DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 99–ANM–08]

Proposed Establishment of Class E Airspace, Glendive, MT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: This proposal would establish a Class E En Route Domestic Airspace Area in the vicinity of Glendive, MT. The intended effect of this action is to provide controlled airspace for the development of an off-airway route between Bismarck, ND, and Glendive, MT.

DATES: Comments must be received on or before October 18, 1999.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Airspace Branch, ANM–520, Federal Aviation Administration, Docket No. 99–ANM–08, 1601 Lind Avenue SW, Renton, Washington 98055–4056.

The official docket may be examined in the office of the Assistant Chief Counsel for the Northwest Mountain Region at the same address.

An informal docket may also be examined during normal business hours in the office of the Manager, Air Traffic Division, Airspace Branch, at the address listed above.

FOR FURTHER INFORMATION CONTACT: Dennis Ripley, ANM–520.6, Federal Aviation Administration, Docket No. 99–ANM–08, 1601 Lind Avenue SW, Renton, Washington 98055–4056: telephone number: (425) 227–2527.

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. 99–ANM–08.'' 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 the light of comments received. All comments submitted will be available for examination at the address listed above, 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 NPRM by submitting a request to the Federal Aviation Administration, Airspace Branch, ANM–520, 1601 Lind Avenue SW, Renton, Washington 98055–4056. 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 considering an amendment to Title 14 Code of Federal Regulations, part 71 (14 CFR part 71) to establish a Class E En Route Domestic Airspace Area in the vicinity of Glendive, MT. this proposal is in support of an air taxi operator request to reclassify Class G uncontrolled airspace to Class E airspace for the purpose of conducting direct routing in Instrument Flight Conditions (IFR) between Bismarck, ND, and Glendive, MT. The FAA establishes Class E airspace in those areas where there is a requirement to provide IFR en route air traffic control services but the Federal airway segment is inadequate. This proposal would allow controlled airspace between the two cities, thereby allowing direct route flight and saving considerable time over present available non-direct routes.

The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas designated as en route domestic airspace areas are published in Paragraph 6006 of FAA Order 7400.9F dated September 10, 1998, and effective September 16, 1998, 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. 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, 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 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 6006 Class E airspace designated as an en route domestic airspace area

* * * * *

Glendive, MT

That airspace extending upward from 1,200 feet AGL bounded on the east by the west edge of V–493, on the south by the north edge of V–2, and on the northwest by the southeast edge of V–545.

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Issued in Seattle, Washington, on August 18, 1999.

Daniel A. Boyle,

Assistant Manager, Air Traffic Division, Northwest Mountain Region.

[FR Doc. 99–22754 Filed 8–31–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 2

[Docket No. 97N–0023]

RIN 0910–AA99

Use of Ozone-Depleting Substances; Essential Use Determinations

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its regulation on the use of chlorofluorocarbon (CFC) propellants in self-pressurized containers to make it consistent with other laws. FDA is proposing to set the standard it will use to determine when the use of an ozone-depleting substance (ODS) in a product regulated by FDA is essential under the Clean Air Act. Under the Clean Air Act, FDA, in consultation with the Environmental Protection Agency (EPA), is required to determine whether the use of an ODS in an FDA-regulated product is essential. FDA is also proposing in this rule to remove current essential-use designations for products no longer marketed and for metered-dose steroid human drugs for nasal inhalation. FDA would add or remove specific essential use designations for other products by engaging in separate notice-and-comment rulemaking.

DATES: Written comments on the proposed rule should be submitted by November 30, 1999. See section V of this document for the proposed effective date of a final rule based on this document.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See section III.B.15 of this document for electronic access addresses.

FOR FURTHER INFORMATION CONTACT: Leanne Cusumano, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION:

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I. Background

The United States, as a party to an international agreement called the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) (September 16, 1987, S. Treaty Doc. No. 10, 100th Cong., 1st sess., 26 I. L. M. 1541 (1987)), has agreed to phase out production and importation of ODS's, including CFC's. The United States has generally banned the use of CFC's in consumer aerosols for decades and eliminated almost all manufacture and importation of CFC's as of January 1, 1996. The Montreal Protocol permits Parties to the Protocol to continue to produce or import CFC's for use in essential medical products upon approval by the Parties.

FDA, in consultation with EPA, determines whether a medical product is essential under the Clean Air Act. FDA lists essential medical products in § 2.125 (21 CFR 2.125). Most of the medical products listed as essential are metered-dose inhalers (MDI's). FDA will continue to designate ODS medical products such as MDI's as essential until non-ODS medical products adequately serve the needs of patients. The United States, through EPA, must apply annually to the Parties to the Montreal Protocol for a specific CFC production or importation allowance for CFC–MDI's that FDA has designated as essential. However, the United States has agreed to eventually phase out all uses of CFC's. FDA is developing a strategy to ensure that the health and safety of patients in the United States are protected during the transition away from CFC use in medical products.

In the **Federal Register** of March 6, 1997 (62 FR 10242), FDA published an advanced notice of proposed rulemaking (ANPRM) that sought public comment on transition options. One approach that FDA suggested was that ODS products be considered nonessential if: (1) Alternative product(s) is (are) being marketed (a) with the same active moiety, (b) by the same route of administration, (c) for the same indication, and (d) with approximately the same level of convenience of use compared to the product containing CFC's; (2) adequate supplies and production capacity exist for the alternative products to meet the needs of the population; (3) at least 1 year of postmarketing use data for each product are available and persuasive evidence shows patient acceptance of the alternative product(s) in the United States; and (4) there is no persuasive evidence to rebut a presumption that all significant patient subpopulations are served by the alternative product(s). FDA received almost 10,000 comments on the ANPRM, and addresses those comments later in this proposed rule.