kentucky allows the permittee’s liability insurance coverage to take the place of additional bond coverage for the water supply, to the extent that applicable coverage is available. We find that Kentucky’s proposed regulations at subsections (4)(b) are consistent with and no less effective than the Federal regulation at 30 CFR 800.14(c), which allows liability insurance in lieu of a bond, and can be approved.

At subsection (4)(c), Kentucky provides for the prompt release of the additional bond amount after the water replacement has been completed successfully based on the permittee’s application and submitted information and Kentucky’s own investigation as appropriate. This proposal regarding release of additional bond addresses two aspects: first, when bond release may be granted for water replacement, and second, the process/requirements to be used in releasing the additional bond. The Federal rule for underground mining activities at 30 CFR 817.121(c)(5) expressly requires that the additional bond must be held “until the * * * replacement is completed.” There is no parallel regulation for surface coal mining operations. Nonetheless, that aspect of Kentucky’s proposed rules for surface and underground mining operations is consistent with and no less effective than the Federal rule. Unlike the Kentucky proposal, however, the Federal rule does not include a separate
bond release process as proposed by Kentucky. Instead, in response to comments that no bond release provisions were included in the Federal rule, the preamble states “procedures for bond release are set forth in sections 800.17 and 800.40.” 60 FR 16742. Generally, section 800.17 requires compliance with 30 CFR 800.40. Thus, it is clear that the bond release process of Section 800.40 is to be followed in releasing the additional bond. Because the Kentucky proposal circumvents much of that procedure, we are not approving the proposed rule to the extent that it provides for a less effective bond release process than the Federal rule. Kentucky’s existing approved bond release procedures will continue to be applicable to the release of bond following water replacement.

18. 405 KAR 18:001 Section (1)—Kentucky proposes to define “Angle of Draw” as the angle of inclination between the vertical at the edge of the underground mine workings and the point of zero vertical displacement at the edge of a subsidence trough. As noted in finding 8–13 above, the Federal regulations at 30 CFR 784.20(a)(3), as they pertain to the requirements to perform a survey of the condition of all noncommercial buildings or occupied residential structures that may be materially damaged within the areas encompassed by the applicable angle of draw, were suspended by OSM. Kentucky subsequently deleted 405 KAR 18:210 Section (14) because it was substantively identical to the suspended portion of the corresponding Federal regulations. OSM approved the deletion on May 7, 2002. Because the related regulations to which the definition of “Angle of Draw” pertained were deleted, the definition has no effect and OSM is not taking any action on this definition and it is not considered part of Kentucky’s approved program.

19. 405 KAR 18:210 Section 2(1) and (3)—Kentucky proposes to require that a permittee mail a notification to all owners and occupants of surface property and structures within the area above the underground workings at least 90 days prior to mining. The notification shall include at a minimum the specific areas in which mining will take place, dates that 2 specific areas are anticipated to be undermined and the location where the subsidence control plan may be examined. The Federal regulations at 30 CFR 817.122 require that a notification be made at least six months prior to mining, or within that period if approved by the regulatory authority. Because the regulatory authority has discretionary authority to alter the notification period and the notification includes those items listed in the Federal regulations, we find that Kentucky’s proposed regulations are no less effective than the Federal regulations and can be approved.

20. 405 KAR 18:210 Section 3(5)(a)—Kentucky proposes to require that the permittee obtain additional performance bond if subsidence-related material damage to land, structures, or facilities occurs. If repair or compensation is completed within 90 days, no additional bond is necessary. Kentucky may extend the grace period for up to one year. The proposed regulations are substantively identical to the Federal regulations at 30 CFR 817.121(c)(5) with one exception; the Federal regulations also require an additional performance bond if a protected water supply is affected. Kentucky, however, addresses this contingency at 405 KAR 16:060 Section 8 and 18:060 Section 12 at subsection 4(a) (see finding 8–17 above). We find that Kentucky’s proposed regulations at 18:210 Section 3(5)(a), when read in conjunction with the proposed regulations at 16:001 Section 12 and 18:060 Section 12, are no less effective than the corresponding Federal regulations and can be approved.

