

challenging this rule. However, the administrative procedures specified in 9 CFR 390.7 must be exhausted prior to any judicial challenge of the application of the provisions of this rule, if the challenge involves any decision of an FSIS employee relating to a denial of access of information.

Paperwork Requirements

There are no paperwork or recordkeeping requirements associated with this rule under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, in an effort to ensure that the public and in particular minorities, women, and persons with disabilities, are aware of this final rule, FSIS will announce it on-line through the FSIS Web page located at <http://www.fsis.usda.gov>.

The Regulations.gov Web site is the central online rulemaking portal of the United States government. It is being offered as a public service to increase participation in the Federal government's regulatory activities. FSIS participates in Regulations.gov and will accept comments on documents published on the site. The site allows visitors to search by keyword or Department or Agency for rulemakings that allow for public comment. Each entry provides a quick link to a comment form so that visitors can type in their comments and submit them to FSIS. The Web site is located at <http://www.regulations.gov>.

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and other types of information that could affect or would be of interest to our constituents and stakeholders. The update is communicated via Listserv, a free e-mail subscription service consisting of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. The update also is available on the FSIS Web page. Through Listserv and the Web page, FSIS is able to provide information to a much broader, more diverse audience.

List of Subjects in 9 CFR Part 319

Meat inspection, Standards of identity or composition.

■ For the reasons set forth in the preamble, 9 CFR part 319 is amended to read as follows:

PART 319—DEFINITIONS AND STANDARDS OF IDENTITY OR COMPOSITION

■ 1. The authority citation for part 319 is revised as follows:

Authority: 7 U.S.C. 450, 1901–1906; 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 2. Section 319.312 is revised to read as follows:

§ 319.312 Pork with barbecue sauce and beef with barbecue sauce.

“Pork with Barbecue Sauce” and “Beef with Barbecue Sauce” shall consist of not less than 50 percent cooked meat of the species specified on the label. Mechanically Separated (Pork) may be used in accordance with § 319.6.

Done at Washington, DC, on: June 18, 2004.

Barbara J. Masters,
Administrator.

[FR Doc. 04–14194 Filed 6–22–04; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2004–18012; Airspace Docket No. 04–ACE–41]

Modification of Class E Airspace; Chardon, NE

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Direct final rule; request for comments.

SUMMARY: This action amends Title 14 Code of Federal Regulations, part 71 (14 CFR part 71) by revising Class E airspace areas at Chardon, NE. A review of the Class E airspace surface area and the Class E airspace area extending upward from 700 feet above ground level (AGL) at Chardon, NE reveals the Class E airspace surface area does not comply with criteria for extensions and neither area complies with criteria for diverse departures. Also, the Class E airspace area extending upward from 700 feet AGL does not reflect the current Chardon Municipal Airport airport reference point (ARO). These airspace areas are enlarged and modified to conform to the criteria in FAA Orders.

DATES: This direct final rule is effective on 0901 UTC, September 30, 2004. Comments for inclusion in the Rules Docket must be received on or before July 29, 2004.

ADDRESSES: Send comments on this proposal to the Docket Management System, U.S. Department of Transportation, Room Plaza 401, 400 Seventh Street, SW., Washington, DC 20590–0001. You must identify the docket number FAA–2004–18012/ Airspace Docket No. 04–ACE–41, at the beginning of your comments. You may also submit comments on the Internet at <http://dms.dot.gov>. You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1–800–647–5527) is on the plaza level of the Department of Transportation NASSIF Building at the above address.

FOR FURTHER INFORMATION CONTACT: Brenda Mumper, Air Traffic Division, Airspace Branch, ACE–520A, DOT Regional Headquarters Building, Federal Aviation Administration, 901 Locust, Kansas City, MO 64106; telephone: (816) 329–2524.

