Feasibility, Practicability, and Appropriateness Determination for the Proposed Rule to Require Special Packaging for Products Containing Minoxidil,'' December 16, 1997.

5. Memorandum from Michael T. Bogumill, CRM, to Val Schaeffer, Ph.D., EH, ''Special Packaging of Oral Prescription Drugs in Dropper Bottles,'' December 17, 1997.

6. Briefing memorandum from Suzanne Barone, Ph.D., EH, to the Commission, ''Final Rule to Require Child-Resistant Packaging for Topical Minoxidil,'' October 9, 1998.

7. Memorandum from Martha A. Kosh, OS, Comments on the Proposed Rule for Requirements for Child-resistant Packaging; Minoxidil Preparation with More than 14 mg of Minoxidil per Package (CP98–3), June 2, 1998.

8. Memorandum from Charles Wilbur, EH, to Suzanne Barone, Ph.D., EH, ''Technical Feasibility, Practicability, and Appropriateness Determination for the Final Rule to Require Special Packaging for Products Containing Minoxidil,'' August 21, 1998.

9. Memorandum from Marcia P. Robins, EC, to Suzanne Barone, Ph.D., EH, ''Child-Resistant Packaging for Preparations Containing Minoxidil: Small Business Effects,'' August 24, 1998.

[FR Doc. 98–29732 Filed 11–13–98; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF THE INTERIOR

Office of the Surface Mining Reclamation and Enforcement

30 CFR Part 944

[SPATS No. UT–039–FOR]

Utah Regulatory Program

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

ACTION: Final rule; approval of amendment.

SUMMARY: The Office of Surface Mining Reclamation and Enforcement (OSM) is approving a proposed amendment to the Utah regulatory program (the ''Utah program'') under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Utah proposed changes in its requirements for coal mine permit application approval at section 40–10–11 of the Utah Code Annotated (UCA, or the ''Utah Code''). The State proposed the changes to update language used to describe the approval process and information that needs to be documented during that process. In addition, Utah proposed to change paragraph (f) of UCA 40–10–11(2) to clarify limitations on the authority of the Division of Oil, Gas and Mining and of the Board of Oil, Gas and Mining with respect to property right disputes. Utah also proposed to revise provisions concerning a permit applicant's list of violations of air and water protection provisions at subsection (3) of UCA 40–10–11 in response to an amendment required by OSM and described at 30 CFR 944.16(f)(2). The amendment revised the Utah program to be consistent with the Surface Mining Control and Reclamation Act of 1977 (SMCRA) regulations and to improve operational efficiency.

EFFECTIVE DATE: November 16, 1998.

FOR FURTHER INFORMATION CONTACT: James F. Fulton, Chief, Denver Field Division, telephone: (303) 844–1424; e-mail address: jfulton@osmre.gov.

SUPPLEMENTARY INFORMATION:

I. Background on the Utah Program

On January 21, 1981, the Secretary of the Interior conditionally approved the Utah program. General background information on the Utah program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Utah program can be found in the January 21, 1981, **Federal Register** (46 FR 5899). Subsequent actions concerning Utah's program and program amendments can be found at 30 CFR 944.15, 944.16, and 944.30.

II. Proposed Amendment

Utah submitted a proposed amendment (SPATS No. UT–039–FOR, administrative record No. 1117) to its program pursuant to SMCRA (30 U.S.C. 1201 *et seq.*) by letter dated June 8, 1998. The State submitted the proposed amendment at its own initiative and in response to a requirement at 30 CFR 944.16(f)(2) imposed by the Director resulting from OSM's review of a previous amendment to the Utah Code.

The proposed amendment consisted of revisions to UCA 40–10–11. This section of the Utah Code pertains to actions by the Division of Oil, Gas and Mining (the Division) to approve or deny coal mine permit applications. UCA 40–10–11 also includes provisions for considering, during the permit approval/denial process, an applicant's violations of air and water protection provisions, whether an area proposed for mining includes prime farmlands, and information related to land ownership and the probable impacts of mining on the hydrologic balance.