21. 405 KAR 18:210 Section 3(5)(b)—Kentucky proposes to allow the reduction of the additional performance bond required at Section 3(5)(a) by the amount of a permittee’s liability insurance applicable to subsidence damage. Such insurance would not prevent bond forfeiture under 405 KAR 10:050. The Federal rules allow a permittee to use a performance bond policy to cover the obligations under 30 CFR 817.121(c) instead of a performance bond. Because both the Federal and Kentucky regulations allow for the substitution of liability insurance in lieu of bonding, we find that Kentucky’s proposed regulation is no less effective than the Federal regulation at 30 CFR 800.14(c) and can be approved.

22. 405 KAR 18:210 Section 3(5)(c)—Kentucky proposes to provide for the prompt release of the additional bond amount described in Section 3(5)(a) if it determines that the permittee has satisfactorily completed the required repair or compensation. As discussed above in finding 8–17, at 405 KAR 16:060 Section 8 and 18:060 Section 12(4)(c), to the extent that this section provides a bond release process that is less effective than that contained in 30 CFR 800.40, we are not approving it. Kentucky proposes to require that a permittee submit an annual plan of existing subsidence conditions, underground workings that includes maps and descriptions of significant features, extraction ratios, protective measures, full extraction areas and other confidential information. Other maps may be used so long as all the required information is provided. The Federal regulation at 30 CFR 817.121(g) requires that a plan with the same information as required by Kentucky be submitted within a schedule approved by the regulatory authority. The Federal rules also provide that the operator may request confidentiality of information pursuant to 30 CFR 773.6(d). In the May 26, 2000, letter, we noted that Kentucky’s rules did not allow for confidentiality of submitted information. Kentucky, in its response dated August 10, 2000, stated that the procedures for requesting confidentiality are set forth in 405 KAR 8:010 Section 12. We find that Kentucky’s proposed regulations in conjunction with its clarification of confidentiality procedures are no less effective than the corresponding Federal regulations and can be approved.

[c] Revisions To Kentucky’s Rules With No Corresponding Federal Regulations

1. 405 KAR 8:001/16:001/18:001 Section 1(3)—Kentucky proposes to add the term “acquisition” and defines it as the purchase, lease, or option of the land for the purposes of conducting or allowing through resale, lease, or option, the conduct of surface coal mining and reclamation operations. This definition was formerly included in Kentucky’s definition of “historically used for cropland.” Kentucky submitted the definition in response to OSM’s finding on October 22, 1980, (45 FR 69947) that the term was not defined in Kentucky’s regulations. The Federal rules have no counterpart definition. However, the Federal rules define “historically used for cropland.” In that definition, OSM discusses the acquisition of lands citing the examples used by Kentucky in its definition of “acquisition.” Accordingly, we find that Kentucky’s proposed definition of the term is not inconsistent with the requirements of SMCRA and the Federal regulations and can be approved.

ASTM Standard D 388–77 is no less effective than the Federal rules. There is no Federal counterpart to Slake Durability Index. However, we find that Kentucky’s proposed regulations add specificity to the Kentucky program and are not inconsistent with the requirements of SMCRA and the Federal regulations and can be approved.

3. 405 KAR 8:030/8:040 Section 20(3)—Kentucky proposes to revise its requirement that wetland delineations in permit applications must be conducted in accordance with the Corps of Engineers Wetlands Delineation Manual, U.S. Army Corps of Engineers Regulatory Guidance Letter No. 90–7, National Lists of Plant Species that Occur in Wetlands and Biological Reports and Summary and List of Hydric Soils of the U.S., All Kentucky Counties. The Federal regulations at 30 CFR 780.16 and 784.21 require site specific resource information when the permit and adjacent areas are likely to include wetlands. However, the Federal regulations do not specify what the permittee must follow to delineate the wetlands. Because the wetland references provide an additional level of specificity, we find that Kentucky’s proposed regulations are not inconsistent with the requirements of SMCRA and the Federal regulations and can be approved.

