

(h) Repetitive Inspections

Repeat the inspection required in paragraph (g)(3) of this AD before 10,000 hours since last overhaul if after last overhaul the HMU is exposed to TS-1 fuel.

(i) Paperwork Reduction Act Burden Statement

A federal agency may not conduct or sponsor, and a person is not required to respond to, nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a current valid OMB Control Number. The OMB Control Number for this information collection is 2120-0056. Public reporting for this collection of information is estimated to be approximately 5 minutes per response, including the time for reviewing instructions, completing and reviewing the collection of information. All responses to this collection of information are mandatory. Comments concerning the accuracy of this burden and suggestions for reducing the burden should be directed to the FAA at: 800 Independence Ave. SW., Washington, DC 20591, Attn: Information Collection Clearance Officer, AES-200.

(j) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request.

(k) Related Information

(1) For more information about this AD, contact Martin Adler, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781-238-7157; fax: 781-238-7199; email: martin.adler@faa.gov.

(2) Refer to EASA Airworthiness Directive No. 2012-0123, dated July 9, 2012, and CFM SBs CFM56-5 S/B 73-0182, Revision 7, dated September 25, 2012, and CFM56-5B S/B 73-0122, Revision 9, dated September 25, 2012, for related information.

(3) For service information identified in this AD, contact CFM International Inc., Aviation Operations Center, 1 Neumann Way, M/D Room 285, Cincinnati, OH 45125; International phone: 1-513-552-3272; USA phone: 877-432-3272; International fax: 1-513-552-3329; USA fax: 877-432-3329; email: geae.aoc@ge.com; or CFM International SA, Customer Support Center, International phone: 33 1 64 14 88 66; fax: 33 1 64 79 85 55; email: sneema.csc@sneema.fr.

(4) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781-238-7125.

Issued in Burlington, Massachusetts, on January 4, 2013.

Robert J. Ganley,

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

[FR Doc. 2013-00529 Filed 1-11-13; 8:45 am]

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DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Docket No. FAA-2012-0966; Airspace Docket No. 12-AWA-5]

RIN 2120-AA66

Proposed Modification of Class B Airspace; Las Vegas, NV

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM); Reopening of comment period.

SUMMARY: This action reopens the comment period for an NPRM that was published on October 26, 2012. In that document, the FAA proposed to modify the Las Vegas, NV, Class B airspace area to ensure the containment of large turbine-powered aircraft within Class B airspace.

DATES: The comment period for the NPRM published in the **Federal Register** on October 26, 2012 (77 FR 65332) closed on December 26, 2012, is reopened until February 13, 2013.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, M-30, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001; telephone: (202) 366-9826. You must identify FAA Docket No. FAA-2012-0966 and Airspace Docket No. 12-AWA-5, at the beginning of your comments. You may also submit comments through the Internet at <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace Policy and ATC Procedures Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267-8783.

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-2012-0966 and Airspace Docket No. 12-AWA-5) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the Internet at <http://www.regulations.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 Docket Nos. FAA-2012-0966 and Airspace Docket No. 12-AWA-5." 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://www.regulations.gov>.

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Western Service Center, Operations Support Group, Federal Aviation Administration, 1601 Lind Ave. SW., Renton, WA 98057.

Persons interested in being placed on a mailing list for future NPRMs 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.

Background

In the **Federal Register** of October 26, 2012, the FAA issued a NPRM entitled

“Proposed Modification of Class B Airspace; Las Vegas, NV” (77 FR 65332). The FAA requested that comments on that proposal be received on or before December 26, 2012. By letter dated December 7, 2012, the Aircraft Owners and Pilots Association (AOPA) requested that the FAA extend the comment period for at least 30 days. AOPA stated that the original comment period encompassed two Federal holidays and that no comments had been posted to the docket as of the date of their letter. AOPA added that an extension would provide additional time for the public to review the NPRM and submit substantive comments on the proposal.

Reopening of Comment Period

The FAA has reviewed AOPA's request for additional time to comment on the NPRM and has determined that reopening of the comment period is consistent with the public interest and that good cause exists for taking this action.

Accordingly, the comment period for Docket No. FAA-2012-0966; Airspace Docket No. 12-AWA-5, is reopened as indicated in the **DATES** section, above.

Issued in Washington, DC, on January 8, 2013.

Gary A. Norek,

Manager, Airspace Policy and ATC Procedures Group.

[FR Doc. 2013-00646 Filed 1-10-13; 4:15 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 872

[Docket No. FDA-2012-N-0677]

Dental Devices; Reclassification of Blade-Form Endosseous Dental Implant

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the blade-form endosseous dental implant, a preamendments class III device, into class II (special controls). On its own initiative, based on new information, FDA is proposing to revise the classification of blade-form endosseous dental implants.

DATES: Submit either electronic or written comments on this proposed order by April 15, 2013. See section XI

of this document for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA-2012-N-0677, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

Written Submissions

Submit written submissions in the following ways:

- *Mail/Hand delivery/Courier (for paper or CD-ROM submissions):* Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA-2012-N-0677 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, 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.regulations.gov> and insert Docket No. FDA-2012-N-0677 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:

Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1646, Silver Spring, MD 20993, 301-796-5616, melissa.burns@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94-295), the Safe Medical Devices Act of 1990 (Pub. L. 101-629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105-115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), the Medical Devices Technical Corrections Act (Public Law 108-214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110-85), and the Food and Drug

Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144), establish a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting 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).

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices), are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a premarket approval application (PMA) until FDA issues a final order under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval or until the device is subsequently reclassified into class I or class II.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) of the FD&C Act changing the process for reclassifying a preamendments device from rulemaking to an administrative order.