

Class E airspace at Grand Rapids, MN, to accommodate aircraft executing the proposed GPS Rwy 16 SIAP and the VOR or GPS Rwy 34 SIAP, Amdt 10, at Grand Rapids/Itasca County, Gordon Newstrom Field Airport by modifying the existing controlled airspace. Controlled airspace extending upward from the surface, and controlled airspace extending upward from 700 to 1200 feet AGL, is needed to contain aircraft executing the approaches. The area would be depicted on appropriate aeronautical charts. Class E airspace designations for airspace areas designated as a surface area for an airport are published in paragraph 6002, and Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005, of FAA Order 7400.9E dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore this, proposed regulation—(1) is not a “significant regulatory action” under Executive Order 12866; (2) is not a “significant rule” under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

#### List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

#### The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

#### PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D, AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

**Authority:** 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

#### § 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

*Paragraph 6002 Class E airspace areas designated as a surface area for an airport.*

\* \* \* \* \*

#### AGL MN E2 Grand Rapids, MN [Revised]

Grand Rapids/Itasca County, Gordon Newstrom Field Airport, MN

(Lat. 47°12'40"N., long. 93°30'35"W.)

Grand Rapids VOR/DME

(Lat. 47°09'49"N., long. 93°29'19"W.)

Within a 4.4-mile radius of Grand Rapids/Itasca County, Gordon Newstrom Field Airport, and that airspace extending from the surface within 2.4 miles each side of the Grand Rapids VOR 160° radial, extending from the 4.4-mile radius to 7.0 miles southeast of the VOR/DME. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airman. The effective date and time will thereafter be continuously published in the Airport/facility Directory.

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*Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.*

\* \* \* \* \*

#### AGL MN E5 Grand Rapids, MN [Revised]

Grand Rapids/Itasca County, Gordon Newstrom Field Airport, MN

(Lat. 47°12'40"N., long. 93°30'35"W.)

Grand Rapids VOR/DME

(Lat. 47°09'49"N., long. 93°29'19"W.)

That airspace extending upward from 700 feet above the surface within a 6.8-mile radius of the Grand Rapids/Itasca County, Gordon Newstrom Field Airport, and 4.4 miles each side of the Grand Rapids VOR 161° radial, extending from the 6.8-mile radius to 7.0 miles southeast of the VOR/DME.

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Issued in Des Plaines, Illinois on July 29, 1998.

**Richard K. Petersen,**

*Acting Assistant Manager, Air Traffic Division.*

[FR Doc. 98–21471 Filed 8–10–98; 8:45 am]

BILLING CODE 4910–13–M

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**21 CFR Parts 3, 5, 10, 20, 207, 310, 312, 316, 600, 601, 607, 610, 640, and 660**

[Docket No. 98N–0144]

RIN 0910–AB29

### Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License; Public Workshop

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Proposed rule; notice of workshop.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing a public workshop to present issues related to the agency's proposed rule entitled “Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License” issued recently in the **Federal Register**. The purpose of the public workshop is to provide interested persons an opportunity to more clearly understand the proposed rule and its effect on industry and the public.

**DATES:** The public workshop will be held on Wednesday, September 2, 1998, 9 a.m. to 3 p.m. Submit written comments by October 14, 1998. Fax registration information to the contact person by August 21, 1998.

**ADDRESSES:** The public workshop will be held at the Hyatt Regency Hotel, One Bethesda Metro, Bethesda, MD 20814, 301–657–6406. Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

**FOR FURTHER INFORMATION:** Kathy A. Eberhart, Center for Biologics Evaluation and Research (HFM–43), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–1317, FAX 301–827–3079, e-mail “eberhart@cber.fda.gov”.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of July 31, 1998 (63 FR 40858), FDA published a proposed rule entitled “Biological Products Regulated Under Section 351 of the Public Health Service Act; Implementation of Biologics License; Elimination of Establishment License and Product License” proposing to revise the regulations regarding the procedures for

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.*

[FR Doc. 98-21406 Filed 8-10-98; 8:45 am]

BILLING CODE 4160-01-F

## 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