As provided in 5 CFR 1320.5(c)(1), collections of information in a direct final rule are subject to the procedures set forth in 5 CFR 1320.10. Interested persons and organizations may submit comments on the information collection requirements of this direct final rule by June 19, 1998, to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

At the close of the 60-day comment period, FDA will review the comments received, revise the information collection provisions as necessary, and submit these provisions to OMB for review. FDA will publish a notice in the **Federal Register** when the information collection provisions are submitted to OMB, and an opportunity for public comment to OMB will be provided at that time. Prior to the effective date of the direct final rule, FDA will publish a notice in the **Federal Register** of OMB's decision to approve, modify, or disapprove the information collection provisions. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VI. Request for Comments

Interested persons may, on or before July 6, 1998, submit to the Docket Management Branch (address above) written comments regarding this proposal. This comment period runs concurrently with the comment period for the companion proposed rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. All comments received will be considered comments regarding the proposed rule and this direct final rule. In the event the direct final rule is withdrawn, all comments received regarding the companion proposed rule and the direct final rule will be considered comments on the proposed rule.

List of Subjects in 21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 610 is amended as follows:

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

1. The authority citation for 21 CFR part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371; 42 U.S.C. 216, 262, 263, 263a, 264.

2. Section 610.11 is amended by revising paragraph (g) to read as follows:

§ 610.11 General safety.

* * * * *

(g) *Exceptions*—(1) The test prescribed in this section need not be performed for Whole Blood, Red Blood Cells, Cryoprecipitated AHF, Platelets, Plasma, or Cellular Therapy Products.

(2) For products other than those identified in paragraph (g)(1) of this section, a manufacturer may request from the Director, Center for Biologics Evaluation and Research, an exemption from the general safety test. The manufacturer shall submit information as part of a license application submission or supplement to an approved license application establishing that because of the mode of administration, the method of preparation, or the special nature of the product a test of general safety is unnecessary to assure the safety, purity, and potency of the product or cannot be performed. The request shall include any alternate procedures, if any, to be performed. The Director, Center for Biologics Evaluation and Research, upon finding that the manufacturer's request justifies an exemption, may exempt the product from the general safety test subject to any condition necessary to assure the safety, purity, and potency of the product.

Dated: April 10, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–10314 Filed 4–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 920

[MD–042–FOR]

Maryland Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Maryland regulatory program (hereinafter referred to as the ''Maryland program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Maryland proposed revisions to the Maryland regulations regarding a reduced bond liability period for lands remined. The amendments are intended to revise the Maryland program to be consistent with the corresponding Federal regulations and SMCRA.

EFFECTIVE DATE: April 20, 1998.

FOR FURTHER INFORMATION CONTACT: George Rieger, Program Manager, OSM, Appalachian Regional Coordinating Center, 3 Parkway Center, Pittsburgh, PA 15220. Telephone: (412) 937–2153.

SUPPLEMENTARY INFORMATION:

I. Background on the Maryland 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 Maryland Program

On December 1, 1980, the Secretary of the Interior conditionally approved the Maryland program. Background information on the Maryland program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the December 1, 1980, **Federal Register** (45 FR 79449). Subsequent actions concerning conditions of approval and program amendments can be found at 30 CFR 920.12, 920.15, and 920.16.

II. Submission of the Proposed Amendment

Maryland provided an informal amendment to OSM regarding a reduced bond liability period for lands remined in a letter dated August 21, 1996. OSM completed its review of the informal amendment and submitted comments to Maryland in a letter dated August 4, 1997. By letter dated October 9, 1997 (Administrative Record No. MD–579–00), Maryland submitted its response to OSM's comments in the form of a proposed amendment to its program pursuant to SMCRA. OSM's review of the proposed amendment resulted in additional questions for Maryland, to which they responded in a fax dated February 26, 1998 (Administrative Record No. 579–04).

OSM announced receipt of the proposed amendment in the November 21, 1997 **Federal Register** (62 FR 62273), 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 December 22, 1997.

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 paragraph notations to reflect organizational changes resulting from this amendment.

1. COMAR 26.20.01.02B Definitions

Specifically, Maryland proposes to delete the existing definition at (49), ''keyway,'' and add a new definition at (49) as follows:

Lands eligible for remining means any land that would otherwise be eligible for expenditures under Environment Article, Title 15, Subtitle 11, Annotated Code of Maryland.

