

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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 Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects

##### 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

##### 21 CFR Part 522

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 parts 510 and 522 are amended as follows:

#### PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

**Authority:** Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "Chanelle Pharmaceuticals Manufacturing Ltd.," and in the table in paragraph (c)(2) by numerically adding a new entry for "061651" to read as follows:

##### § 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

*	*	*	*	*
(c)	*	*	*	
(1)	*	*	*	

Firm name and address	Drug labeler code
* * * *	*
Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.	061651
* * *	*
(2) * * *	
Drug labeler code	Firm name and address
* * * *	*
061651 ....	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 522 continues to read as follows:

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

4. Section 522.2662 is amended by revising the first sentence in paragraph (b) to read as follows:

##### § 522.2662 Xylazine hydrochloride injection.

\* \* \* \*

(b) *Sponsor.* See 000856 and 061651 in § 510.600(c) of this chapter for use as horses, wild deer, and elk. \* \* \*

\* \* \* \*

Dated: June 15, 1995.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-15594 Filed 6-26-95; 8:45 am]

BILLING CODE 4160-01-F

#### DEPARTMENT OF THE INTERIOR

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

##### 30 CFR Part 917

[KY-206]

##### Kentucky Regulatory Program

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

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** OSM is approving, with two exceptions, an amendment to the Kentucky regulatory program (hereinafter referred to as the "Kentucky

program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The revisions to the Kentucky Revised Statutes (KRS) pertain to remining, permits, definitions, appeal rights, water replacement, and permit revisions. The amendment is intended to revise the Kentucky program to be consistent with SMCRA.

**EFFECTIVE DATE:** June 27, 1995.

##### FOR FURTHER INFORMATION CONTACT:

William J. Kovacic, Director, Lexington Field Office, OSM, 2675 Regency Road, Lexington, Kentucky 40503. Telephone: (606) 233-2896.

##### SUPPLEMENTARY INFORMATION:

- I. Background on the Kentucky 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 Kentucky Program

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the May 18, 1982, **Federal Register** (47 FR 21404). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 917.11, 917.13, 917.15, 917.16, and 917.17.

##### II. Submission of the Proposed Amendment

By letter dated April 29, 1994 (Administration Record No. KY-1279), Kentucky submitted a proposed amendment to its program pursuant to SMCRA. Kentucky proposed to revise the following sections of its statutes: KRS 42, 177, 211, 350, 351, and 352. The revisions pertain to remining, permits, definitions, appeal rights, water replacement, and permit revisions and are contained in Senate Bills 208, 214, 249, and House Bills 338 and 707.

OSM announced receipt of the proposed amendment in the May 20, 1994, **Federal Register** (59 FR 26472), and in the same document, opened the public comment period and provided an opportunity for a public hearing on the adequacy of the proposed amendment. The public comment period closed on June 20, 1994.

By letter dated September 1, 1994 (Administrative Record No. KY-1319), Kentucky submitted additional explanatory information. Because the information merely clarified certain provisions of the proposed revisions,

OSM did not reopen the comment period.

### III. Director's Findings

Set forth below, pursuant to SMCRA and the Federal regulations at 30 CFR 732.15 and 732.17, are the Director's findings concerning the proposed amendment.

Revisions not specifically discussed below concern nonsubstantive wording changes, or revised cross-reference and paragraph notations to reflect organizational changes resulting from this amendment.

#### A. Senate Bill 208

Senate Bill 208, deals for the most part, with the new reining provisions of the Energy Policy Act of 1992. The Energy Policy Act of 1992, enacted on October 24, 1992, amended section 404 of SMCRA and added sections 510(e), 515(b) (20)(B), 701(33) and 701(34) of SMCRA. It should be noted that OSM has proposed rules on reining to reflect the changes enacted by the Energy Policy Act of 1992. These rules are not final. Therefore, the Kentucky regulatory program may need to be amended if it is later found to be inconsistent with the federal rules.

