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. 96–AAL–31]

Proposed Revision of Class E Airspace; Klawock, AK

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action revises Class E airspace at Klawock, AK. The revision of the Global Positioning System (GPS) instrument approach and creation of a non-directional beacon (NDB) instrument approach to RWY 1 has made this action necessary. The area would be depicted on aeronautical charts for pilot reference. The intended effect of this proposal is to provide adequate controlled airspace for IFR operations at Klawock, AK.

DATES: Comments must be received on or before April 18, 1997.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, System Management Branch, AAL–530, Docket No. 96–AAL–31, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587.

The official docket may be examined in the Office of the Assistant Chief Counsel for the Alaskan Region at the same address.

An informal docket may also be examined during normal business hours in the Office of the Manager, System Management Branch, Air Traffic Division, at the address shown above.

FOR FURTHER INFORMATION CONTACT: Robert van Haastert, System Management Branch, AAL–538, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587; telephone number: (907) 271–5863; email: Robert.van.Haastert@faa.dot.gov.

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. 96–AAL–31.'' 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 System Management Branch, Air Traffic Division, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK, 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 System Management Branch, AAL–530, Federal Aviation Administration, 222 West 7th Avenue, Box 14, Anchorage, AK 99513–7587. 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 part 71 of the Federal Aviation Regulations (14 CFR part 71) to revise Class E airspace for GPS and NDB instrument approach procedures at Klawock, AK. The coordinates for this airspace docket are based on North American Datum 83. The Class E airspace areas designated as 700/1200 foot transition areas are published in paragraph 6005 of FAA Order 7400.9D, dated September 4, 1996, and effective September 16, 1996, which is incorporated by reference in 14 CFR 71.1 (61 FR 48403; September 13, 1996). 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—[AMENDED]

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9D, Airspace Designations and Reporting Points, dated September 4, 1996, and effective September 16, 1996, is amended as follows:

* * * * *

AAL AK E5 Klawock, AK [Revised]

Klawock Airport, AK
(Lat. 55°34′48″ N, long. 133°04′30″ W)
Klawock NDB/DME
(Lat. 55°34′07″ N, long. 133°04′46″ W)

That airspace extending upward from 700 feet above the surface within a 6.7-mile radius of the Klawock Airport and 6.5 miles north and 10 miles south of the 243° bearing from the Klawock NDB/DME extending to 16 miles southwest of the NDB/DME; and that airspace extending upward from the 1,200 feet above the surface within 6.7 miles northwest and 9.5 miles southeast of the 039° bearing from the airport extending from the airport to 6.7 miles northeast of the airport and within 6.7 miles northwest and 9.5 miles southeast of the 219° bearing from the airport extending from the airport to 32 miles southwest of the airport and 6.5 miles north and 10 miles south of the 243° bearing from the Klawock NDB/DME beginning 16 miles west of the NDB/DME and extending to 35 miles west of the NDB/DME.

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Issued in Anchorage, AK, on February 25, 1997.

Willis C. Nelson,

Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 97–5292 Filed 3–3–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. 97N–0068]

Proposed Approach to Regulation of Cellular and Tissue-Based Products; Availability and Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of proposed regulatory approach; public meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled, ''Proposed Approach to Regulation of Cellular and Tissue-Based Products.'' In addition, FDA is announcing a public meeting to solicit information and views from the interested public on the agency's proposed regulatory approach for such products. These actions are taken in response to the Administration's ''Reinventing Government'' initiative which seeks to streamline regulatory requirements to ease the burden on regulated industry, while providing adequate protection to the public health.

DATES: Written comments may be submitted at any time; however, comments should be submitted by April 17, 1997, to ensure their adequate consideration in preparing FDA's final approach to the regulation of cellular and tissue-based products.

The public meeting will be held on March 17, 1997, from 8 a.m. to 4:30 p.m. Submit written notices of participation by March 10, 1997, including a summary of the presentation, which will be submitted to the docket, and approximate time requested.

Registration is not required; however, groups are asked to limit the number of individuals attending because of the anticipated broad interest in the meeting and the limited available seating.

ADDRESSES: The public meeting will be held at the Parklawn Bldg., conference rooms D and E, 5600 Fishers Lane, Rockville, MD 20857.

Submit written requests for single copies of the document ''Proposed Approach to Regulation of Cellular and Tissue-Based Products'' to the Office of Communication, Training and Manufacturer's Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request. The document may also be obtained by mail or by calling the CBER Voice information System at 1–800–835–4709, or 301–827–1800, or FAX at 1–888–CBER–FAX, or 301–827–3844.

Persons with access to the Internet may obtain the document using the world wide web (WWW) or bounce-back-e-mail. For WWW access, connect to CBER at ''http://www.fda.gov/cber/cberftp.html''. To receive the document by bounce-back e-mail, send a message to ''CELL TISSUE@a1.CBER.FDA.GOV''.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. Two copies of any comments are to be submitted, except individuals may submit one copy. Requests and comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document and received comments are available for public examination in the Dockets Management Branch, address above, between 9 a.m. and 4 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT:

For information regarding the meeting or to submit a notice of intent to participate: Martha A. Wells, Center for Biologics Evaluation and Research (HFM–305), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–0967, FAX 301–827–2844.

For information regarding this document: Sharon A. Carayiannis, Center for Biologics Evaluation and Research (HFM–630), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–594–3074.

SUPPLEMENTARY INFORMATION:

FDA is announcing the availability of a document entitled ''Proposed Approach to Regulation of Cellular and Tissue-Based Products.'' This document is being issued as a part of FDA's continuing effort to reduce unnecessary burdens for industry without diminishing public health protection.

FDA has designed a new regulatory framework for cells and tissues. The document describes this new approach, which FDA believes would provide adequate protection of public health, both from the risks of transmission of communicable disease and from the risks of therapies that may be ineffective or dangerous, while enabling investigators to develop new therapies and products with as little regulatory burden as possible. The proposed approach would encompass, but not be limited to, the regulation of the following: Human tissue intended for transplantation, currently regulated under 21 part CFR 1270; demineralized bone; reproductive tissue; heart valves; peripheral blood hematopoietic stem cells; placental/umbilical cord blood hematopoietic stem cells; somatic cell therapy products; and gene therapy products.

The approach does not encompass vascularized organs or minimally-manipulated bone marrow, transfusable blood products (e.g., whole blood, red blood cells, platelets, and plasma), tissues derived from animals, products used in the propagation of cells or tissues, or products that are secreted by or extracted from cells or tissues (e.g., human milk, collagen, urokinase, cytokines, and growth factors and hormones). Such products generally raise different safety and effectiveness issues, and generally are covered by other rules, regulations, and/or