4. 405 KAR 8:030 Section 38/8:040 Section 39—Kentucky proposes to incorporate by reference: Standard Methods for the Examination of Water and Wastewater, 1975; Corps of Engineers Wetlands Delineation Manual, 1987; U.S. Army Corps of Engineers Regulatory Guidance Letter No. 90–7, 1990; National Lists of Plant Species that Occur in Wetlands, and Biological Reports and Summary, 1988; and List of Hydric Soils of the United States, All Kentucky Counties, 1991. As previously stated, the Federal regulations at 30 CFR 780.21(a) and 784.14(a) refer to the 15th edition of the Standard Methods for the Examination of Water and Wastewater. Because the 15th edition is substantively different from the 14th edition, we find that Kentucky’s proposed incorporation by reference is less effective than the Federal regulations and can be approved.

Also as previously discussed, we find the remaining references add specificity to the Kentucky program and are not inconsistent with the requirements of SMCRA and the Federal regulations.

5. 405 KAR 16:001 Section 1(32) and 18:001 Section 1(35)—Kentucky proposes to add the term “durability rock” and defines it as “rock that does not slake in water, is not reasonably expected to degrade to a size that will adversely affect the effectiveness of the internal drainage system, and has a slake durability index value of 90 percent or greater.” The Federal regulations have no counterpart definition but address durable rock fills at 30 CFR 816/817.73(b). In response to comments, the Federal rules were revised to refer to durable rock as that type of rock that does not slake in water and will not degrade to soil materials. Soil materials, in relation to durable rock fills, any materials that have degraded or will degrade to such a size as to block or cause failure of the underdrain system. 48 FR 32910, 32921 (July 19, 1983). Thus, the Federal rules contemplated that “the rock must remain rock” and not block the drainage. Kentucky’s definition is no less effective than 30 CFR 816/817.73 because it refers to rock that will not slake and meets the objective of the Federal rule, i.e., that it will not degrade to a size that will adversely affect the drainage system. Accordingly, we find that the definition is not inconsistent with the Federal rules at 30 CFR 816/817.73 and can be approved.

6. 405 KAR 16:001 Section 1(108) and 18:001 Section 1(109)—Kentucky proposes to add the term “surface blasting operations” and defines it as the on-site storage, transportation, and use of explosives in association with a coal exploration operation, surface mining activities, or a surface disturbance of underground mining activities. It includes the design of the actual blast; implementation of a blast design; initiation of a blast; monitoring of an blast and ground vibration; the use of access, warning and all-clear signals; and other protective measures. The Federal regulations have no counterpart definition but address surface blasting activities at 30 CFR 816/817 61–68. We find that Kentucky’s proposed definition is not inconsistent with the requirements of SMCRA and the Federal regulations at 30 CFR 816/817.61–68 and can be approved.

IV. Summary and Disposition of Comments

Public Comments

We solicited public comments and provided an opportunity for a public hearing on the amendment. Because no one requested an opportunity to speak, a hearing was not held. The Kentucky Resources Council, Inc. (KRC) submitted written comments on four different occasions in response to the original Kentucky submission and the subsequent revisions. The comments are summarized below and organized by date of submission. Only those comments pertaining to the issues contained in this rule are included here.

July 11, 2002 (administrative record no. KY–1553)—KRC addressed several issues contained in OSM’s May 26, 2000, issue letter and Kentucky’s subsequent response on August 10, 2000. The remarks supplement previous comments on record by the KRC.

(a) 405 KAR 8:040 Section 16/8:040 Section 32(5)(e)/18:060 Section 12—KRC believes that Kentucky’s use of “proximate cause” is problematic to the extent that the State would reject a claim of water damage traceable to mining. As we stated in our findings, we believe Kentucky’s use of the phrase “proximate result” is consistent with Congressional intent and that it is reasonable to use “proximate result.”

(b) 405 KAR 16:060 Section 8/18:060 Section 12—KRC objects to the removal of the requirement that a notice of violation be issued when a water supply is damaged. We refer to our findings at b–17. It is the failure to promptly replace a damaged water supply, rather than damaging a water supply, that constitutes a violation under the Federal rule.