SUPPLEMENTARY INFORMATION: This amendment to 14 CFR 71 modifies the Class E surface area and the Class E airspace area extending upward from 700 feet AGL at Chardon, NE. An examination of controlled airspace for Chardon, NE revealed that neither airspace area is in compliance with FAA Orders 7400.2E, Procedures for Handling Airspace Matters, and 8260.19C, Flight Procedures and Airspace. The extension to the Class E surface area is redefined relative to the Whitney nondirectional radio beacon and the area is enlarged from a 4.2 to a 5.7-mile radius of Chardon Municipal Airport. The Class E airspace area extending upward from 700 feet AGL is increased from a 7.4 to a 10.7-mile radius of Chardon Municipal Airport in order to provide required airspace for diverse departures. The Chardon Municipal Airport ARP is corrected in the legal description. These modifications bring the legal descriptions of the Chardon, NW Class E airspace areas into compliance with FAA Orders 7400.2E and 8260.19C. Class E airspace areas designated as surface areas are published in Paragraph 6002 of FAA Order 7400.9L, Airspace Designations and Reporting Points, dated September 2, 2003, and effective September 16, 2003, which is incorporated by reference in 14 CFR 71.1. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of the same Order. The Class E airspace designations listed in

this document would be published subsequently in the Order.

The Direct Final Rule Procedure

The FAA anticipates that this regulation will not result in adverse or negative comment and, therefore, is issuing it as a direct final rule. Previous actions of this nature have not been controversial and have not resulted in adverse comments or objections. Unless a written adverse or negative comment, or a written notice of intent to submit an adverse or negative comment is received within the comment period, the regulation will become effective on the date specified above. After the close of the comment period, the FAA will publish a document in the **Federal Register** indicating that no adverse or negative comments were received and confirming the date on which the final rule will become effective. If the FAA does receive, within the comment period, an adverse or negative comment, or written notice of intent to submit such a comment, a document withdrawing the direct final rule will be published in the **Federal Register**, and a notice of proposed rulemaking may be published with a new comment period.

Comments Invited

Interested parties are invited to participate in this 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 and be submitting 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 Docket No. FAA-2004-18012/Airspace Docket No. 04-ACE-41." The postcard will be date/time stamped and returned to the commenter.

Agency Findings

The regulations adopted herein will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, it is determined that this final rule does not

have federalism implications under Executive Order 13132.

The FAA has determined that this regulation is noncontroversial and unlikely to result in adverse or negative comments. For the reasons discussed in the preamble, I certify that this regulation (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, 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).

Adoption of the Amendment

■ Accordingly, 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 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 7400.9L, dated September 2, 2003, and effective September 16, 2003, is amended as follows:

Paragraph 6002 Class E Airspace Designated as Surface Areas.

* * * * *

ACE NE E2 Chadron, NE

Chadron Municipal Airport, NE
(Lat. 42°50'15" N., long. 103°05'44" W.)
Whitney NDB
(Lat. 42°49'44" N., long. 103°05'37" W.)

Within a 5.7-mile radius of Chadron Municipal Airport and within 2.5 miles each side of the 021° bearing from Whitney NDB extending from the 5.7-mile radius of the airport to 7 miles northeast of the NDB. 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.

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

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ACE NE E5 Chadron, NE

Chadron Municipal Airport, NE
(Lat. 42°50'15" N., long. 103°05'44" W.)

That airspace extending upward from 700 feet above the surface within a 10.7-mile radius of Chadron Municipal Airport.

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Issued in Kansas City, MO, on June 10, 2004.

Paul J. Sheridan,

Acting Manager, Air Traffic Division, Central Region.

[FR Doc. 04–14202 Filed 6–22–04; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868, 870, and 882

[Docket No. 2003N–0468]

Medical Devices; Effective Date of Requirement for Premarket Approval for Three Class III Preamendments Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is requiring the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following three class III preamendments devices: Indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, and the ocular plethysmograph. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. This action implements certain statutory requirements.

DATES: This rule is effective June 23, 2004. Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before September 21, 2004, for any indwelling blood oxyhemoglobin concentration analyzer, cardiopulmonary bypass pulsatile flow generator, or ocular plethysmograph that was in commercial