There are no Federal counterparts to the term ''keyway'', nor is it used in the Maryland Code for anything related to the Maryland program. Therefore, the Director finds that the proposed deletion does not render the Maryland program less effective than the Federal regulations. Additionally, since subtitle 11 of the Maryland statute is the State's counterpart to Title IV of SMCRA (Abandoned Mine Lands), the Director finds that the proposed definition of ''lands eligible for remining'' is substantively identical to and therefore no less stringent than the Federal definition at section 701(34) of SMCRA.

2. COMAR 26.20.14.05 Duration of Performance Bonds

Paragraph B. is modified by adding to the opening phrase, ''except on lands eligible for remining''. Paragraph B. currently specifies that the period of liability for a bond shall continue for a minimum period of not less than 5 years, beginning with the last year of augmented seeding, fertilizing, irrigation, or other work. The addition of the phrase ''except on lands eligible for remining'' indicates that lands eligible for remining would therefore be subject to a different period of time, which is covered in new paragraph C. below. Since the addition of this phrase to the opening sentence in paragraph B. simply adds a qualification to exempt lands eligible for remining from the 5-year period of liability, the Director finds the change no less effective than the corresponding federal regulations at 816/817.116(c) in view of the additional change explained below.

New paragraph C. is added as follows:

On lands eligible for remaining included in permits issued before September 30, 2004, or any later date authorized by the federal Surface Mining Control and Reclamation Act, or any renewal thereof, the period of liability for a bond shall continue for a period of not less than 2 full years, beginning with the last year of augmented seeding, fertilizing, irrigation, or other work. The period of liability shall begin again when augmented seeding, fertilizing, irrigation or other work is ordered by the Bureau to correct a failure to maintain the permanent vegetative cover required under COMAR 08.20.29 on the site.

The federal rule at 30 CFR 816/817.116(c) requires that on lands eligible for remining, the operator must assume responsibility for successful revegetation for a period of 2 full years after the last year of augmented seeding, fertilizing, irrigation or other work to comply with applicable standards. Although Maryland's proposed rule includes the words ''beginning with the last year * * *'' and the Federal rule includes the words ''after the last year. * * *'' the rules do not conflict because of other regulatory sections in the Maryland program. The preamble to the Federal Rule at 48 FR 40155, dated September 2, 1983 regarding responsibility periods explained that the responsibility period could begin from the point at which the operator completes seeding and fertilizing. Maryland interprets the rule for unmined lands in this manner, and will interpret the proposed rule in the same manner. *See* February 26, 1998 fax (Administrative Record No. 579–04), Maryland's statute at § 15–513 and Maryland's regulations at COMAR 26.20.29.05 requires an operator to complete a backfilling and planting report when an affected area has been backfilled, regraded and planted in accordance with the statute and the approved reclamation plan. This report is reviewed by the on-site inspector, approved by his/her supervisor, and then approved by the Department. Only when approved by the Department does the responsibility period in Maryland begin. This is the actual practice in Maryland as monitored by OSM. Maryland's proposed regulation also requires the restart of the liability period when there is augmented seeding, fertilizing, irrigation or other work to correct a failure to maintain permanent vegetative cover. Therefore, the Director finds that the proposed revision at COMAR 26.20.14.05C is no less effective than the revegetation provisions of 816/817.116(c) that requires the period of extended responsibility for remined sites to last for two full years after the last augmented seeding.

Existing paragraph C. is re-lettered as D. and the 5-year reference is deleted. This paragraph currently specifies that if the bureau approves a long term intensive agricultural postmining land use, the applicable 5-year period of liability shall commence at the date of initial planting for such long-term intensive agricultural land use. The deletion of the 5-year reference from this paragraph allows it to pertain to all lands, i.e., lands not remined must still meet the 5-year criteria included in paragraph B., whereas lands remined would be subject to the two year criteria included in the changes outlined above in paragraph C. Since the deletion of the 5-year reference does not change the appropriate liability periods, the Director finds the change no less effective than the corresponding federal regulations at 816/817.116(c) in view of the additional changes explained above.