1. At KRS 350.010(22), Kentucky proposes to define "unanticipated event or condition" as an event or condition encountered in a reining operation that was not contemplated by the applicable surface coal mining and reclamation permit. At KRS 350.010(23), Kentucky proposes to define "lands eligible for reining as those lands that would otherwise be eligible for expenditures under KRS 350.560 (1) or (2) (Lands and Waters Eligible for Reclamation or Drainage Abatement Expenditures).

The Director finds the proposed definitions at KRS 350.010 (22) and (23) substantively identical to sections 701 (33) and (34) of SMCRA and therefore no less stringent than these sections.

2. At KRS 350.085(7), Kentucky proposes that if a permit applicant has a violation resulting from an unanticipated event or condition at a surface coal mining operation eligible for and under a reining permit, then the applicant would not be permit blocked for such a violation. The term "violation would mean the same as in KRS 350.085(6) and as Kentucky stated in a September 1, 1994 letter, the exemption from permit blocking would only apply to violations on reining operations which occurred after July 15, 1994. This exemption would expire on September 30, 2004.

The Energy Policy Act of 1992, enacted on October 24, 1992, added

section 510(e) of SMCRA. As of October 24, 1992, section 510(e) of SMCRA exempts permit applicants from permit blocks for violations resulting from unanticipated events or conditions that occurred on lands eligible for reining which were under a permit by the permit applicant. The Director finds that KRS 350.087 is no less stringent than 510(e) of SMCRA because the Kentucky statute, as interpreted by Kentucky's Natural Resources and Environmental Protection Cabinet, would only allow the permit block exemption for violations resulting from an unanticipated event or condition occurring after July 15, 1994 on lands eligible for reining.

3. At KRS 350.095(1), Kentucky proposes that the permittee shall assume responsibility for successful revegetation for a period of five full years after the last year in which augmented seeding, fertilizing, irrigation, or other work occurs.

The Director finds the proposed revision at KRS 350.095(1) substantively identical to and therefore no less stringent than the language at section 515(b)(20)(A) of SMCRA.

At KRS 350.095(2), Kentucky proposes that on lands eligible for reining, the permittee shall assume responsibility for successful revegetation for a period of two full years after the last year in which augmented seeding, fertilizing, irrigation, or other work occurs in order to assure compliance with the applicable standards. The authority for this section terminates on September 30, 2004.

The Director finds the proposed revision at KRS 350.095(2) substantively identical to and therefore no less stringent than section 515(b)(20)(B) of SMCRA.

4. At KRS 350.560(1), Kentucky proposes that surface coal mining operations on lands eligible for reining not affect the eligibility of those lands for reclamation and restoration after the release of the bond or deposit for a reining operation. In the event the bond or deposit for a surface coal mining operation on lands eligible for reining is forfeited, available funds maybe used if the amount of the bond or deposit is not sufficient to provide for adequate reclamation or abatement.

The Director finds the proposed revision at 350.560(1) substantively identical to and therefore no less stringent than the language of section 404 of SMCRA.

#### B. Senate Bill 214

1. At new KRS 350.0285 and KRS 351.070(14), Kentucky proposes to require that the Cabinet and the Commissioner of the Department of Mines and Minerals (Department) notify the Transportation Cabinet every six months of permits issued for mine openings and mine closings under their authority. At KRS 352.420(3), Kentucky proposes to require that the operator or superintendent of a mine notify the Commissioner every six months of a mine opening and a mine closure under his authority.

The Federal rules contain no counterpart requirements. The Director finds the proposed provisions at KRS 350.0285, KRS 351.070(14), and KRS 352.420(3) not inconsistent with the requirements of SMCRA and the Federal regulations.

2. At KRS 42.470(1)(c), Kentucky proposes to require that all counties receive an annual payment from the local government economic assistance fund which is based on the average of total ton miles within the county during the most recent three-year period.