(c) 405 KAR 16:060 Section 8(2)(e)/18:060 Section 12(2)(e)—KRC does not support the 20-year timeframe specified by Kentucky as the repayment period for operation and maintenance costs related to water replacement. KRC feels that a fixed 20 years may “understate the durability of some private well water systems which have functioned * * * well beyond 20 years.” In its letter dated August 10, 2000, Kentucky stated that it uses the 20-year standard, but the permittee and water supply owner may agree on an alternate time period, as specified in the Federal definition of “replacement of water supply” at 30 CFR 701.5. As discussed in finding b–17, we found Kentucky’s provisions acceptable in light of the option to prescribe a period of time, which could be longer than the 20-year standard (OSM issue 11 in the May 26, 2000, letter).

(d) 405 KAR 8:030/8:040 Section 18(4)(c) /18:060 Section 12(4)(c)/18:210 Section 3(5)(c)—KRC feels that the proposed release of the additional bond after water replacement has been successfully
completed is not acceptable. KRC feels the bond should remain in place through Phase II and the bond release determination be subject to reopening if the system proves to not be adequate over the long term. As discussed in finding b–17, the Federal rule requires the additional bond only until water replacement has been completed.

(f) 405 KAR 16:001 Section 1(63)—KRC opposes the deletion of the “noxious plants” reference and feels that Kentucky should be required to develop a list of noxious plants. OSM does not have the authority to require state regulatory authorities to develop state noxious plant lists. Because the Federal definition of “noxious plants” is limited to state noxious plant lists, and Kentucky lacks such a list, the deletion of the definition is not inconsistent with the Federal regulations.


(a) 405 KAR 8:030—KRC commented that OSM should include specific language in its approval of the proposed amendment binding the state to the broader interpretation of “surface mining activities” as it appears in Section 16. KRC sought and received clarification from Kentucky that the scope of the alternative water supply requirement is as broad in coverage as that required of surface coal mines. We note that because the term “surface mining activities” is not being revised in this submission, the comment is outside the scope of this rulemaking.

KRC also asserts that the identification of alternative water sources “that could be developed” is a substantially lower threshold than the provisions of Section 508(a)(13) of SMCRA. We again note that this portion of the Kentucky regulations is not being revised. The comment is therefore outside the scope of this rulemaking. KRC notes that in Section 34, it sought and received clarification that Kentucky’s use of the broader term “coal mine waste” which replaced “coal processing waste,” is not intended to allow use of underground development waste in a manner that is inconsistent with 405 KAR 16:18:060 Section 4.

KRC also received clarification that the provision does not eliminate any obligation to account for any disposal of underground waste that is generated within the permit area and disposed of under another permit, or the requirement that all such disposal areas be under permit. KRC asserts that the proposal in Section 34 to defer much of the technical review of impoundment stability to MSHA is illegal. We disagree with the comment. Kentucky is not waiving any technical reviews of the design, location, foundation, or other requirements of impoundments and sedimentation structures. Kentucky affirms in its November 14, 1997, Statement of Consideration, that it “does not intend to accept MSHA’s approval in lieu of its own, nor will it rely on MSHA’s approval to avoid making its own review.” Kentucky is complying with Federal requirements at 30 CFR 780.25(c) as discussed in finding b–10.

(b) 405 KAR 8:040—KRC opposes the proposal in Section 26 and 405 KAR 18:210 (Section 1(4)) to allow the permit applicant to defer collecting the presubsidence condition information until after permit issuance. KRC asserts this deprives the landowners of the opportunity to assure before the permit is approved that their concerns regarding subsidence control are fully addressed. We disagree. In its Statement of Consideration dated November 14, 1997, Kentucky stated that property owners are identified in the public notice published in the newspaper, and have the opportunity to comment on all aspects of the application, including the subsidence control plan. 405 KAR on 8:040 Section 26(1) specifically requires that the permit application include a water quality and quantity survey for each protected water supply. As noted in finding b–13, because of a Federal court decision vacating portions of the Federal rules, our subsequent suspension and modification of the Federal rules at 30 CFR 784.20(a)(3), and Kentucky’s proposed corresponding changes, we find Kentucky’s revisions no less effective than the corresponding Federal regulations. OSM’s decision on a portion of 405 KAR 18:210 Section 1(4) was addressed in a previously published Federal Register Notice dated May 7, 2002, (67 FR 30549, KY–229–FOR).