Most of the changes Utah proposed reword existing provisions of UCA 40–10–11 in current writing style and break-up existing provisions into subsections. In that context, specific changes included: Recodifying existing provisions of UCA 40–10–11(1) as subsections (1)(a)(i) and (ii), (1)(b), (1)(c), and (1)(c)(i) and (ii); recodifying existing provisions of UCA 40–10–11(2)(d) to include subsections 1(d)(i) and 2(d)(ii); recodifying existing provisions of UCA 40–10–11(2)(e)(i) to include subsections (e)(i)(A) and (B); recodifying, in part, existing provisions of UCA 40–10–11(2)(f)(i) to include subsection (2)(f)(i)(A), and adding new subsection (2)(f)(i)(B); recodifying existing provisions of UCA 40–10–11(3) as subsections (3)(a)(i), (ii), and (3)(b) and (c); and recodifying existing provisions of UCA 40–10–11(4)(a) as (4)(a)(i) and (ii). Utah proposed to reword several parts of UCA 40–10–11(1), (2), (3), (4) and (5) as well.

In two cases, the State either expanded existing provisions of the Utah Code or added a new provision. At UCA 40–10–11(2)(f)(i)(B), Utah added a new statement to the effect that nothing in UCA 40–10–11(2) shall be construed ''* * * to authorize the board or divisions to adjudicate property right disputes * * *'' in cases where permit applications involve lands on which the private mineral estate has been severed from the private surface estate. Second, at recodified UCA 40–10–11(3)(c), Utah proposed to preclude permit issuance in cases in which the Board finds that an applicant or operator controls, or has controlled, mining operations with a demonstrated pattern of willful violations. Such a pattern includes violations of SMCRA, the implementing regulations, or of any State or Federal programs enacted under SMCRA or under other provisions of the approved Utah program, in addition to violations of the Utah Code. The State proposed this new provision in response to the required amendment described at 30 CFR 944.16(f)(2). That section requires the Utah Code's provision for denying permits on the basis of patterns of violations to be no less stringent than the Federal counterpart provision at section 510(c) of SMCRA. The required amendment resulted from OSM's review of a previous amendment to the Utah Code (UT–024–FOR; 60 FR 37002, July 19, 1995; administrative record No. UT–1066). OSM later reiterated the need for Utah to amend UCA 40–10–11(3) in its review of Code amendment UT–035–FOR (62 FR 41845, August 4, 1997; administrative record No. UT–1098).

OSM announced receipt of this proposed amendment in the July 8, 1998, **Federal Register** (63 FR 36868; administrative record No. UT–1120). That announcement provided an opportunity for anyone to request a public hearing or meeting on the amendment's substantive adequacy. It also invited public comment on its

adequacy. No one requested a public hearing or meeting, so OSM did not hold either one. The public comment period ended on August 7, 1998.

III. Director's Findings

In accordance with SMCRA and 30 CFR 731.15 and 732.17, and as discussed below, the Director finds that the proposed program amendment submitted by Utah on June 8, 1998, is no less stringent than SMCRA. Accordingly, the Director approves Utah's amendment.

1. Nonsubstantive Revisions to the Utah Code

Utah proposed revisions to the following previously approved provisions of the Utah Code that are nonsubstantive in nature. These proposed revisions consist of recodification changes. They also include wording and punctuation changes made to reflect contemporary writing style and to make the State's provisions clearer or more specific. Corresponding SMCRA provisions are listed in parentheses.

UCA 40–10–11(1)(a)(i), (a)(ii), (1)(b), (1)(c), (c)(i), and (c)(ii), decision to approve, deny, or require modification of a permit application after receipt of a complete application and reclamation plan (section 510(a) of SMCRA);

UCA 40–10–11(2), (2)(a), (2)(b), and (2)(c), required finding that the permit application is complete and all requirements of UCA 40–10 have been complied with; required demonstration in the application and finding by the Division as a prerequisite to Division approval that reclamation requirements under UCA 40–10 can be accomplished; and finding that an assessment has been made of mining's cumulative impacts on the hydrologic balance and that the operation is designed to prevent material damage to the hydrologic balance outside the permit area (sections 510(b), (b)(1), (b)(2), and (b)(3) of SMCRA);

UCA 40–10–11(2)(d), (d)(i), and (d)(ii), demonstration in the application and finding by the Division that the proposed mining area is not in an area designated as unsuitable for mining or under study for that designation (section 510(b)(4) of SMCRA);

UCA 40–10–11(2)(e), (2)(e)(i), (e)(i)(A), and (e)(i)(B), demonstration in the application and finding by the Division that the proposed mining will not adversely affect farming on alluvial valley floors in certain cases (sections 510(b)(5) and (b)(5)(A) of SMCRA);

UCA 40–10–11(2)(e)(ii), demonstration in the application and finding by the Division that the proposed mining will not materially damage surface and ground water systems that supply alluvial valley floors, with certain exceptions (section 510(b)(5)(B) of SMCRA);

