TABLE 1—AFFECTED PARTS

Part name	Part No.
Upper Pin	600–92384–5
Upper Pin	600–92384–7
Upper Pin	601R92310–1
Lower Pin	600–92383–5
Lower Pin	600–92383–7
Lower Pin	601R92309–1
Trunnion	601R92386–1

(h) Replacement

If, during any inspection required by paragraph (g) of this AD, any gouges, scratches, or corrosion are found: Before further flight, replace the affected part with a part other than one identified in table 1 of this AD, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 601R–27–160, dated September 29, 2011.

(i) Re-Identification

If, during any inspection required by paragraph (g) of this AD, no gouges, scratches or corrosion are found: Before further flight, add serial numbers and new part numbers to the trunnions, upper pins, and lower pins, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 601R–27–160, dated September 29, 2011.

(j) Revise Maintenance Program

Within 30 days after the effective date of this AD, revise the maintenance program to incorporate the information specified in Bombardier Temporary Revisions 2B–2180, dated August 8, 2011; and 2B–2186, dated August 8, 2011; to Appendix B—Airworthiness Limitations, of Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 Maintenance Requirements Manual (MRM). The compliance time for doing the initial replacement for the HSTA trunnion support and attaching hardware is before the accumulation of 80,000 landings or within 60 days after the effective date of this AD, whichever occurs later. The compliance time for doing the initial inspection of the upper and lower installation pins of the horizontal stabilizer pitch trim actuator is before the accumulation of 40,000 landings or within 60 days after the effective date of this AD, whichever occurs later.

(k) No Alternative Actions or Intervals

After accomplishing the revision required by paragraph (j) of this AD, no alternative actions (e.g., inspections) or intervals may be used unless the actions or intervals are approved as an alternative method of compliance (AMOC) in accordance with the procedures specified in paragraph (l)(1) of this AD.

(l) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York Aircraft Certification Office, ANE–170, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the ACO, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO, 1600 Stewart Avenue, Suite 410, Westbury, New York 11590; telephone 516–228–7300; fax 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office. The AMOC approval letter must specifically reference this AD.

(2) *Airworthy Product:* For any requirement in this AD to obtain corrective actions from a manufacturer or other source, use these actions if they are FAA-approved. Corrective actions are considered FAA-approved if they are approved by the State of Design Authority (or their delegated agent). You are required to assure the product is airworthy before it is returned to service.

(m) Related Information

(1) Refer to MCAI Canadian Airworthiness Directive CF–2011–45, dated December 19, 2011, and the service information specified in paragraphs (m)(1)(i), (m)(1)(ii), and (m)(1)(iii) of this AD, for related information.

(i) Bombardier Service Bulletin 601R–27–160, dated September 29, 2011.

(ii) Bombardier Temporary Revision 2B–2180, dated August 8, 2011, to Appendix B—Airworthiness Limitations, of Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 Maintenance Requirements Manual.

(iii) Bombardier Temporary Revision 2B–2186, dated August 8, 2011, to Appendix B—Airworthiness Limitations, of Part 2, Airworthiness Requirements, of the Bombardier CL–600–2B19 Maintenance Requirements Manual.

(2) For service information identified in this AD, contact Bombardier, Inc., 400 Côte-Vertu Road West, Dorval, Québec H4S 1Y9, Canada; telephone 514–855–5000; fax 514–855–7401; email *thd.crj@aero.bombardier.com;* Internet *http://www.bombardier.com.* You may review copies of the referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, Washington. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on June 11, 2012.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–15063 Filed 6–19–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2011–0222; Directorate Identifier 2010–NM–056–AD]

RIN 2120–AA64

Airworthiness Directives; Dassault Aviation Airplanes

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Proposed rule; withdrawal.

SUMMARY: The FAA withdraws a notice of proposed rulemaking (NPRM) that proposed a new airworthiness directive (AD) for certain Dassault Aviation Model FALCON 7X airplanes. The proposed AD would have required revising the maintenance program to incorporate a limitation that reduced time between overhauls, and required an initial overhaul, of the direct current (DC) generator (bearings). Since the proposed AD was issued, we have received new data that confirm the identified unsafe condition is not sufficient to warrant issuance of an AD. Accordingly, the proposed AD is withdrawn.