The Federal rules contain no counterpart requirements. The Director finds the proposed revisions at KRS 42.470(1)(c) not inconsistent with the requirements of SMCRA and the Federal regulations.

3. At KRS 177.977(2), Kentucky proposes to require that a copy of the information furnished to the Cabinet pursuant to the provisions of section 1 of this Act and a copy of the information furnished to the Department pursuant to the provisions of sections 2 and 3 of this Act be submitted to the Transportation Cabinet.

The Federal rules contain no counterpart requirements. The Director finds the proposed provisions at KRS 177.977(2) not inconsistent with the requirements of SMCRA and the Federal regulations.

4. At KRS 211.390(1), Kentucky proposes to revise its definition of "fluidized bed energy production facility" to mean a fluidized bed combustion unit installed in a plant facility, subject to certain conditions.

The Federal rules contain no counterpart definition. The Director finds the proposed revision at KRS 211.390(1) not inconsistent with the requirements of SMCRA and the Federal regulations.

5. At KRS 211.392(1), Kentucky proposes to substitute "fluidized bed combustion unit" for "structure" and to delete the provision that the Governor's Office for Coal and Energy Policy will provide technical assistance and factual

information as requested in writing by the Revenue Cabinet.

The Federal rules contain no counterpart provisions. The Director finds the proposed revisions at KRS 211.392(1) not inconsistent with the requirements of SMCRA and the Federal regulations.

6. At KRS 211.392(2), Kentucky proposes to require that before the denial, revocation, or modification of a fluidized bed combustion technology tax exemption certificate, the Revenue Cabinet is required to give the applicant written notice and afford the applicant an opportunity for a hearing. The requirement that the special assistant to the Governor for coal and energy policy be notified of the hearing along with the applicant is deleted.

The Federal rules contain no counterpart provisions. The Director finds the proposed revisions at KRS 211.392(2) not inconsistent with the requirements of SMCRA and the Federal regulations.

7. At KRS 211.392(5), Kentucky proposes to delete the requirement that the notice of issuance or notice of denial, revocation, or modification of the tax exemption certificate be sent to the special assistant to the Governor for coal and energy policy. Also deleted is the designation of the above-referenced special assistant and applicant as parties for the purposes of review in appeals. At KRS 211.392(6), Kentucky proposes to specify that any applicant or holder of certificate aggrieved by the refusal to issue, revocation, or modification of a fluidized bed combustion tax exemption certificate has certain appeal rights. At KRS 211.392(8), Kentucky proposes to delete the requirement that in the event that the purpose for which a combustion unit with an exemption certificate is held changes, the above-referenced special assistant must be notified by the holder of the certificate.

The Federal rules contain no counterpart provisions. The Director finds the proposed revisions at KRS 211.392(5), (6), and (8) not inconsistent with the requirements of SMCRA and the Federal regulations.

8. At KRS 211.392(9), Kentucky proposes to allow a fluidized bed combustion facility to be exempt from 211.392 as well as sections KRS 132, 136, 138, and 139. Kentucky also proposes to require that each exemption certificate remain in force for a period of eight years from the date of issuance and elapse at the end of the said period. Any fluidized bed combustion unit previously exempt shall not be eligible for recertification upon completion of the eight year certificate period.

The Federal rules contain no counterpart provisions. The Director finds the proposed revisions at KRS 211.392(9) not inconsistent with the requirements of SMCRA and the Federal regulations.

#### C. Senate Bill 249

1. At KRS 350.010(1), Kentucky proposes to clarify that excavation for the purpose of obtaining coal includes extraction of coal from refuse piles is included in the definition of "surface coal mining operations."

The Director finds the proposed definition of "surface coal mining operation" at 350.010(1) substantively identical to and therefore no less stringent than the Federal definition at 701(28) of SMCRA.