UCA 40–10–11(2)(f), (2)(f)(i), and (f)(i)(A), requirement for the surface owner's written consent to surface mining where the private mineral estate has been severed from the private surface estate, with the provision that UCA 40–10–11(2)(f) shall not be construed to change any property right established under State law (section 510(b)(6) and (b)(6)(A) of SMCRA, with no SMCRA counterpart to recodified UCA 40–10–11(2)(f)(i)(A));

UCA 40–10–11(2)(f)(iii), requirement for an application to include documentation, consistent with state law, that establishes the status of the surface-subsurface legal relationship as an alternative to including a conveyance expressly granting or reserving the right to extract coal by surface mining in cases where the private surface estate has been severed from the private mineral estate (section 510(b)(6)(C) of SMCRA);

UCA 40–10–11(3)(a)(i), (a)(ii), and (3)(b), requirement for an applicant to submit a list of violations with the permit application and for the Division to consider such violations in deciding to approve or deny a permit (section 510(c) of SMCRA);

UCA 40–10–11(4)(a)(i), (a)(ii), and (4)(b), permit findings required in some cases if the area proposed to be mined contains prime farmland (section 510(d)(1) and (2) of SMCRA); and

UCA 40–10–11(5)(a), provision that the prohibition against permit issuance at UCA 40–10–11(3) shall not apply to a permit application if the violation resulted from an unanticipated situation that occurred at a surface mine on lands eligible for remining under a permit held by the person applying for a mining permit (section 510(e) of SMCRA).

Because the proposed revisions to these previously-approved statutory provisions are nonsubstantive in nature, the Director finds these proposed statutory provisions are no less stringent that SMCRA. The Director approves these proposed changes to the Utah Code.

2. UCA 40–10–11(2)(f)(i)(B), Limitation on Division and Board Authority in Property Rights Disputes

Utah proposed to add UCA 40–10–11(2)(f)(i)(B) to provide that nothing in subsection (2) of UCA 40–10–11 shall be construed to authorize the Board or Division to adjudicate property right disputes. The counterpart provision in SMCRA is at section 510(b)(6)(C). The State's proposed provision is very similar to the SMCRA provision except for its reference to the ''Division'' and the ''Board'' not having the power to adjudicate disputes, while SMCRA refers to the ''regulatory authority''. The Division is the regulatory authority in Utah and the Board oversees the Division's activities, is the rulemaking body, and hears appeals of actions taken by the Division. UCA 40–10–6 describes the duties, functions, and powers of the Division and Board but does not specifically describe their authority with respect to property rights disputes, particularly those that might arise when permit applications involve lands on which the private surface estate is severed from the private mineral estate. Utah's proposed addition of UCA 40–10–11(2)(f)(i)(B) provides the necessary clarification of Division and Board authority in such cases and is consistent with SMCRA in that respect.

For the reasons explained above, the Director finds Utah's proposed addition of UCA 40–10–11(2)(f)(i)(B) to be consistent with, and no less stringent than, the counterpart provision at section 510(b)(6)(C) of SMCRA. Accordingly, the Director approves the proposed revision to the Utah Code.

3. UCA 40–10–11(3)(c), List of Violations in Permit Applications

Utah proposed to revise UCA 40–10–11(3) in response to the required amendment described at 30 CFR 944.16(f)(2). During its review of a previous amendment to the Utah Code, OSM noted that the part of UCA 40–10–11(3) dealing with patterns of violations only addressed violations of the State statute. OSM explained that Utah's provision needed to require consideration of other violations as well and cited previous rulemaking in support of that explanation. Specifically, in finding No. 7 of the final rule announcing its approval of amendment UT–024–FOR (60 FR 37002, 37006, July 19, 1995; administrative record No. UT–1066), OSM concluded that UCA 40–10–11(3) was less stringent than SMCRA. As a result, OSM imposed a required amendment at 30 CFR 944.16(f)(2). That subsection specifically required Utah to revise UCA 40–10–11(3) to provide that the pattern of violations determination include violations of SMCRA, the implementing Federal regulations, any State or Federal programs enacted under SMCRA, and other provisions of the approved Utah program.

With this amendment, Utah's proposed change addresses the required amendment at 30 CFR 944.16(f)(2) by

revising UCA 40–10–11(3) to add a provision at new subsection (3)(c). That provision requires including violations of SMCRA, the implementing Federal regulations, any State or Federal programs enacted under SMCRA, or other provisions of the approved Utah program in findings of patterns of violations. As proposed, UCA 40–10–11(3)(c) is no less stringent than the counterpart provision at section 510(c) of SMCRA and satisfies the requirement described at 30 CFR 944.16(f)(2). The Director approves Utah's revision at UCA 40–10–11(3)(c) and removes the required amendment at 30 CFR 944.16(f)(2).