KRC seeks clarification that the term “present users” in Section 32 is not intended to limit Kentucky’s protective obligations to those users at time of permit issuance. As discussed in finding b–14, we reference Kentucky’s clarification that “users of water” should not be limited to present users. In a related point in Section 32, KRC indicates that the term “at the time the application is submitted” is ambiguous and could be read to limit the water supply replacement obligation to supplies in existence at the time of permit issuance, rather than to limit the PHC determination to current water users. In fact, Federal rules do limit the water supply replacement obligation to the supplies in existence at the time of permit application (but not those users or owners of the supplies). We are satisfied that Kentucky’s regulation is not inconsistent with the Federal regulation at 30 CFR 784.14(e)(3)(iv) which states that the permittee must identify any well or spring that was in existence at the time the permit application was submitted.

(c) 405 KAR 16:060 Section 8/18:060 Section 12—KRC supports the inclusion of “promptly” as it modifies the replacement of water supply. KRC notes that it sought and received clarification that the phrase “an owner of interest” includes a joint owner of an undivided interest in a property who desires water replacement, even where the coal company acquires an undivided interest in the same property and does not want water replacement. KRC believes that the proposed time frames for water replacement appear generally appropriate. KRC does, however, believe that more rigorous timeframes for temporary replacement supplies be imposed. KRC notes that subsection (1) appears to exclude the presubsidence survey information. We refer to KRC’s prior comment at (b) above and the discussion at finding b–17. With respect to water replacement, KRC opposes the use of “a presumptive 20-year limit to the obligation to pay operation and maintenance costs in excess of customary and reasonable delivery costs.” KRC also opposes payments that exceed the permit term. The Federal rules allow for annual or periodic payments. Terms and conditions of the payments are within the discretion of the parties. However, as stated in the preamble to the Federal rule, a lump sum payment may be preferable to avoid excessive paperwork/calculations or to avoid the risk of permittee’s financial insolvency. See 60 FR at 16726 and our discussion in comment section (c) above. Both the 20-year period and the option to allow a series of payments are acceptable in light of the Federal definition of “replacement of water supply.” KRC asserts that the most “significant and troublesome” of Kentucky’s proposed changes is the deletion of the requirement to issue a notice of noncompliance if a protected water supply has been affected. KRC made the same comment in its July 11, 2002, letter, which we addressed in an earlier portion of this rule.

(d) 405 KAR 18:210—KRC again registers its objection to the provision allowing presubsidence surveys to be delayed until after permit issuance. KRC also objects to the change in notice requirements as insufficient to allow a landowner to implement measures to
protect structures and property from potential subsidence damage. These comments pertain to issues addressed in a previously published Federal Register Notice dated May 7, 2002 (67 FR 30549, KY–229–FOR) and are not relevant to this rulemaking. Next, KRC points out that Kentucky cannot allow an insurance policy to stand in lieu of a bond where subsidence has occurred unless it is adequate to cover all costs and to insure against all other risks, and the duration of the policy equals that of the bond. Kentucky’s regulation allows liability insurance if the permittee can show that the insurance will cover the increased bond amount. Additionally, as Kentucky stated in its Statement of Consideration, a “performance bond may be forfeited if the permittee fails to fulfill his water replacement obligations, even if the applicable liability insurance is available.” Please see our finding b–22 for additional discussion. Kentucky acknowledged that the insurance may not cover all the costs or there may be delays. If so, bond forfeiture is available as a remedy. KRC also commented that a bond posted for repair cannot be released until after the applicable liability period has lapsed. The Federal rule is clear that the additional bond is required until replacement is completed. Therefore, we disagree with the comment. As stated in our findings, Kentucky does have its existing approved bond release procedures that will be applicable in all cases.

July 25, 1998 (administrative record no. KY–1432)–KRC submitted a request for a 30-day period based on Kentucky’s final regulations submitted to OSM on July 14, 1998. OSM did reopen the comment period on June 5, 2002. KRC notes its concern with the proposed changes to 405 KAR 16/18:060 in which the provision to issue a notice of noncompliance for a damaged water supply is deleted. We disagree and note that this comment was addressed in response to KRC’s letter dated July 11, 2002. We refer to the discussion at comment section (b) above.