2. At KRS 350.010(9), in response to the required amendment at 30 CFR 917.16(j)(2), see 58 FR 42001 (August 6, 1993), Kentucky proposes to revise the definition of "person" to mean any individual, partnership, corporation, association, society, joint stock company, firm, company, or other business organization; and shall also include any agency, unit, instrumentality of Federal, State, or local government including any publicly owned utility or publicly owned corporation of Federal, State, or local government.

The Director finds the proposed definition of "person" substantively identical to and therefore no less effective than the Federal definition at 30 CFR 700.5. He is removing the required amendment at 30 CFR 917.16(j)(2), which required Kentucky to revise its definition of "person" to include all entities encompassed by the Federal definition.

3. At KRS 350.0301(4), Kentucky is proposing to require that all hearings be open to the public. The phrase "except as ordered by the hearing officer" is deleted in response to the required amendment at 30 CFR 917.16(j)(1) which required Kentucky to delete the phrase. Therefore, the Director finds that the deletion of the phrase renders this section no less stringent than 525 of SMCRA. The Director is removing the required amendment at 30 CFR 917.16(j)(1).

At KRS 350.0305(1), Kentucky is proposing to delete its hearing provisions and transfer them, with minor revisions, to 350.0301(1). At KRS 350.0305, Kentucky is proposing to require that judicial review of a final order resulting from a hearing on the issuance of a notice of noncompliance, the issuance of an order for cessation and immediate compliance, the assessment of civil penalties, or a bond

forfeiture be in compliance with KRS 350.032. At KRS 350.032(2), Kentucky is proposing to permit any person aggrieved by a final order of the Cabinet resulting from a hearing on the issuance of a notice of noncompliance, the issuance of an order for cessation and immediate compliance, the assessment of civil penalties, or a bond forfeiture to obtain a review of the order by filing a written petition in the appropriate county circuit court.

Section 526(e) of SMCRA requires that actions of the State Regulatory Authority be subject to judicial review by a court of competent jurisdiction. Kentucky is providing judicial review of its enforcement actions and therefore the Director finds KRS 350.0305 and 350.032(a) to be in accordance with 526(e) of SMCRA.

#### D. House Bill 338

At KRS 350.421 (1) and (2), Kentucky proposes to extend its water rights and replacement provisions to water resources and supplies affected by underground mining, as well as surface mining.

It should be noted that KRS 350.255(2) is deleted. This deletion was previously approved by OSM on August 6, 1993 at 58 FR 42001, 42003. Consequently, the deletion does not need to be addressed in this rulemaking.

The Federal law at section 720(a)(2) requires the prompt replacement of any drinking, domestic or residential water supply from a well or spring in existence prior to the application for a surface coal mining permit which has been affected by contamination, diminution or interruption resulting from underground coal mining operations. The Kentucky statute also provides for the replacement of any drinking, domestic or residential water supply but is silent on whether or not the replacement of water supplies will be prompt. Therefore, the Director finds KRS 350.421 no less stringent than 720(a)(2) of SMCRA except to the extent that the Kentucky statute does not provide for the prompt replacement of water supplies.

He is requiring that Kentucky amend its program to provide for prompt replacement. In its letter dated September 1, 1994, Kentucky stated that it is not authorized by State law to retroactively apply the water replacement requirements to water losses which occurred between October 24, 1992, and July 15, 1994, the effective date of House Bill 338. The Director is deferring decision on the enforcement of the provisions of SMCRA section 720(a) during the period from the effective date of SMCRA section 720 (October 24,

1992) to the effective date of KRS 350.421 (1) and (2) (July 15, 1994). Pursuant to newly promulgated 30 CFR 843.25, OSM intends to publish by July 31, 1995, for each State with a regulatory program, including Kentucky, final rule notices concerning the enforcement of the provisions of the Energy Policy Act in those States.

#### *E. House Bill 707*

At KRS 350.070(1), Kentucky proposes to permit extensions of the underground mining area that are not incidental boundary revisions and do not include planned subsidence or other new proposed surface disturbances to be made by application for a major revision to the permit.