IV. Summary and Disposition of Comments

Following are summaries of all written comments OSM received on the proposed amendment.

1. Public Comments

The Utah Mining Association responded in June 30, 1998, letter by expressing its support for the proposed amendment and urging OSM to approve it (administrative record No. UT–1121). The Mining Association said it worked closely with the Division to develop the amendment and was involved in its consideration and passage in the 1998 session of the Utah Legislature. Also, the Mining Association stated that, in its opinion, changes proposed in this amendment are consistent with SMCRA and are supported by the Utah coal industry.

2. Federal Agency Comments

OSM solicited comments on the proposed amendment from various Federal agencies with an actual or potential interest in the Utah program, as required by 30 CFR 732.17(h)(11)(i).

The Utah Field Office of U.S. Department of the Interior, Fish and Wildlife Service (FWS) responded in a letter dated July 20, 1998 (administrative record No. UT–1123). FWS offered no comments on the proposed amendment.

3. Environmental Protection Agency (EPA) Concurrence and Comments

OSM is required by 30 CFR 732.17(h)(11)(ii) to solicit EPA's written concurrence on provisions of the proposed amendment relating to air and water quality standards promulgated under the authority of the Clean Air Act (42 U.S.C. 7401 *et seq.*) or the Clean Water Act (33 U.S.C. 1251 *et seq.*). None of the changes Utah proposed in amendment UT–039–FOR pertain to air or water quality standards. As a result, OSM did not request EPA's concurrence.

Nevertheless, OSM solicited EPA's comments on the proposed amendment as required by 30 CFR 732.17(h)(11)(i) (administrative record No. UT–1118). OSM did not receive any comments from EPA.

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

OSM solicited comments on the proposed amendment from the Utah SHPO and the ACHP as required by 30 CFR 732.17(h)(4) (administrative record No. UT–1118). OSM did not receive any comments from the SHPO or ACHP.

V. Director's Decision

Based on the above findings, the Director approves Utah's proposed amendment as submitted on June 8, 1998.

The Director approves, as discussed in: Finding No. 1, UCA 40–10–11(1) through (1)(c)(ii), recodification and rewording of provisions pertaining to the decision to approve, deny, or require modification of a permit application after receipt of a complete application and reclamation plan; UCA 40–10–11(2)(a), (b), and (c), reworded requirement for a finding of permit application completeness and compliance with UCA 40–10, for demonstration in the application and finding by the Division that reclamation requirements under UCA 40–10 can be accomplished, and for a finding that an assessment has been made of mining's cumulative impacts on the hydrologic balance and that the operation is designed to prevent material damage to the hydrologic balance outside the permit area; UCA 40–10–11(2)(d), (d)(i), and (d)(ii), recodified and reworded requirement for a demonstration in the application and finding by the Division that the proposed mining area is not in an area designated as unsuitable for mining or under study for that designation; UCA 40–10–11(2)(e), (e)(i), (e)(i)(A), (e)(i)(B), recodified and reworded requirement for a demonstration in the application and finding by the Division that the proposed mining will not adversely affect farming on alluvial valley floors in certain cases; UCA 40–10–11(2)(e)(ii), reworded requirement for a demonstration in the application and finding by the Division that the proposed mining will not materially damage surface and ground water systems that supply alluvial valley floors, with certain exceptions; UCA 40–10–11(2)(f), (f)(i), and (f)(i)(A), recodified and reworded requirement for the surface owner's written consent to surface mining where the private mineral estate has been severed from the private surface estate, with the provision that UCA 40–10–11(2)(f) shall not be construed to change any property right established under State law; UCA 40–10–11(2)(f)(iii), reworded requirement for documentation in an application establishing the status of the surface-subsurface legal relationship as an alternative to a conveyance expressly granting or reserving the right to extract coal by surface mining where the private surface estate has been severed from the private mineral estate; UCA 40–10–11(3)(a)(i), (a)(ii), and (3)(b), recodified and reworded requirement for an applicant to submit a list of violations with the permit application and for the Division to consider such violations in deciding to approve or deny a permit; UCA 40–10–11(4)(a)(i), (a)(ii), and (4)(b), recodified and reworded provision requiring permit findings in some cases prime farmland to be mined; and UCA 40–10–11(5)(a), reworded provision that the prohibition against permit issuance at UCA 40–10–11(3) shall not apply to a permit application if the violation resulted from an unanticipated situation that occurred at a surface mine on lands eligible for remining under a permit held by the person applying for a mining permit; Finding No. 2, UCA 40–10–11(2)(f)(i)(B), provision that nothing in subsection (2) of UCA 40–10–11 shall be construed to authorize the Board or Division to adjudicate property right disputes; and Finding No. 3, UCA 40–10–11(3)(c), requirement that the pattern of violations determination include violations of SMCRA, the implementing Federal regulations, any State or Federal programs enacted under SMCRA, and other provisions of the approved Utah program.

