

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, is amended as follows:

* * * * *

Paragraph 6005 Class E Airspace Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

AAL AK E5 Soldotna, AK [Revised]

Soldotna, Soldotna Airport, AK
(Lat. 60°28'30" N., long. 151°02'17" W.)
Soldotna NDB
(Lat. 60°28'30" N., long. 150°52'44" W.)

That airspace extending upward from 700 feet above the surface within a 10.1-mile radius of the Soldotna Airport and within 4 miles either side of the 270° bearing of the Soldotna NDB, AK, extending from the 10.1-mile radius to 21 miles west of the Soldotna Airport, AK, and within 4.6 miles north and 4 miles south of the 090° bearing of the Soldotna NDB, AK, extending from the 10.1-mile radius to 14.3 miles east of the Soldotna Airport, AK; and that airspace extending upward from 1,200 feet above the surface within a 73-mile radius of the Soldotna Airport.

* * * * *

Issued in Anchorage, AK, on December 11, 2007.

Anthony M. Wylie,

Manager, Alaska Flight Services Information Area Group.

[FR Doc. E7-24409 Filed 12-18-07; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2007-29012; Airspace Docket No. 07-AAL-15]

Revision of Class E Airspace; McGrath, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action revises Class E airspace at McGrath, AK to provide adequate controlled airspace to contain aircraft executing Standard Instrument Approach Procedures (SIAPs). Five SIAPs and a textual departure procedure (DP) are being amended for the McGrath Airport. Additionally, one SIAP is being developed. This action revises existing Class E airspace upward from 700 feet (ft.) and 1,200 ft. above the surface at the McGrath Airport, McGrath, AK.

DATES: *Effective Date:* 0901 UTC, February 14, 2008. The Director of the Federal Register approves this incorporation by reference action under title 1, Code of Federal Regulations, part 51, subject to the annual revision of FAA Order 7400.9 and publication of conforming amendments.

FOR FURTHER INFORMATION CONTACT: Gary Rolf, AAL-538G, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513-7587; telephone number (907) 271-5898; fax: (907) 271-2850; e-mail: gary.ctr.rolf@faa.gov. Internet address: <http://www.alaska.faa.gov/at>.

SUPPLEMENTARY INFORMATION:**History**

On Tuesday, October 16, 2007, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise Class E airspace upward from 700 ft. above the surface and from 1,200 ft. above the surface at McGrath, AK (72 FR 58569). The action was proposed in order to create Class E airspace sufficient in size to contain aircraft while executing SIAPs for the McGrath Airport. Class E controlled airspace extending upward from 700 ft. above the surface and from 1,200 ft. above the surface in the McGrath Airport area is revised by this action.

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments were received. The rule is adopted as proposed.

The area will be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as surface areas are published in paragraph 6002 of FAA Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace areas designated as 700/1,200 ft. transition areas are published in paragraph 6005 of FAA Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designations listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 revises Class E airspace at the McGrath Airport, Alaska. This Class E airspace is revised to accommodate aircraft

executing new and amended SIAPs, and will be depicted on aeronautical charts for pilot reference. The intended effect of this rule is to provide adequate controlled airspace for Instrument Flight Rules (IFR) operations at the McGrath Airport, McGrath, Alaska.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(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 will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

The FAA’s authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle 1, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency’s authority.

This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart 1, Section 40103, Sovereignty and use of airspace. Under that section, the FAA is charged with prescribing regulations to ensure the safe and efficient use of the navigable airspace. This regulation is within the scope of that authority because it creates Class E airspace sufficient in size to contain aircraft executing instrument procedures for the McGrath Airport and represents the FAA’s continuing effort to safely and efficiently use the navigable airspace.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

■ In consideration of the foregoing, the Federal Aviation Administration amends 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 Federal Aviation Administration Order 7400.9R, *Airspace Designations and Reporting Points*, signed August 15, 2007, and effective September 15, 2007, is amended as follows:

* * * * *

Paragraph 6002 Class E Airspace Designated as Surface Areas.

AAL AK E2 McGrath, AK [Revised]

McGrath, McGrath Airport, AK
(Lat. 62°57'10" N., long. 155°36'20" W.)

That airspace within a 7.6-mile radius of the McGrath Airport. This Class E airspace area is effective during the specific dates and times established in advance by a Notice to Airmen. The effective date and time will thereafter be continuously published in the Airport/Facility Directory.

* * * * *

Paragraph 6005 Class E Airspace Extending Upward from 700 feet or More Above the Surface of the Earth.

* * * * *

AAL AK E5 McGrath, AK [Revised]

McGrath, McGrath Airport, AK
(Lat. 62°57'10" N., long. 155°36'20" W.)

