Issued in Renton, Washington, on June 22, 2007.

Ali Bahrami,

Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. E7–12817 Filed 7–2–07; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2007–28235; Airspace Docket No. 07–ANM–9]

Proposed Establishment of Class E Airspace; Hulett, WY

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This action proposes to establish Class E airspace at Hulett, WY. Additional controlled airspace is necessary to accommodate aircraft using a new Area Navigation (RNAV) Global Positioning System (GPS) Instrument Approach Procedure (IAP) at Hulett Municipal Airport. The FAA is proposing this action to enhance the safety and management of aircraft operations at Hulett Municipal Airport, Hulett, WY.

DATES: Comments must be received on or before August 17, 2007.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room @12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590. Telephone (202) 366–9826. You must identify FAA Docket No. FAA–2007–28235; Airspace Docket No. 07–ANM–9, at the beginning of your comments. You may also submit comments through the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Ed Haeseker, Federal Aviation Administration, Western Service Area Office, System Support Group, 1601 Lind Avenue, SW., Renton, WA 98057; telephone (425) 917–6714.

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 both docket numbers (FAA Docket No. FAA–2007–28235 and Airspace Docket No. 07–ANM–9) and be submitted in triplicate to Docket Operations (see ''**ADDRESSES**'' section for address and phone number). You may also submit comments through the Internet at *http://dms.dot.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed stamped postcard on which the following statement is made: ''Comments to FAA Docket No. FAA–2007–28235 and Airspace Docket No. 07–ANM–9''. 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 action may be changed in light of comments received. All comments submitted will be available for examination in the public 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

An electronic copy of this document may be downloaded through the Internet at *http://dms.dot.gov.* Recently published rulemaking documents can also be accessed through the FAA's web page at *http://www.faa.gov* or the **Federal Register**'s web page at *http://www.gpoaccess.gov/fr/index.html.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see the ''**ADDRESSES**'' section for the address and phone number) between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the Northwest Mountain Regional Office of the Federal Aviation Administration, Air Traffic Organization, Western Service Area, System Support Group, 1601 Lind Avenue, SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRM's should contact the FAA's Office of Rulemaking, (202) 267–9677, for a copy of Advisory Circular No. 11–2A, Notice of Proposed Rulemaking Distribution System, which describes the application procedure.

The Proposal

The FAA is proposing an amendment to Title 14 Code of Federal Regulations (14 CFR) part 71 by establishing Class E airspace at Hulett, WY. Controlled airspace is necessary to accommodate aircraft using the new RNAV (GPS) IAP at Hulett Municipal Airport. This action would enhance the safety and management of aircraft operations at Hulett Municipal Airport, Hulett, WY.

Class E airspace designations are published in paragraph 6005 of FAA Order 7400.9P, dated September 1, 2006, and effective September 15, 2006, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in this 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, when promulgated, would 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, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE 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 FAA Order 7400.9P, Airspace Designations and Reporting

Points, dated September 1, 2006, and effective September 15, 2006 is amended as follows:

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

* * * * *

ANM WY, E5 Hulett, WY [New]

Hulett Municipal Airport, WY
(Lat. 44°39′46″ N., long. 104°34′04″ W.)

That airspace extending upward from 700 feet above the surface within an 8.0-mile radius of Hulett Municipal Airport; that airspace extending upward from 1,200 feet above the surface beginning at lat. 44°50′00″ N., long. 105°00′00″ W.; thence to lat. 44°50′00″ N., long. 104°00′00″ W.; thence south along long. 104°00′00″ W., to V–536; thence west along V–536 to Newcastle VOR; thence west on V–536 to lat. 44°09′00″ N., long. 105°00′00″ W.; thence to point of beginning.

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Issued in Seattle, Washington, on June 13, 2007.

Clark Desing,

Manager, System Support Group, Western Service Area.

[FR Doc. E7–12793 Filed 7–2–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 878

[Docket No. 2006P–0071]

General and Plastic Surgery Devices; Reclassification of the Tissue Adhesive for Topical Approximation of Skin Device

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the device, tissue adhesive for the topical approximation of skin, from class III (premarket approval) into class II (special controls). Tissue adhesives for non-topical uses would remain in class III and continue to require premarket approval applications (PMAs). FDA is proposing this reclassification in accordance with the Federal Food, Drug, and Cosmetic Act (the act). Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document that would serve as the special control if FDA reclassifies this device.

DATES: Submit written comments by September 4, 2007. See section IX of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. 2006P–0071, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described in the Electronic Submissions portion of this paragraph.

Instructions: All submissions received must include the agency name and Docket No. for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: George J. Mattamal, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–3619.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The act, as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

The 1976 amendments broadened the definition of ''device'' in section 201(h) of the act (21 U.S.C. 321(h)) to include certain articles that were once regulated as drugs. Under the 1976 amendments, Congress classified all transitional devices, i.e., those devices previously regulated as new drugs, into class III. SMDA amended section 520(l) of the act (21 U.S.C. 360j(l)) to direct FDA to collect certain safety and effectiveness information from the manufacturers of transitional devices still remaining in class III to determine whether the devices should be reclassified into class II (special controls) or class I (general controls). The legislative history of the SMDA reflects congressional concern that many transitional devices were being overregulated in class III (H. Rept. 808, 101st Cong., 2d sess. 26–27 (1990); S. Rept. 513, 101st Cong., 2d sess. 27 (1990)).

Accordingly, in the **Federal Register** of November 14, 1991 (56 FR 57960), FDA issued an order under section 520(l)(5)(A) of the act, requiring manufacturers of transitional devices, which included tissue adhesives for use in general surgery (47 FR 2810, January 19, 1982), to submit to FDA a summary of and a citation to any information known or otherwise available to them respecting the devices, including adverse safety or effectiveness information, that had not been submitted under section 519 of the act (21 U.S.C. 360i).

Manufacturers were to submit the summaries and citations to FDA by January 13, 1992. However, because of misunderstandings and uncertainties regarding the information required by the order, and regarding whether the order applied to certain manufacturers' devices, many transitional class III device manufacturers failed to comply