The Federal rules do not require that areas overlying proposed underground workings be included in the permit area if no surface disturbance is planned. The Director finds the proposed revisions at KRS 350.070(1) not inconsistent with the requirements of SMCRA and the Federal rules.

### **IV. Summary and Disposition of Comments**

#### *Public Comments*

The Director solicited public comments and provided an opportunity for a public hearing on the proposed amendment. Two public comments were received. Because no one requested an opportunity to speak at a public hearing, no hearing was held.

The Coal Operators and Associates Inc. expressed its general support for the amendment. The Kentucky Resources Council, Inc. (KRC) had several comments:

1. *House Bill 383*—The KRC was concerned with the practical implementation of the new protections of KRS 350.421 (1) and (2). The KRC anticipates proof difficulties where mine related water loss or quality diminution occurs. The KRC then recommended several courses of action. The Director notes that the scope of this amendment are the revisions to the Kentucky statutes and that the concerns raised by the KRC are beyond the scope of this rulemaking and do not pertain to KRS 350.421, which the KRC found to be consistent with SMCRA.

2. *Senate Bill 208*—The KRC stated that this Bill does not provide a commencement date for the operation of the statute's provisions and could be construed to require waiving permit blocking for violations that occurred before 1992 on pre-1992 permitted remining sites. KRC asserts that Congress did not intend section 510(e) to apply either to violations which

occurred prior to October 24, 1992 or to permits issued before that date. KRC posits the purpose of section 510(e) is to provide solely post-enactment date incentives for remining. KRC also cautioned of the difficulty of establishing the existence of unanticipated events or conditions at permits issued before October 24, 1992.

OSM disagrees with part of the comment. As to the date the violation occurs, Kentucky will exempt permit applicants from permit blocks for violations that occurred after July 15, 1994 as a result of an unanticipated event or condition on lands eligible for remining.

Regarding the date the remining permit is issued, the plain language of section 510(e) of SMCRA does not require that the remining permit have been issued after October 24, 1992, only that the application for the new permit be on or after October 24, 1992. While the legislative history of section 2503 of the Energy Policy Act indicates that the remining amendments to SMCRA were, as a whole, meant to provide incentives to industry to extract coal which would otherwise be bypassed, the text of section 510(e) is also consistent with Congressional awareness of, and a need to correct the inequality of permit applicants being permit blocked for a violation resulting from an event or condition at a remining site which they could not have reasonably anticipated nor over which they had any control, regardless of the date of permit issuance.

The application of section 510(e) should also not be limited on the basis of the potential difficulty of establishing unanticipated events or conditions on permits issued before October 24, 1992. As with any permit requirement, the burden is on the applicant to make the required demonstration. Regulatory authorities will decide whether to apply section 510(e) based upon information set forth in the permit application. Moreover, any difficulty a regulatory authority might experience in evaluating whether the event or condition underlying the potentially permit blocking violation was reasonably unanticipated or whether the violation occurred on lands eligible for remining would be no greater on October 23, 1992, the day before section 510(e) was enacted, than on the following day. Accordingly, OSM does not interpret this section to impose a post-October 24, 1992 limitation on when permits must have been issued. This issue may, however, become increasingly academic for there are ever fewer pre-October 24, 1992 remining permits which are still in active mining reclamation.

The KRC was concerned that revisions to KRS 350.032, 350.0301 and 350.0305 may be construed to eliminate the ability to obtain under KRS 350.032(4) temporary relief of cabinet orders and determinations that are not related to bond forfeitures or enforcement orders. In a letter dated September 1, 1994, Kentucky stated that KRS 350.032(4), its temporary relief provision, applies to orders issued "under this chapter." Kentucky interprets KRS 350.032(4) to authorize temporary relief in appeals under both KRS 350.0305 and KRS 350.032. The Director agrees with Kentucky's interpretation since the phrase "under this chapter" means Chapter 350 and sections 350.032, 350.0301 and 350.0305 all are within Chapter 350.

