

application for approval to market a biological product regulated under section 351 of the Public Health Service Act (42 U.S.C. 262 *et seq.*). Currently, most manufacturers must submit an establishment license application (ELA) and a product license application (PLA) when requesting approval to market a biological product in interstate commerce. Under the proposed regulations, a manufacturer would submit to FDA the appropriate establishment and product information in a single biologics license application (BLA) in lieu of filing a separate ELA and PLA. The BLA is intended to replace the many different ELA and PLA forms currently in use. Upon approval of the BLA, a manufacturer would receive a single biologics license to market the product in interstate commerce.

Interested persons may submit written comments on the proposed rule (63 FR 40858) to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number found in brackets in the heading of this document and should be submitted by October 14, 1998. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

**Registration:** Fax registration information (including name, title, firm name, address, telephone, and fax number) to the contact person by Friday, August 21, 1998. There is no registration fee for the workshop. Space is limited, therefore interested parties are encouraged to register early.

If you need special accommodations due to a disability, please contact Kathy A. Eberhart at least 7 days in advance.

**Transcripts:** Transcripts of the workshop may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857, approximately 15 working days after the workshop at a cost of 10 cents per page.

Dated: August 5, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

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## DEPARTMENT OF THE INTERIOR

### Office of Surface Mining Reclamation and Enforcement

#### 30 CFR Part 902

[AK-007-FOR, Amendment No. VII]

#### Alaska Regulatory Program

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

**ACTION:** Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

**SUMMARY:** The Office of Surface Mining Reclamation and Enforcement (OSM) is announcing receipt of a proposed amendment to the Alaska regulatory program (hereinafter, the "Alaska program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment consists of revisions to rules pertaining to general permitting requirements, general permit application information requirements, environmental resource information requirements, reclamation and operation plan requirements, permitting for special categories of mining, coal exploration, self-bonding requirements, performance standards, and general provisions. The amendment is intended to revise the Alaska program to provide additional safeguards, to clarify ambiguities, and to improve operational efficiency.

**DATES:** Written comments must be received by 4:00 p.m., m.d.t., September 10, 1998. If requested, a public hearing on the proposed amendment will be held on September 8, 1998. Requests to present oral testimony at the hearing must be received by 4:00 p.m., m.d.t., August 26, 1998.

**ADDRESSES:** Written comments should be mailed or hand delivered to James F. Fulton at the address listed below.

Copies of the Alaska program, the proposed amendment, and all written comments received in response to this document will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Denver Field Division.

James F. Fulton, Chief, Denver Field Division, Office of Surface Mining Reclamation and Enforcement, 1999 Broadway, Suite 3320, Denver, Colorado 80202-5733.

Robert Loeffler, Large Mine Project Manager, Alaska Division of Mining and Water Management, 3601 C

Street, Suite 800, Anchorage, Alaska 99503-5935, Telephone: 907-269-8627.

**FOR FURTHER INFORMATION CONTACT:** James F. Fulton, Telephone: 303-844-1424; Internet address: JFULTON@OSMRE.GOV.

#### SUPPLEMENTARY INFORMATION:

#### I. Background on the Alaska Program

On March 23, 1983, the Secretary of the Interior conditionally approved the Alaska program. General background information on the Alaska program, including the Secretary's findings, the disposition of comments, and conditions of approval of the Alaska program can be found in the March 23, 1983, **Federal Register** (48 FR 12274).

Subsequent actions concerning Alaska's program and program amendments can be found at 30 CFR 902.15 and 902.16.

