

assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent a piston pin failure from causing secondary engine damage that results in loss of oil or total power failure, and from causing jamming of the engine crankshaft resulting in a catastrophic engine failure, accomplish the following:

(a) If an engine has not had a piston pin installed after August 1, 1994, or if an engine has had a piston pin installed after August 1, 1994, but it was installed by Teledyne Continental Motors, then no action is required.

(b) For engines that had a piston pin installed after August 1, 1994, by an entity other than Teledyne Continental Motors, within 25 hours time in service (TIS) after the effective date of this AD, referring to Superior Air Parts, Inc. Mandatory Service Bulletin (SB) No. 96-001, dated August 5, 1996,

determine if a suspect Superior Air Parts, Inc. PMA piston pin, P/N SA629690, could have been installed. If unable to verify that a suspect piston pin was not installed using a records check, disassemble the engine in accordance with the applicable Maintenance Manual or Overhaul Manual, visually inspect or verify for suspect piston pins, and accomplish the following:

(1) If it is determined that suspect Superior Air Parts, Inc. PMA piston pins, P/N SA629690, could have been installed, remove from service defective piston pins and replace with serviceable piston pins.

(2) If it is determined that suspect Superior Air Parts, Inc. PMA piston pins, P/N SA629690, could not have been installed, no further action is required.

(c) For the purpose of this AD, a serviceable piston pin is any piston pin approved for the application that has been verified not to be a Superior Air Parts, Inc. PMA piston pin, P/N SA629690, shipped from Superior Air Parts, Inc., from August 1, 1994, through June 20, 1996. Installation of a Superior Air Parts Inc. PMA piston pin, P/N SA629690, that can

not be verified to be outside of the suspect shipping period range, is prohibited after the effective date of this AD.

(d) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Special Certification Office. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Special Certification Office.

Note 3: Information concerning the existence of approved alternative methods of compliance with this airworthiness directive, if any, may be obtained from the Special Certification Office.

(e) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the aircraft to a location where the inspection may be performed.

(f) The actions required by this AD shall be done referring to the following Superior Air Parts, Inc. Mandatory Service Bulletin:

| Document No. | Pages | Revision | Date |
|----------------|-------|----------------|-----------------|
| 96-001 | 4 | Original | August 5, 1996. |
| Total Pages: 4 | | | |

This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies of Superior Air Parts, Inc. Mandatory Service Bulletin No. 96-001 may be obtained from Superior Air Parts, Inc., 14280 Gillis Road, Dallas, TX. 75244; telephone (800) 400-5949, fax (800) 238-8471. Copies may be inspected at the FAA, New England Region, Office of the Regional Counsel, 12 New England Executive Park, Burlington, MA; or at the Office of the Federal Register, 800 North Capitol Street NW., suite 700, Washington, DC.

(g) This amendment becomes effective on November 9, 1998.

Issued in Burlington, Massachusetts on August 31, 1998.

Donald E. Plouffe,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 98-24089 Filed 9-9-98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Airspace Docket No. 98-AGL-42]

Establishment of Class E Airspace; Crosby, ND

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes Class E airspace at Crosby, ND. A Global Positioning System (GPS) Standard Instrument Approach Procedure (SIAP) to Runway (Rwy) 30 has been developed for Crosby Municipal Airport. Controlled airspace extending upward from 700 to 1200 feet above ground level (AGL) is needed to contain aircraft executing the approach. This action creates controlled airspace at Crosby Municipal Airport to accommodate the approach.

EFFECTIVE DATE: 0901 UTC, December 3, 1998.

FOR FURTHER INFORMATION CONTACT:

Michelle M. Behm, Air Traffic Division, Airspace Branch, AGL-520, Federal Aviation Administration, 2300 East Devon Avenue, Des Plaines, Illinois 60018, telephone (847) 294-7568.

SUPPLEMENTARY INFORMATION:

History

On Tuesday, June 23, 1998, the FAA proposed to amend 14 CFR part 71 to establish Class E airspace at Crosby, ND (63 FR 34137). The proposal was to add controlled airspace extending upward from 700 to 1200 feet AGL to contain Instrument Flight Rules (IFR) operations in controlled airspace during portions of the terminal operation and while transiting between the enroute and terminal environments.