#### *Federal Agency Comments*

Pursuant to 30 CFR 732.17(h)(11)(i), the Director solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the Kentucky program. The U.S. Department of the Interior, Bureau of Land Management and Bureau of Mines; the U.S. Department of Labor, Mine Safety and Health Administration; and the U.S. Department of Agriculture, Soil Conservation Service, concurred without comment. The U.S. Department of the Interior, Fish and Wildlife Service, commented that the reduction in the period of responsibility for revegetation success for remining sites from five years to two years would result in lost opportunities to assure vegetative success on highly erosive sites. It recommended that the regulation remain unchanged. The Director notes Kentucky's proposed revision is identical to SMCRA's standards at section 515(b)(20)(B).

#### *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.*).

On May 13, 1994, OSM solicited EPA's concurrence with the proposed amendment. By letter dated May 17, 1995, EPA concurred with the provisions of the proposed amendment.

### **V. Director's Decision**

Based on the above findings, the Director approves, with two exceptions, the proposed amendment as submitted by Kentucky on April 29, 1994. As

noted in Finding D concerning the proposed revisions at KRS 350.421(1) and (2), the Director is requiring that Kentucky amend its program to provide for the prompt replacement of water supplies. He is deferring decision on the enforcement of the provisions of SMCRA section 720 during the period from the effective date of SMCRA section 720 (October 24, 1992) to the effective date of KRS 350.421(1) and (2) (July 15, 1994). As noted in Finding C, the Director is also removing the required amendments at 30 CFR 917.16(j)(1) and (j)(2).

On March 31, 1995, OSM published final rules on subsidence to reflect the changes enacted by the Energy Policy Act of 1992, Pub. L. 102-486 (60 FR 16722). OSM intends to publish by July 31, 1995, for each State with a regulatory program, including Kentucky, final rule notices concerning the enforcement of the provisions of the Energy Policy Act in those States. Therefore, those portions of the Kentucky amendment that reflect changes because of the Energy Policy Act of 1992, are approved with the understanding that Kentucky may have to amend its program to correct any inconsistencies that may arise after the publication of the Federal final rules on July 31, 1995.

The Federal regulations at 30 CFR Part 917, codifying decisions concerning the Kentucky program, are being amended to implement this decision. This final rule is being made effective immediately to expedite the State program amendment process and to encourage States to bring their programs into conformity with the Federal standards without undue delay. Consistency of State and Federal standards is required by SMCRA.

#### *Effect of Director's Decision*

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 alteration of an approved State program be submitted to OSM for review as a program amendment. Thus, any changes to the State program are not enforceable until approved by OSM. The Federal regulations at 30 CFR 732.17(g) prohibit any unilateral changes to approved State programs. In the oversight of the Kentucky program, the Director will recognize only the statutes, regulations and other materials approved by OSM, together with any consistent implementing policies, directives and other materials, and will require the enforcement by Kentucky of only such provisions.

## **VI. Procedural Determinations**

### *Executive Order 12866*

This rule is exempted from review by the Office of Management and Budget (OMB) under Executive Order 12866 (Regulatory Planning and Review).

### *Executive Order 12778*

The Department of the Interior has conducted the reviews required by section 2 of Executive Order 12778 (Civil Justice Reform) and has determined that, to the extent allowed by law, this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments since each such program is drafted and promulgated by a specific State, not by OSM. Under sections 503 and 505 of SMCRA (30 U.S.C. 1253 and 1255) and 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on 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.

### *National Environmental Policy Act*

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 1292(d)) provides that agency decisions on proposed 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. 43332(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. Accordingly, this rule will ensure that

existing requirements previously promulgated 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.

### **List of Subjects in 30 CFR Part 917**

Intergovernmental relations, Surface mining, Underground mining.

Dated: June 16, 1995.