October 6, 1997 (administrative record no. KY–1415)–KRC submitted comments on several issues already addressed in the comment sections above. To avoid redundancy, we will not repeat them here. KRC stated that the term “replacement of water supply” should be defined in the regulations, as well as in 405 KAR 16/18:060; though it appears from the July 11, 2002, comments that KRC changed its position and supports Kentucky’s interpretation. We agree with Kentucky’s clarification that, because Kentucky has placed the substantive requirements of the definition in its performance standards at 405 KAR 16/18:060, it is not necessary for Kentucky to add the definition.

KRC also suggested that the order of some of the language of 405 KAR 8:030 be reorganized to track the Federal language. Kentucky did make the changes in its subsequent submission.

Federal Agency Comments

According to 30 CFR 732.17(h)(11)(i), we solicited comments on the proposed amendment submitted on July 30, 1997, and revised on March 4, 1998, and July 14, 1998, from various Federal agencies with an actual or potential interest in the Kentucky program. By letters dated June 20, 2002, and July 18, 2002, the Department of Labor’s Mine Safety and Health Administration commented that the proposed amendment had no apparent impact on its program (administrative record nos. KY–1542 and KY–1554).

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.) This amendment did not pertain to air or water quality standards, but by letter dated November 28, 2000, the EPA submitted comments (administrative record no. KY–1501). We note that the comments EPA made in response to the proposed changes at 405 KAR 16/18:090 were addressed in the July 17, 2003, rulemaking. We also note that the comments EPA made referencing 405 KAR 16/18:060 Sections 1 and 11 pertain to regulations previously approved by OSM and not being revised at this time. Those specific comments are, therefore, outside the scope of this rulemaking. EPA commented that the provisions of 405 KAR 18:210 Section 3 should be revised to require that stream subsidence damage be held to the same feasibility criteria as subsidence damage to structures. As discussed in finding III(a) above, Kentucky’s proposed regulations are no less effective than the corresponding Federal regulations. The Kentucky program requires the same level of subsidence damage prevention and mitigation for streams as required by the Federal regulations.

V. OSM’s Decision

Based on the above findings, we are not approving 405 KAR 16:060 Section 8(4)(c), 18:060 Section 12(4)(c), and 18:210 Section 3(5)(c) and approving the remainder of the amendment as submitted by Kentucky on July 30, 1997, and revised on March 4, 1998, and July 14, 1998, and as clarified by Kentucky. We are removing the required amendment at 30 CFR 917.16(m) that required Kentucky to amend its program to clarify that it provides for the prompt replacement of water supplies.

To implement this decision, we are amending the Federal regulations at 30 CFR part 917 which codify decisions concerning the Kentucky program. We find that good cause exists under 5 U.S.C. 553(d)(3) to make this final rule effective immediately. Section 503(a) of SMCRA requires that Kentucky’s program demonstrate that it has the capability of carrying out the provisions of the Act and meeting the Act’s purposes. Making this regulation effective immediately will expedite that process. OSMCRA requires consistency of State and Federal standards.

Effect of OSM’s Decision

Initial enforcement of the underground coal mine subsidence control and water replacement requirements in Kentucky will be accomplished with a combination of State enforcement and direct Federal enforcement. This portion of the notice explains how OSM’s decision on this proposed amendment affects the regulation of underground mining impacts in Kentucky. After consultation with Kentucky and consideration of public comments on this issue, OSM announced its decision in a Federal Register Notice dated July 28, 1995 (60 FR 38682). Kentucky will enforce its provisions that correspond to the Federal regulations at 30 CFR 817.42(c)(2) pertaining to the repair or compensation of material damage resulting from subsidence. Kentucky has statutory provisions in place that correspond to the Federal regulations and has the authority to implement its provisions for all underground mining activities conducted after October 24, 1992. It will also enforce its provisions that correspond to 30 CFR 817.41(j) pertaining to water replacement for the period after July 16, 1994, the effective date of Kentucky’s statutory provisions for water replacement. For those underground mining activities conducted after October 24, 1992, and before July 16, 1994, OSM will enforce the provisions of 30 CFR 817.41(j) because Kentucky does not have the statutory authority to retroactively apply water replacement requirements to water losses prior to the effective date of its statute.
As discussed in this notice, OSM is approving provisions that are no less effective than the Federal regulations. However, we are not approving several provisions affording less protection than the minimum level required by the counterpart Federal regulations.