3. COMAR 26.20.14.08. Criteria and Schedule for Release of Performance Bond

Paragraph D. discusses the schedule for release of performance bonds. Existing paragraph D.(2) is deleted and new paragraph D.(2) is added as follows:

For acreage on which Reclamation Phase II has been completed and for which a bond release application has been submitted, an amount of bond not to exceed 50 percent of the per acre rate submitted in accordance with Regulation .03D of this chapter may be released;

Existing paragraph D.(3) is deleted and new paragraph D.(3) is added as follows:

For acreage on which Reclamation Phase III has been completed and for which a bond release application has been submitted, the remaining amount of bond equal to 50 percent of the per acre rate submitted in accordance with Regulation .03D of this chapter may be released;

New paragraph D.(4) is added as follows:

On lands eligible for remining, for acreage on which Reclamation Phases II and III have been completed and for which a bond release application has been submitted, bond in the amount of the per acre rate submitted in accordance with Regulation .03D of this chapter may be released.

The primary difference in paragraphs D.(2) and D.(3) added above from those deleted is a reference change from 03E. to 03D. of this regulation. Paragraph 03E of this regulation states that the minimum amount of the total bonds shall be $10,000 for the entire area under one permit, whereas 03D states the minimum amount of revegetation

bond shall be $600 per acre of affected land. These proposed paragraphs only change the reference from one of an overall minimum bond amount to a per acre minimum bond amount. Additionally, new paragraph D.(4) has been added to specifically address bond release on lands eligible for remining, which likewise requires that said release be performed subject to the same criteria, i.e. minimum bond amounts per acre in the same 03D reference. Since paragraph D.(4) requires the completion of Phase II and III work on lands eligible for remining before bond release, and the changes in proposed paragraphs D.(2) and (3) do not conflict with corresponding federal regulations, the Director finds that the proposed amendments are consistent with 30 CFR 800.40(c)(2) and (3).

4. COMAR 26.20.29.07. Standards for Success

Existing paragraph B.(8) is revised by adding the phrase ''except on lands eligible for remining as provided in § B.(9) of this regulation.'' Paragraph B.(8) currently specifies that the period of liability for a bond shall continue for a minimum period of not less than 5 years. The addition of the phrase indicates that lands eligible for remining would therefore be subject to a different period of time, which is covered in new paragraph B.(9) below. Since the addition of this phrase to the opening sentence in paragraph B.(8) simply adds a qualification to exempt lands eligible for remining from the 5-year period of liability, the Director finds the change no less effective than the corresponding federal regulations at 816/817.116(c) in view of the additional changes explained above.

Paragraph B. of COMAR 26.20.29.07 requires that the success standards for revegetation be applied in accordance with the approved post mining land use and now Maryland is adding the following condition for remined lands as set forth in new paragraph B.(9), which states:

On lands eligible for remining included in permits issued before September 30, 2004, or on any later date authorized by the federal Surface Mining Control and Reclamation Act, or any renewal thereof, the period of responsibility shall continue for a period of not less than 2 full years.

New paragraph C. is added as follows:

On lands eligible for remining included in any permit, the lands shall equal or exceed the standards for success during the growing season of the last year of the responsibility period in § B(9) of this regulation.

The Director finds that these revisions are substantively identical and no less effective than the corresponding Federal regulations at 30 CFR 816 and 817.116(c)(2)(ii).

5. COMAR 08.20.14.14 Release of Bonds on Remining Areas

Maryland proposed to add, and the Office of Surface Mining approved, this section as published in the **Federal Register** (62 FR 12028) dated March 25, 1996. However, Maryland subsequently chose not to promulgate this regulation. Instead, Maryland now proposes the changes enumerated in Items 1. through 4. above, which are approved by the Director as stated. Since these revisions are no less effective than the federal rules, OSM finds that the non-promulgation of this section does not render the Maryland program less effective, and OSM is now deleting this section from the approved Maryland program.

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. No comments were received and because no one requested an opportunity to speak at a public hearing, no hearing was held.

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 Maryland program. MSHA responded in its letter dated November 19, 1997, (Administrative Record No. 579–02), that it anticipated no further action regarding the proposed amendment. No other comments were received.

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.*). The Director has determined that this amendment contains no such provisions and that EPA concurrence is therefore unnecessary. Also, EPA did not respond to OSM's request for comments.

V. Director's Decision

The Federal regulations at 30 CFR Part 920, codifying decisions concerning the Maryland 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.