**Robert A. Penn,**

*Acting Regional Director, Appalachian Regional Coordinating Center.*

For the reasons set out in the preamble, Title 30, Chapter VII, Subchapter T of the Code of Federal Regulations is amended as set forth below:

### **PART 917—KENTUCKY**

1. The authority citation for part 917 continues to read as follows:

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

2. Section 917.15 is amended by adding paragraph (yy) to read as follows:

#### **§ 917.15 Approval of regulatory program amendments.**

\* \* \* \* \*

(yy) The following statutes, as submitted to OSM on April 29, 1994, and supplemented with additional explanatory information on September 1, 1994, are approved effective June 27, 1995, except to the extent that KRS 350.421 does not provide for the prompt replacement of water supplies:

KRS 350.010(2), (16), (22), (23).	Definitions.
KRS 350.421 .....	Water Supplies.
KRS 350.085(1), (7) ..	Violations.
KRS 350.095(1), (2) ..	Revegetation.
KRS 350.560(1) .....	Bonds.
KRS 350.0285 .....	Notification Procedures.
KRS 351.070(14) .....	Notification Procedures.
KRS 352.420(3) .....	Notification Procedures.
KRS 42.470(1)(c) .....	Reimbursement.
KRS 211.390(1) .....	Definitions.
KRS 211.392(1), (2) ..	Exemption Application.
KRS 211.392(5) .....	Exemption Certificate.
KRS 132, 136, 138, 139.	Term of Certificate.
KRS 350.010(1) .....	Definitions.
KRS 350.010(9) .....	Definitions.
KRS 350.0301(1) and (4).	Hearing Procedures.
KRS 350.0305 .....	Judicial Review.
KRS 350.032(2), (4) ..	Hearing Procedures.
KRS 350.421(1), (2) ..	Water Replacement.
KRS 350.070(1) .....	Permit Revision.

KRS 177.977 ..... Coal Transportation.  
KRS 351.070(13) ..... Authority Provi-  
sions.  
KRS 211.392(6), (8) .. Exemption Certifi-  
cates.

The Director is deferring decision on the enforcement of the provisions on SMCRA section 720 during the period from the effective date of SMCRA section 720 (October 24, 1992) to the effective date of KRS 350.421(1) and (2) (July 15, 1994).

3. Section 917.16 is amended to remove and revise paragraph (j) and to add paragraph (m) to read as follows:

**§ 917.16 Required regulatory program amendments.**

\* \* \* \* \*

(j) [Reserved]

\* \* \* \* \*

(m) By August 28, 1995, Kentucky shall submit either a proposed amendment or a description of an amendment to be proposed, together with a timetable for adoption of proposed revisions to its program to specify that Kentucky's program provide for the prompt replacement of water supplies.

[FR Doc. 95-15344 Filed 6-26-95; 8:45 am]

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## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 100

[CGD 05-95-026]

**Special Local Regulations for Marine Events; Welcome America Fireworks and Lighted Boat Parade; Delaware River, Philadelphia, PA**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of Implementation of 33 CFR 100.509.

**SUMMARY:** This notice implements 33 CFR 100.509 for the Welcome America Fireworks Display and Lighted Boat Parade. The boat parade will begin at Penn Treaty Park and conclude at Penn's Landing, Delaware River, Philadelphia, Pennsylvania on July 1, 1995. The fireworks display will be launched from barges anchored off Penns Landing, Delaware River, Philadelphia, Pennsylvania on July 3, 1995. The regulations in 33 CFR 100.509 are needed to control vessel traffic in the immediate vicinity of the event due to the confined nature of the waterway and expected spectator craft congestion during the event. The regulations restrict general navigation in the area for

the safety of life and property on the navigable waters during the event.

**EFFECTIVE DATES:** The regulations in 33 CFR 100.509 are effective from 8 p.m. to 11 p.m., July 1, 1995 and from 8:30 p.m. to 11:30 p.m., July 3, 1995. If inclement weather causes the postponement of the event, the regulations are effective from 8 p.m. to 11 p.m., July 2, 1995 and from 8:30 p.m. to 11:30 p.m., July 4, 1995.