ADDRESSES: You may examine the AD docket on the Internet at *http://www.regulations.gov;* or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD action, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone 800–647–5527) is the Document Management Facility, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.

FOR FURTHER INFORMATION CONTACT: Tom Rodriguez, Aerospace Engineer, International Branch, ANM–116, Transport Airplane Directorate, FAA, 1601 Lind Avenue SW., Renton, Washington 98057–3356; telephone (425) 227–1137; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION:

Discussion

We proposed to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) with a notice of proposed rulemaking (NPRM) for a new AD for certain Dassault Aviation Model FALCON 7X airplanes. That NPRM was published in the **Federal Register** on March 15, 2011 (76 FR 13924). That

NPRM would have required revising the maintenance program to incorporate a limitation that reduced time between overhauls, and required an initial overhaul, of the DC generator (bearings). That NPRM resulted from mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country to identify and correct an unsafe condition on an aviation product. The MCAI described the unsafe condition as:

> Time between overhaul (TBO) of DC [direct current] generator bearings is set at 1,000 flight hours (FH) in the airworthiness limitations section of the Falcon 7X Aircraft Maintenance Manual Chapter 5.40.
>
> In service report has shown that the bearing current design cannot sustain the current TBO. * * *
>
> * * * * *
>
> Failure to comply with those revised maintenance tasks could constitute an unsafe condition.

The proposed actions were intended to prevent failure of the DC generator bearings, which could lead to loss of the generator and potential loss of electrical power to the fly-by-wire system and subsequent loss of control of the airplane.

Actions Since NPRM (76 FR 13924, March 15, 2011) Was Issued

Since we issued the NPRM (76 FR 13924, March 15, 2011), the airplane manufacturer provided further information on the redundancy of the electrical system that supplies power to the fly-by-wire system. There are three DC generators that can supply electrical power to the fly-by-wire system. Electrical power can also be supplied by two independent permanent magnet alternator converters that are dedicated to that system. Failure of all three DC generators to supply electrical power automatically triggers a command to deploy the ram air turbine, which will supply the airplane systems (including fly-by-wire) with sufficient electrical power for continued safe flight and landing.

FAA's Conclusions

Upon further consideration, we have determined that, based on the airplane design, and the multiple electrical power generation sources, the potential loss of one DC generator due to an un-reduced maintenance interval would not result in loss of electrical power to the airplane. Therefore, the potential loss of one DC generator does not constitute an unsafe condition. Accordingly, the NPRM (76 FR 13924, March 15, 2011) is withdrawn.

Withdrawal of the NPRM (76 FR 13924, March 15, 2011) does not preclude the FAA from issuing another related action or commit the FAA to any course of action in the future.

Regulatory Impact

Since this action only withdraws an NPRM (76 FR 13924, March 15, 2011), it is neither a proposed nor a final rule and therefore is not covered under Executive Order 12866, the Regulatory Flexibility Act, or DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979).

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Withdrawal

Accordingly, we withdraw the NPRM, Docket No. FAA–2011–0222, Directorate Identifier 2010–NM–056–AD, which was published in the **Federal Register** on March 15, 2011 (76 FR 13924).

Issued in Renton, Washington, on June 12, 2012.

Kalene C. Yanamura,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2012–15097 Filed 6–19–12; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2012–N–0303]

Gastroenterology-Urology Devices; Reclassification of Implanted Blood Access Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the implanted blood access device preamendments class III device into class II (special controls). FDA is proposing this reclassification on its own initiative based on new information. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

DATES: Submit either electronic or written comments on the proposed rule by September 18, 2012. Please see section XIII of this document for the effective date of any final rule that may publish based on this proposal.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–0303 by any of the following methods, except that comments on information collection issues under the Paperwork Reduction Act of 1995 must be submitted to the Office of Regulatory Affairs, Office of Management and Budget (OMB) (see the ''Paperwork Reduction Act of 1995'' section of this document).

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:

- *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.

Instructions: All submissions received must include the Agency name and docket number 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 the docket number, 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: Jeffrey Cooper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G228, Silver Spring, MD 20993, 301–796–6517.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The FD&C Act, as amended by the 1976 amendments (Pub. L. 94–295), the SMDA (Pub. L. 101–629), the FDAMA