Section 503 of SMCRA provides that a State may not exercise jurisdiction under SMCRA unless the State program is approved by the Secretary. Similarly, 30 CFR 732.17(a) requires that any change of an approved State program be submitted to OSM for review as a program amendment. The Federal regulations at 30 CFR 732.17(g) prohibit any changes to approved State programs that are not approved by OSM. In the oversight of the Kentucky program, we will recognize only the statutes, regulations, and other materials we have approved, together with any consistent implementing policies, directives, and other materials. We will require Kentucky to enforce only approved provisions.

VI. Procedural Determinations

Executive Order 12630—Takings

This rule does not have takings implications. This determination is based on the analysis performed for the counterpart Federal regulation.

Executive Order 12866—Regulatory Planning and Review

This rule is exempt from review by the Office of Management and Budget under Executive Order 12866.

Executive Order 12988—Civil Justice Reform

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12988 and has determined that 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 because 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 the Federal regulations at 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.

Executive Order 13132—Federalism

This rule does not have Federalism implications. SMCRA delineates the roles of the Federal and State governments with regard to the regulation of surface coal mining and reclamation operations. One of the purposes of SMCRA is to “establish a nationwide program to protect society and the environment from the adverse effects of surface coal mining operations.” Section 503(a)(1) of SMCRA requires that State laws regulating surface coal mining and reclamation operations be “in accordance with” the requirements of SMCRA, and section 503(a)(7) requires that State programs contain rules and regulations “consistent with” regulations issued by the Secretary pursuant to SMCRA.

Executive Order 13175—Consultation and Coordination With Indian Tribal Governments

In accordance with Executive Order 13175, we have evaluated the potential effects of this rule on Federally-recognized Indian tribes and have determined that the rule does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

The basis for this determination is that our decision is on a State regulatory program and does not involve a Federal regulation involving Indian lands.

Executive Order 13211—Regulations That Significantly Affect the Supply, Distribution, or Use of Energy

On May 18, 2001, the President issued Executive Order 13211 which requires agencies to prepare a Statement of Energy Effects for a rule that is (1) considered significant under Executive Order 12866, and (2) likely to have a significant adverse effect on the supply, distribution, or use of energy. Because this rule is exempt from review under Executive Order 12866 and is not expected to have a significant adverse effect on the supply, distribution, or use of energy, a Statement of Energy Effects is not required.

National Environmental Policy Act

This rule does not require an environmental impact statement because section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed State regulatory programs 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 certifies 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 counterpart 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. 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 counterpart Federal regulations.

Small Business Regulatory Enforcement Fairness Act

This rule is not a major rule under 5 U.S.C. 804(2), the Small Business Regulatory Enforcement Fairness Act. This rule: (a) Does not have an annual effect on the economy of $100 million; (b) Will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) Does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based upon the fact that the State submittal which is the subject of this rule is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation was not considered a major rule.

Unfunded Mandates

This rule will not impose an unfunded mandate on State, local, or tribal governments or the private sector of $100 million or more in any given year. This determination is based upon the fact that the State submittal, which is the subject of this rule, is based upon counterpart Federal regulations for which an analysis was prepared and a determination made that the Federal regulation did not impose an unfunded mandate.
Establishing a temporary security zone

SUMMARY:

For the reasons set out in the preamble, 30 CFR part 917 is amended as set forth below:

<table>
<thead>
<tr>
<th>Original amendment submission date</th>
<th>Date of final publication</th>
<th>Citation/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 30, 1997</td>
<td>August 11, 2004</td>
<td>*</td>
</tr>
<tr>
<td>*</td>
<td>*</td>
<td>405 KAR 8:001 Section 1(3), (20), (24), (46), (60), (65), (69), (86) and (108), Section 2(1) and (2); 405 KAR 8:030 Section 3(3)(d), Section 11(2)(a), Section 12(4)(a) and (b), Section 13(1)(b) and (3), Section 14(5), Section 15(5), Section 16, Section 20(3), Section 23(1)(g), Section 24(4)(e), Section 26(3), Section 27(2)(e), Section 32(3)(e), Section 34, Section 37(1)(b), Section 38(1) and (2); 405 KAR 8:040 Section 3(3)(d)(1), Section 11(2)(a) and (4)(a), (b), Section 13(1)(b)2 and (3), Section 14(5), Section 15(5), Section 16, Section 20(3), Section 26, Section 32(1)(b)5 and (3)(e), Section 34, Section 37(1)(b), Section 39(1) and (2); 405 KAR 16:001 Section 1(3), (32), (46), (53), (63)- deleted, (81), (98), (99), (108), Section 2(1) and (2), 405 KAR 16:060 Section 14(4)(b), Section 22(2), Section 4(1), Section 8(1)(a), (b), (2)(a)–(e); 405 KAR 18:001 (3), (6), (24), (35), (49), (55), (61), (62)- deleted, (67), (68), (84), (100), (109), Section 2(1) and (2); 405 KAR 18:060 Section 1(4)(b), Section 2(2), Section 4(1), Section 12(1)(a), (b), (2)(a)–(e); 405 KAR 18:210 Section 1(1), (2) and (3), Section 1(3) and (3), Section 3, Section 4 and Section 5.</td>
</tr>
</tbody>
</table>

§ 917.15 Approval of Kentucky regulatory program amendments.

* * * * *

§ 917.16 [Amended]

3. Section 917.16 is amended by removing and reserving paragraph (m).

4. Section 917.17 is amended by revising the section heading and adding paragraph (a) to read as follows:

§ 917.17 State regulatory program amendments not approved.

(a) The amendment to Kentucky's regulations at 405 KAR 16:060 Section 8(4)(c); 18:060 Section 12(4)(c) and 18:210 Section 3(5)(c) which were originally submitted by Kentucky on July 30, 1997 and later amended are disapproved.

* * * * * [FR Doc. 04–18291 Filed 8–10–04; 8:45 am] BILLING CODE 4310–05–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Francisco Bay 04–020]

RIN 1625–AA87

Security Zone; Suisun Bay, Concord, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone in the navigable waters of the United States adjacent to Pier Three at the Military Ocean Terminal Concord (MOTCO), California (formerly United States Naval Weapons Center Concord, California). In light of recent terrorist actions against the United States, this security zone is necessary to ensure the safety of the public from potential subversive acts. The security zone will prohibit all persons and vessels from entering, transiting through or anchoring within a portion of Suisun Bay within 500 yards of Pier Three at the MOTCO facility unless authorized by the Captain of the Port (COTP) or his designated representative.

DATES: This rule is effective from 7 a.m. on August 6, 2004, to 11:59 p.m. on September 6, 2004. If the need for this security zone ends before the scheduled termination time, the Captain of the Port will cease enforcement of the security zone and will announce that fact via Broadcast Notice to Mariners.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket (COTP San Francisco Bay 04–020) and are available for inspection or copying at Coast Guard Marine Safety Office San Francisco Bay, Coast Guard Island, Alameda, California 94501, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant Doug L. Ebbers, U.S. Coast Guard Marine Safety Office San Francisco Bay, at (510) 437–2770.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(2), the Coast Guard finds that good cause exists for not publishing an NPRM because the duration of the NPRM rulemaking process would extend beyond the actual period of the scheduled operations and defeat the protections afforded by the temporary rule to the cargo vessels, their crews, the public, and national security.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the Federal Register as the schedule and other logistical details were not known until a date fewer than 30 days prior to the start date of the military operation. Delaying this rule's effective date would be contrary to the public interest since the safety and security of the people, ports, waterways, and properties of the Port Chicago and Suisun Bay areas would be jeopardized without the protection afforded by this security zone.

Background and Purpose

Since the September 11, 2001, terrorist attacks on the World Trade...