**FOR FURTHER INFORMATION CONTACT:** Mr. Stephen L. Phillips, Chief, Boating Affairs Branch, Fifth Coast Guard District, 431 Crawford Street, Portsmouth, Virginia 23704-5004 (804) 398-6204, or Commander, Coast Guard Group Philadelphia (215) 271-4825.

**DRAFTING INFORMATION:** The drafters of this notice are QM2 Gregory C. Garrison project officer, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, and CDR C.A. Abel, project attorney, Fifth Coast Guard District Legal Staff.

**DISCUSSION OF REGULATIONS:** The Welcome America Committee submitted an application to hold the Welcome America Fireworks Display and Lighted Boat Parade. The display will be launched from barges anchored off Penns Landing, Delaware River, Philadelphia, Pennsylvania. Since many spectator vessels are expected to be in the area to watch the fireworks, the regulations in 33 CFR 100.509 are being implemented for this event. The fireworks will be launched from within the regulated area. The waterway will be closed during the display. Since the closure will not be for an extended period, commercial traffic should not be severely disrupted.

Dated: June 12, 1995.

**W. J. Ecker,**

*Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.*

[FR Doc. 95-15754 Filed 6-26-95; 8:45 am]

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#### 33 CFR Part 100

[CGD 05-95-036]

**Special Local Regulations for Marine Events; Great American Picnic and Fireworks, Elizabeth River, Town Point, Norfolk and Portsmouth, VA**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Notice of Implementation of 33 CFR 100.501.

**SUMMARY:** This notice implements 33 CFR 100.501 for the Great American Picnic and Fireworks Display to be held in the Waterside area of the Elizabeth River between Norfolk and Portsmouth, Virginia. These special local regulations

are needed to control vessel traffic within the immediate vicinity of Waterside due to the confined nature of the waterway and the expected vessel congestion during the event. The effect will be to restrict general navigation in the regulated area for the safety of participants and spectators.

**EFFECTIVE DATES:** The regulations in 33 CFR 100.501 are effective from 12:01 p.m. to 11 p.m., July 4, 1995.

**FOR FURTHER INFORMATION CONTACT:**

Stephen L. Phillips, Chief, Boating Affairs Branch, Fifth Coast Guard District 431 Crawford Street, Portsmouth, Virginia 23705 (804) 398-6204, or Commander, Coast Guard Group Hampton Roads (804) 483-8559.

**DRAFTING INFORMATION:** The drafters of this notice are QM2 Gregory C. Garrison, project officer, Boating Affairs Branch, Boating Safety Division, Fifth Coast Guard District, and CDR C.A. Abel, project attorney, Fifth Coast Guard District Legal Staff.

**DISCUSSION OF REGULATION:** Norfolk Festevents, Ltd. has submitted an application to hold the Great American Picnic in the Waterside area of the Elizabeth River. This area is described by 33 CFR 100.501 and generally includes the waters of the Elizabeth River between Town Point Park, Norfolk, Virginia, the mouth of the Eastern Branch of the Elizabeth River, and Hospital Point, Portsmouth, Virginia. Since this event is of the type contemplated by this regulation and the safety of the participants and spectators viewing this event will be enhanced by the implementation of special local regulations for the Elizabeth River, 33 CFR 100.501 will be in effect during the Great American Picnic. The waterway will be closed during the fireworks displays and air shows. Since the waterway will not be closed for an extended period, commercial traffic should not be severely disrupted. In addition to regulating the area for the safety of life and property, this notice of implementation also authorizes the Patrol Commander to regulate the operation of the Berkley drawbridge in accordance with 33 CFR 117.1007(b), and authorizes spectators to anchor in the special anchorage areas described in 33 CFR 110.72aa.

Dated: June 14, 1995.

**W. J. Ecker,**

*Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.*

[FR Doc. 95-15755 Filed 6-26-95; 8:45 am]

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