Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 97–AAL–10]

Proposed Realignment of Colored Federal Airway A–1; AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to modify a Colored Federal Airway, Amber-1 (A–1), between Campbell Lake Nondirectional Radar Beacon (NDB) and Takotna River NDB, AK, due to the decommissioning of the Puntilla Lake and Farewell Lake NDB's and their subsequent removal from the National Airspace System (NAS).

DATES: Comments must be received on or before January 30, 1998.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, AAL–500, Docket No. 97–AAL–10, Federal Aviation Administration, 222 West 7th Avenue, #14, Anchorage, AK 99533.

The official docket may be examined in the Rules Docket, Office of the Chief Counsel, Room 916G, 800 Independence Avenue, SW., Washington, DC, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Ken McElroy, Airspace and Rules Division, ATA–400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: ''Comments to Airspace Docket No. 97–AAL–10.'' The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Air Traffic Airspace Management, Attention: Airspace and Rules Division, ATA–400, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267–8783. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2A, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to 14 CFR part 71 to realign A–1 by providing a direct route between Campbell Lake, AK, NDB and Takotna River, AK, NDB due to the decommissioning of the Puntilla Lake and Farewell Lake NDBs and their subsequent removal from the NAS. Colored Federal airways are published in paragraph 6009 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 Colored Federal airway 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 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 rule, when promulgated, 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

In consideration of the foregoing, 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 14 CFR 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 6009(c)—Amber Federal Airways

A–1 [Revised]

From Sandspit, BC, Canada, NDB 96 miles 12 AGL, 102 miles 35 MSL, 57 miles 12 AGL, via Sitka, AK, NDB; 31 miles 12 AGL, 50 miles 47 MSL, 88 miles 20 MSL, 40 miles 12 AGL, Ocean Cape, AK, NDB; INT Ocean Cape NDB 283° and Hinchinbrook, AK, NDB 106° bearings; Hinchinbrook NDB; INT Hinchinbrook NDB 286° and Campbell Lake, AK, NDB 123° bearings; Campbell Lake NDB; Takotna River, AK, NDB; 24 miles 12 AGL, 53 miles 55 MSL; 51 miles 40 MSL, 25 miles 12 AGL, North River, AK, NDB; 17 miles 12 AGL, 89 miles 25 MSL, 17 miles 12 AGL, to Fort Davis, AK, NDB. That airspace within Canada is excluded.

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Issued in Washington, DC, on December 2, 1997.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 97–32569 Filed 12–11–97; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

15 CFR Part 960

[Docket No. 951031259–7103–02]

Licensing of Private Land Remote-Sensing Space Systems

AGENCY: National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Notice; extension of public comment period.

SUMMARY: Pursuant to public request, the National Oceanic and Atmospheric Administration (NOAA) is extending by 90 days its public comment period for the Notice of Proposed Rulemaking concerning the licensing of private land remote-sensing space systems, published on November 3, 1997, 62 FR 59317.

DATES: Comments must be received by April 2, 1998.

ADDRESSES: Comments should be sent to, Charles Wooldridge, NOAA, National Environmental Satellite, Data, and Information Service, 1315 East-West Highway Room 3620 Silver Spring, MD 20910–3282.

FOR FURTHER INFORMATION CONTACT: Charles Wooldridge at (301) 713–2024 ext. 107 or Kira Alvarez, NOAA, Office of General Counsel at (301) 713–1217.

SUPPLEMENTARY INFORMATION: On November 3, 1997, NOAA published a Notice of Proposed Rulemaking (62 FR 59317) proposing regulations revising its regime for the licensing of private Earth remote-sensing space systems under Title II of the Land Remote Sensing Policy Act of 1992, 15 U.S.C. 5601 *et seq.* (1992 Act). These proposed regulations implement the licensing provisions of the 1992 Act and the Presidential Policy announced March 10, 1994. In response to numerous written comments, NOAA is extending the original 60 day public comment period by 90 days. As a result, comments on the notice of proposed rulemaking must now be received by April 2, 1998.

Dated: December 5, 1997.

Gregory W. Withee,

Deputy Assistant Administrator for Satellite and Information Services.

[FR Doc. 97–32472 Filed 12–11–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 808

[Docket No. 97N–0222]

Medical Devices; Preemption of State Product Liability Claims

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulations regarding preemption of State and local requirements applicable to medical devices. This action is being taken to clarify and codify the agency's longstanding position that available legal remedies, including State common law tort claims, generally are not preempted under the Federal Food, Drug, and Cosmetic Act (the act).

DATES: Written comments by February 10, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Introduction

Section 521 of the act (21 U.S.C. 360k) contains an express preemption provision applicable to medical devices regulated by FDA. The Supreme Court recently addressed whether section 521 of the act preempts State common law tort claims arising from allegedly defective medical devices. (See *Medtronic, Inc.* v. *Lohr (Lohr)*, 116 S. Ct. 2240 (1996).) The Court concluded that section 521 of the act did not supplant the State law duties at issue in that case. In reaching that conclusion, the Court noted that FDA has provided interpretive guidance with respect to section 521 of the act's preemptive effect. (See *id.* at 2255–2256 (citing 21 CFR 808.1(d)(2) and 808.5(b)(1)(i) (1995)).) The Court gave ''substantial weight to the agency's view of the statute'' (*Id.* at 2256). (See also *id.* at 2257; *id.* at 2260–2261 (Breyer, J., concurring in part and concurring in the judgment).)

The Court's decision in *Lohr* construed section 521 of the act in the context of a medical device that FDA had cleared for distribution under section 510(k) of the act (21 U.S.C. 360k), which requires premarket notification for certain types of medical devices. The Court did not definitively decide whether section 521 of the act may preempt State law claims in other circumstances. Since *Lohr* was decided, the lower courts have interpreted section 521 of the act inconsistently and have reached conflicting conclusions with respect to whether section 521 of the act preempts State law claims for injuries allegedly resulting from medical devices that have received premarket approval under section 515 of the act (21 U.S.C. 360e), or have received an investigational device exemption (IDE) under section 520(g) of the act (21 U.S.C. 360j(g)).

In light of the confusion among the lower courts in interpreting section 521 of the act since *Lohr*, and in accordance with the Supreme Court's recognition that FDA's interpretation of the preemptive effect of section 521 is entitled to substantial weight, the agency is issuing this proposed interpretive rule, which addresses the circumstances in which section 521 of the act preempts State common tort claims based on injury from allegedly defective medical devices.

II. Background

Congress enacted the Medical Device Amendments of 1976 (the amendments) (21 U.S.C. 360c *et seq.*), ''to provide for the safety and effectiveness of medical devices intended for human use.'' It