That airspace extending upward from 700 feet above the surface within a 8.1-mile radius of the McGrath Airport and within 4 miles north and 8 miles south of the 123° bearing from the McGrath Airport, AK extending from the 8.1-mile radius to 16 miles southeast of the McGrath Airport, AK, and within 4 miles east and west of the 008° bearing from the McGrath Airport, AK, extending from the 8.1-mile radius to 11.2 miles north of the McGrath Airport, AK; and that airspace extending upward from 1,200 feet above the surface within a 74-mile radius of the McGrath Airport.

* * * * *

Issued in Anchorage, AK, on December 11, 2007.

Anthony M. Wylie,

Manager, Alaska Flight Services Information Area Group.

[FR Doc. E7–24410 Filed 12–18–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

**[Docket No. 1980N–0280] (formerly Docket No. 80N–0280)
RIN 0910–AF44**

Over-the-Counter Vaginal Contraceptive and Spermicide Drug Products Containing Nonoxynol 9; Required Labeling

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule establishing new warning statements and other labeling information for all over-the-counter (OTC) vaginal contraceptive drug products (also known as spermicides, hereinafter referred to as vaginal contraceptives or vaginal contraceptives/spermicides) containing nonoxynol 9 (N9). These warning statements will advise consumers that vaginal contraceptives/spermicides containing N9 do not protect against infection from the human immunodeficiency virus (HIV), the virus that causes acquired immunodeficiency syndrome (AIDS), or against getting other sexually transmitted diseases (STDs). The warnings and labeling information will also advise consumers that use of vaginal contraceptives and spermicides containing N9 can irritate the vagina and rectum and may increase the risk of getting the AIDS virus (HIV) from an infected partner. This final rule is part of FDA's ongoing review of OTC drug products. FDA is issuing this final rule after considering public comments on its proposed regulation, and all relevant data and information on N9 that have come to our attention.

DATES: *Effective Date:* This rule is effective June 19, 2008.

Compliance Date: The compliance date for all products subject to this final rule, including products with annual sales less than \$25,000, is June 19, 2008.

FOR FURTHER INFORMATION CONTACT:

Arlene Solbeck, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Silver Spring, MD 20993, 301–796–2090.

SUPPLEMENTARY INFORMATION:

Table of Contents

- I. Background
- II. Comments on the Proposed Rule and FDA's Responses

- A. Should N9 Remain Available as an Active Ingredient in OTC Vaginal Contraceptive Drug Products?
- B. What Issues Were Raised by Comments That Did Not Support the Proposed Warning Statements?
 - 1. Will Warning Labels Be Seen, Understood, or Followed?
 - 2. Are the Warnings Supported by the Scientific Literature?
 - 3. Is FDA Required To Prove Actual Causation To Justify the Warnings?
- C. Should Women Ask a Doctor Before Using N9 Products?
- D. Where Will the Warnings Appear in the Labeling?
- E. Where Will the Condom Usage Statement Appear in the Labeling?
- F. What Were the Comments on Condoms, Sexual Lubricants, and Barrier Methods?
 - 1. Do Warnings Apply to Condoms and Sexual Lubricants?
 - 2. Are Condoms Lubricated With N9 Safe To Use?
 - 3. How Do Warnings Apply to N9 Products Used With Barrier Methods?
- G. Is N9 Safe for Women at Low Risk for HIV/AIDS and STDs?
- H. Is N9 Safe for Rectal Use?
- I. Does N9 Increase the Risk of STDs Other Than HIV?
- J. What Issues Did Other Comments Discuss?
 - 1. Why Did FDA Define Frequent Use of N9 as "More Than Once a Day"?
 - 2. Should "Pharmacist" or "Health Care Provider" Be Included on the Label?
 - 3. What Does "Unprotected Sex" Mean?
 - 4. What Does the Word "Irritation" Mean When Referring To "Vaginal Irritation" in the Warning Language?
 - 5. Should Warnings Be Printed in Both English and Spanish?
- III. FDA's Final Conclusions on Warnings and Other Labeling Information for OTC Vaginal Contraceptive and Spermicide Drug Products Containing N9
 - A. New Labeling Requirements
 - B. Statement About Warnings
- IV. Analysis of Impacts
- V. Paperwork Reduction Act of 1995
- VI. Environmental Impact
- VII. Federalism
- VIII. References

I. Background

In the **Federal Register** of January 16, 2003 (68 FR 2254), FDA (we) published a proposed rule (the proposed rule) to require new labeling warning statements for all OTC vaginal contraceptive drug products containing N9. These proposed warning statements are intended to