VI. Procedural Determinations

Executive Order 12866

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

Executive Order 12998

The Department of the Interior has conducted the reviews required by section 3 of Executive Order 12998 (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. 4332(2)(C)).

Paperwork Reduction Act

This rule does not contain information collection requirements that require approval by OMB under the Paperwork Reduction Act (44 U.S.C. 3507 *et seq.*).

Regulatory Flexibility Act

The Department of the Interior has determined that this rule will not have a significant economic impact on a

substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). The State submittal which is the subject of this rule is based upon corresponding Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. 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 in the analyses for the corresponding Federal regulations.

Unfunded Mandates

This rule will not impose a cost of $100 million or more in any given year on any governmental entity or the private sector.

List of Subjects in 30 CFR Part 920

Intergovernmental relations, Surface mining, Underground mining.

Allen D. Klein,

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 920—MARYLAND

1. The authority citation for part 920 continues to read as follows:

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

2. Section 920.15 is amended in the table by adding a new entry in chronological order by ''Date of Final Publication'' to read as follows:

§ 920.15 Approval of Maryland regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
*	*	* * * * *
October 9, 1997	April 20, 1998	COMMAR 26.20.01.02B(49), 26.20.14.05 B, C & D, 26.20.14.08.D.(2) through (4), 26.20.29.07.B(8), B(9) and (C), deletion of 08.20.14.14.

[FR Doc. 98–10295 Filed 4–17–98; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05–98–020]

Special Local Regulations for Marine Events; Approaches to Annapolis Harbor, Spa Creek, and Severn River, Annapolis, MD

AGENCY: Coast Guard, DOT.

ACTION: Notice of implementation.

SUMMARY: This notice implements the special local regulations for the Blue Angels Airshow, to be held May 19 and 22, 1998, over Spa Creek and the Severn River, near the U.S. Naval Academy, Annapolis, Maryland. These special local regulations are necessary to control vessel traffic in the vicinity of the U.S. Naval Academy due to the confined nature of the waterway and expected vessel congestion during the airshow. The effect will be to restrict general navigation in the regulated area for the safety of spectators and vessels transiting the event area.

DATES: The regulation implemented by this notice is effective from 11:30 a.m. to 4 p.m. on May 19, 1998 and from 11:30 a.m. to 4:30 p.m. on May 20, 1998.

FOR FURTHER INFORMATION CONTACT: Chief Warrant Officer R. L. Houck, Marine Events Coordinator, Commander, Coast Guard Activities Baltimore, 2401 Hawkins Point Road, Baltimore, MD 21226–1971, (410) 576–2674.

SUPPLEMENTARY INFORMATION: The U.S. Naval Academy will sponsor the Blue Angels Airshow over the Severn River near the U.S. Naval Academy, Annapolis, Maryland. The event will consist of 6 high performance jet aircraft flying at low altitudes in formation over the Severn River. Therefore, to ensure the safety of spectators and transiting vessels, 33 CFR 100.511 will be in effect for the duration of the event. Under provisions of 33 CFR 100.511, a vessel may not enter the regulated area unless it receives permission from the Coast Guard Patrol Commander. Spectator vessels may anchor outside the regulated area but may not block a navigable channel. Because these restrictions will be in effect for a limited period, they should not result in a significant disruption of maritime traffic.

Dated: March 25, 1998.

Roger T. Rufe, Jr.,

Vice Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 98–10306 Filed 4–17–98; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD05–98–017]

RIN 2115–AE47

Drawbridge Operation Regulations; Anacostia River, Washington, DC

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the regulations that govern the operation of the Frederick Douglass Memorial (South Capitol Street) bridge across Anacostia River at mile 1.2 in Washington, D.C. Beginning at 8 a.m. on March 11 through 11 p.m. on August 31, 1998, this regulation authorizes the bridge to remain closed to navigation. This action is necessary to facilitate extensive mechanical and electrical rehabilitation and maintain the bridge's operational integrity.

DATES: This regulation is effective from April 2, 1998 to 11 p.m. on August 31, 1998.

ADDRESSES: Douments as indicated in this preamble are available for inspection or copying at the office of the Commander (Aowb), Fifth Coast Guard District, Federal Building, 4th Floor, 431 Crawford Street, Portsmouth, Virginia 23704–5004, between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays. The telephone number is (757) 398–6222.