#### II. Proposed Amendment

By letter dated July 30, 1998, Alaska submitted a proposed amendment (amendment number VII, administrative record No. AK-07-01) to its program pursuant to SMCRA, 30 U.S.C. 1201 *et seq.* Alaska submitted the proposed amendment at its own initiative. The provisions of the Alaska Surface Coal Mining Program Regulations that Alaska proposed to revise were: 11 Alaska Administrative Code (AAC) 90.002(a), (b), and (c), responsibilities, and 11 AAC 90.011[(a)] (1) and (2), permit fees, as provided in Article 2, General Permitting Requirements; 11 AAC 90.025(a)(2), (b), and (c), authority to enter and ownership information, as provided in Article 3, General Permit Application Information Requirements; 11 AAC 90.045(a)(1) and (2), geology description, and 11 AAC 90.049[(a)], [(a)](1), (2), and [(a)](2)(C) through (H) surface water information, as provided in Article 4, Environmental Resource Information Requirements; 11 AAC 90.083(b)(9) and (11), reclamation plan general requirements, and 11 AAC 90.097, transportation facilities, as provided in Article 5, Reclamation and Operation Plan; 11 AAC 90.149(d) and (d)(1), operations near alluvial valley floors, as provided in Article 7, Permitting for Special Categories of Mining; 11 AAC 90.163(a) and (d), exploration that substantially disturbs the natural land surface or occurs in an area designated unsuitable for surface coal mining, as provided in Article 8, Exploration; 11 AAC 90.207(f), self-bonding requirements, as provided in Article 10, Bonding; 11 AAC 90.337(f), impoundment inspection, 11 AAC 90.375(f), public notice of blasting, 11

AAC 90.391(h)(1) and (2) and (s), disposal of excess spoil and coal mine waste, 11 AAC 90.401(e), coal mine waste, refuse piles, 11 AAC 90.407(e), coal mine waste, dams and embankments, 11 AAC 90.423(b) and (h), protection of fish and wildlife, 11 AAC 90.443(d)(1), (k), and (k)(1) and (2), backfilling and grading, and 11 AAC 90.491(e), (f), and (f)(1) and (2), construction and maintenance of roads, transportation and support facilities, and utility installations, as provided in Article 11, Performance Standards; and 11 AAC 90.901(e), applicability, 11 AAC 90.907(c) and (j), public participation, and 11 AAC 90.911(92), definition of "road," as provided in Article 17, General Provisions.

Alaska is proposing numerous editorial changes and recodifications for the purpose of clarity and in order to be consistent with the requirements of the State's "Drafting Manual for Administrative Regulations" (1995 edition). In addition, Alaska specifically proposes at 11 AAC 90.049[(a)](2)(G) to require that water quality data show acidity information if there is potential for acid drainage from the proposed mining operation, and at 11 AAC 90.207(f)(2) to apply certain provisions for self-bonding, including criteria that must be met by the self-bond guarantor.

### III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is seeking comments on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Alaska program.

#### 1. Written Comments

Written comments should be specific, pertain only to the issues proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under **DATES** or at locations other than the Denver Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

#### 2. Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under **FOR FURTHER INFORMATION CONTACT** by 4:00 p.m., m.d.t., August 26, 1998. Any disabled individual who has need for a special accommodation to attend a public hearing should contact the individual listed under **FOR FURTHER INFORMATION CONTACT**. The location and time of the

hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at the public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to testify have been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

#### 3. Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting by contacting the person listed under **FOR FURTHER INFORMATION CONTACT**. All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under **ADDRESSES**. A written summary of each meeting will be made a part of the administrative record.

### IV. 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 has conducted the reviews required by section 3 of Executive Order 12988 (Civil Justice Reform) and has determined that this rule meets the applicable standards of subsections (a) and (b) of that section. However, these standards are not applicable to the actual language of State regulatory programs and program amendments 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 the Federal regulations at 30 CFR 730.11, 732.15, and 732.17(h)(10), decisions on proposed State regulatory programs and program amendments submitted by the States must be based

solely on a determination of whether the submittal is consistent with SMCRA and its implementing Federal regulations and whether the other requirements of 30 CFR Parts 730, 731, and 732 have been met.

#### 3. National Environmental Policy Act

No environmental impact statement is required for this rule since section 702(d) of SMCRA (30 U.S.C. 192(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)).

#### 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 submittal that is the subject of this rule is based upon counterpart Federal regulations for which an economic analysis was prepared and certification made that such regulations would not have a significant economic effect upon a substantial number of small entities. 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 counterpart Federal regulations.

#### 6. 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 902

Intergovernmental relations, Surface mining, Underground mining.

Dated: August 4, 1998.

**Russell F. Price,**

*Acting Regional Director,*

*Western Regional Coordinating Center.*

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