To implement this decision, OSM is amending the Federal regulations at 30 CFR Part 944, which codify decisions concerning the Utah program. By making this final rule effective immediately, OSM is expediting the State program amendment process. OSM encourages States to make their programs conform to the Federal standards without undue delay.

VI. Procedural Determinations

1. 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).

2. Executive Order 12988

The Department of the Interior conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and 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. 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) describe how OSM must make decisions on proposed State regulatory programs and program amendments. As required by those provisions, OSM must base its decision on a State amendment solely on a determination of whether the amendment 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.

3. National Environmental Policy Act

Under section 702(d) of SMCRA (30 U.S.C. 1292(d)), agency decisions on proposed State regulatory program provisions are not major Federal actions within the meaning of section 102(2)(C) of the National Environmental Policy Act (42 U.S.C. 4332(2)(C)). Consequently, an environmental impact statement is not required for this rule.

4. 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.*).

5. 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 amendment that is the subject of this rule is based on counterpart Federal regulations. An economic analysis of those Federal regulations was prepared and certification made that they 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. The Department relied upon the data and assumptions for the counterpart Federal regulations in making the determination as to whether this rule would have a significant economic impact.

6. Unfunded Mandates

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

List of Subjects in 30 CFR Part 944

Intergovernmental relations, Surface mining, Underground mining.

Dated: October 14, 1998.

Richard J. Seibel,

Regional Director, Western Regional Coordinating Center.

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

PART 944—UTAH

1. The authority citation for part 944 continues to read as follows:

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

2. Section 944.15 is amended in the table by adding a new entry in chronological order by ''Date of Final Publication'' to read as follows:

§ 944.15 Approval of Utah regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
*	*	*
June 8, 1998	November 16, 1998	UCA 40–10–11(1)(a)(i), (a)(ii), (1)(b), (1)(c), (c)(i), and (c)(ii); (2), (2)(a), (2)(b), (2)(c), (2)(d), (2)(d)(i), (d)(ii), (2)(e), (2)(e)(i), (e)(i)(A), (e)(i)(B), (e)(ii), (2)(f), (2)(f)(i), (f)(i)(A), (f)(i(B), and (f)(iii); (3)(a)(i), (a)(ii), (3)(b), and (3)(c); (4)(a)(i), (a)(ii), and (4)(b); and (5)(a).

§ 944.16 [Amended]

3. Section 944.16 is amended by removing and preserving paragraph (f) in its entirety.

[FR Doc. 98–30547 Filed 11–13–98; 8:45 am]

BILLING CODE 4310–05–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07–98–068]

RIN 2115–AE46

Special Local Regulations; City of Augusta, GA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary special local regulations are being adopted for the Augusta Port Authority's Head of the South Rowing Regatta. The event will be held from 7 a.m. to 6 p.m. Eastern Standard Time (EST) each day on November 13 and 14, 1998, on the Savannah River at Augusta, GA. These regulations are necessary for the safety of life on navigable waters during the event.

DATES: This rule becomes effective at 6:30 a.m. and terminates at 6:30 p.m. EST each day on November 13 and 14, 1998.

FOR FURTHER INFORMATION CONTACT: LTJG A. Cooper, Project Manager, Coast Guard Group Charleston at (803) 724–7621.

SUPPLEMENTARY INFORMATION:

Background and Purpose

These regulations are needed to provide for the safety of life during the Head of the South Rowing Regatta. The regulations are intended to promote safe navigation on the Savannah River immediately before, during, and after the race by controlling the traffic entering, exiting, and traveling within the regulated area. The anticipated number of participants and spectator vessels poses a safety concern which is addressed in these special local regulations. There will be approximately 6000 participants racing singles, doubles, four, and eight person rowing shells on a fixed course. The event will take place in an area of limited commercial traffic on the Savannah River at Augusta, GA between mile marker 200.2 and marker 197.0.