Interested parties were invited to participate in this rulemaking

proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Class E airspace designations for airspace areas extending upward from 700 feet or more above the surface of the earth are published in paragraph 6005 of FAA Order 7400.9E dated September 10, 1997, and effective September 16, 1997, which is incorporated by reference in 14 CFR 71.1. The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to 14 CFR part 71 establishes Class E airspace at Crosby, ND, to accommodate aircraft executing the proposed GPS Rwy 30 SIAP at Crosby Municipal Airport by creating controlled airspace at the airport. Controlled airspace extending upward from 700 to 1200 feet AGL is needed to contain aircraft executing the approach. The area would be depicted on appropriate aeronautical charts.

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. Therefore, this 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 rule 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).

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 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 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

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

* * * * *

AGL ND E5 Crosby, ND [New]

Crosby Municipal Airport, ND
(Lat. 48°55' 45" N., long. 103°17'56" W.)

That airspace extending upward from 700 feet above the surface within a 6.4-mile radius of the Crosby Municipal Airport, excluding that airspace north of lat. 49° 00' 00"N (Canada/United States Boundary).

* * * * *

Issued in Des Plaines, Illinois, on August 25, 1998.

David B. Johnson,

Acting Manager, Air Traffic Division.

[FR Doc. 98–24290 Filed 9–9–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket Nos. 98N–0426, 98N–0428, 98N–0427, 98N–0423, 98N–0424, 98N–0419, 98N–0422, 98N–0421, and 98N–0420]

Food Labeling: Health Claims; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rules; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to October 8, 1998, the comment period for the nine interim final rules that appeared in the **Federal Register** of June 22, 1998 ((63 FR 34084), (63 FR 34092), (63 FR 34097), (63 FR 34101), (63 FR 34104), (63 FR 34107), (63 FR 34110), (63 FR 34112), and (63 FR 34115)). The rules prohibit the use on food labels of claims that are not appropriately based on authoritative statements from scientific bodies or that otherwise do not meet the specifications of new legislation. Interested persons were given until September 8, 1998, to comment on the interim final rules. This action is being taken in response to requests to reopen the comment period.

DATES: Written comments by October 8, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Christine J. Lewis, Center for Food Safety and Applied Nutrition (HFS–451), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–4168.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 22, 1998 ((63 FR 34084), (63 FR 34092), (63 FR 34097), (63 FR 34101), (63 FR 34104), (63 FR 34107), (63 FR 34110), (63 FR 34112), and (63 FR 34115)), FDA issued nine interim final rules prohibiting the use on food labels of claims that are not appropriately based on authoritative statements from scientific bodies or that otherwise do not meet the specifications of new legislation.

Interested persons were given until September 8, 1998, to comment on the rules. FDA has received several requests for extending the comment period. After evaluating these requests, the agency has decided to reopen the comment

period on the interim final rules until October 8, 1998.

To be considered, written comments regarding the interim final rules must be received by October 8, 1998, by the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with Docket Nos. 98N–0426, 98N–0428, 98N–0427, 98N–0423, 98N–0424, 98N–0419, 98N–0422, 98N–0421, and 98N–0420. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 4, 1998

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–24359 Filed 9–4–98; 4:34 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. 97N–0335]

Obstetric and Gynecologic Devices; Reclassification and Classification of Medical Devices Used for In Vitro Fertilization and Related Assisted Reproduction Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is reclassifying instrumentation intended for use in in vitro fertilization (IVF) and related assisted reproduction technology (ART) procedures, including but not limited to gamete intrafallopian transfer (GIFT), embryo transfer (ET), and intracytoplasmic sperm injection (ICSI), from class III (premarket approval) to class II (special controls). FDA is also reclassifying assisted reproduction microscopes and microscope accessories from class III to class I. This reclassification is on the Secretary of the Department of Health and Human Services' (the Secretary's) own initiative based on new information. Accordingly, the order is being codified in the Code of Federal Regulations. Upon the effective date, this **Federal Register** document may be cited in the absence of an existing predicate device which would be used to support substantial equivalence. Elsewhere in this issue of the **Federal Register**, FDA is announcing the