

compliance time after the effective date of this AD.

(2) Where Boeing Alert Service Bulletin 747-53A2499, Revision 3, dated July 15, 2014, specifies to contact Boeing for repair instructions: Before further flight, repair using a method approved in accordance with the procedures specified in paragraph (l) of this AD.

(k) Credit for Previous Actions

Actions done before the effective date of this AD using the service information identified in paragraph (k)(1) or (k)(2) of this AD are acceptable for compliance with the corresponding requirements of paragraphs (g) and (h) of this AD.

(1) Boeing Alert Service Bulletin 747-53A2499, Revision 1, dated October 30, 2008, which is not incorporated by reference in this AD.

(2) Boeing Alert Service Bulletin 747-53A2499, Revision 2, dated August 12, 2010, which was incorporated by reference in AD 2010-26-10, Amendment 39-16549 (75 FR 81427, December 28, 2010).

(l) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), 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 manager of the ACO, send it to the attention of the person identified in paragraph (m)(1) of this AD. Information may be emailed to: 9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.

(2) 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.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(4) AMOCs approved for AD 2010-26-10, Amendment 39-16549 (75 FR 81427, December 28, 2010), are approved as AMOCs for the corresponding provisions of paragraphs (g) and (h) of this AD.

(m) Related Information

(1) For more information about this AD, contact Nathan Weigand, Aerospace Engineer, Airframe Branch, ANM-120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057-3356; phone: 425-917-6428; fax: 425-917-6590; email: nathan.p.weigand@faa.gov.

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (n)(3) and (n)(4) of this AD.

(n) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Service Bulletin 747-53A2499, Revision 3, dated July 15, 2014.

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H-65, Seattle, WA 98124-2207; telephone 206-544-5000, extension 1; fax 206-766-5680; Internet <https://www.myboeingfleet.com>.

(4) You may view this service information at FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on February 7, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-03219 Filed 2-17-16; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA-2015-4803; Directorate Identifier 2015-CE-034-AD; Amendment 39-18399; AD 2016-04-05]

RIN 2120-AA64

Airworthiness Directives; B-N Group Ltd. Airplanes

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

ACTION: Final rule.

SUMMARY: We are superseding an airworthiness directive (AD) 2014-03-18 for B-N Group Ltd. Models BN-2, BN-2A, BN-2A-2, BN-2A-3, BN-2A-6, BN-2A-8, BN-2A-9, BN-2A-20, BN-2A-21, BN-2A-26, BN-2A-27, BN-2B-20, BN-2B-21, BN-2B-26, BN-2B-27, BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3 airplanes. This AD results from mandatory continuing airworthiness information (MCAI) issued by an aviation authority of

another country to identify and correct an unsafe condition on an aviation product. The MCAI describes the unsafe condition as damage of the cable sliding end assembly and installation of the incorrect end fitting on engine control cable assemblies. We are issuing this AD to require actions to address the unsafe condition on these products.

DATES: This AD is effective March 24, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in the AD as of March 24, 2016.

The Director of the Federal Register approved the incorporation by reference of a certain other publication listed in this AD as of April 1, 2014 (79 FR 10340, February 25, 2014).

ADDRESSES: You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-4803; or in person at the Docket 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 service information identified in this final rule, contact Britten-Norman Aircraft Limited, Commodore House, Mountbatten Business Centre, Millbrook Road East, Southampton SO15 1HY, United Kingdom; telephone: +44 20 3371 4000; fax: +44 20 3371 4001; email: info@bnaircraft.com; Internet: <http://www.britten-norman.com/customer-support/>. You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329-4148. It is also available on the Internet at <http://www.regulations.gov> by searching for Docket No. FAA-2015-4803.

FOR FURTHER INFORMATION CONTACT:

Raymond Johnston, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4159; fax: (816) 329-3047; email: raymond.johnston@faa.gov.

SUPPLEMENTARY INFORMATION:

Discussion

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 by adding an AD that would apply to B-N Group Ltd. Models BN-2, BN-2A, BN-2A-2, BN-2A-3, BN-2A-6, BN-2A-8, BN-2A-9, BN-2A-20, BN-2A-21, BN-2A-26, BN-2A-27, BN-2B-20, BN-2B-21, BN-2B-26, BN-2B-27, BN2A MK. III, BN2A MK. III-2, and

BN2A MK. III-3 airplanes. The NPRM was published in the **Federal Register** on October 29, 2015 (80 FR 66482), and proposed to supersede AD 2014-03-18, Amendment 39-17755 (79 FR 10340; February 25, 2014).

The NPRM proposed to correct an unsafe condition for the specified products and was based on mandatory continuing airworthiness information (MCAI) originated by an aviation authority of another country. The MCAI states that:

Britten-Norman Aircraft Limited was made aware of two occurrences where a failure of engine control cable assemblies has caused engine control difficulties. In both reported cases, the cable sliding end assemblies were in poor condition and in both cases, an incorrect end-fitting was installed, which may have contributed to the failures.

This condition, if not detected and corrected, could result in reduced engine control, possibly resulting in reduced control of the aeroplane.

To address this potential unsafe condition, Britten-Norman Aircraft issued Service Bulletin (SB) 334 to provide inspection instructions, and EASA issued AD 2013-0215 to require a one-time inspection and functional test of the engine control cables and, depending on findings, replacement of the cables.

Subsequently, as it was found that BN2 "Islander" aeroplanes were mistakenly omitted from the AD applicability, EASA issued AD 2013-0263, retaining the requirements of EASA AD 2013-0215, which was superseded, and extending the applicability to BN2 aeroplanes.

Since EASA AD 2013-0263 was issued, it was found that certain parts, specific to BN2A "Trislander" aeroplanes only, were inadvertently not included in SB 334 and, as a consequence, not required by AD 2013-0263 to be inspected.

Prompted by these findings, Britten-Norman revised SB 334 (now at issue 2) to include the missing parts.

For the reason described above, this AD retains the requirements of EASA AD 2013-0263, which is superseded, and adds inspection requirements for the additional parts.

The MCAI can be found in the AD docket on the Internet at: <http://www.regulations.gov/#!documentDetail;D=FAA-2015-4803-0001>.

Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

Conclusion

We reviewed the relevant data and determined that air safety and the public interest require adopting the AD as proposed except for minor editorial

changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM (80 FR 66482, October 29, 2015) for correcting the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM (80 FR 66482, October 29, 2015).

Related Service Information Under 1 CFR Part 51

We reviewed Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 1, dated August 30, 2013; and Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 2, dated July 17, 2015. The service information describes procedures for inspection and replacement if necessary of the engine control cable assemblies. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this final rule.

Costs of Compliance

We estimate that this AD will affect 96 products of U.S. registry. We also estimate that it would take about 1 work-hour per product to comply with the basic requirements of this proposed AD. The average labor rate is \$85 per work-hour.

Based on these figures, we estimate the cost of this AD on U.S. operators to be \$8,160 or \$85 per product.

In addition, we estimate that any necessary follow-on actions would take about 10 work-hours and require parts costing \$6,000, for a cost of \$6,850 per product. We have no way of determining the number of products that may need these actions.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. "Subtitle VII: Aviation Programs," describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in "Subtitle VII, Part A, Subpart III, Section 44701: General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition

that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD 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.

For the reasons discussed above, I certify this AD:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) 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.

Examining the AD Docket

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-4803; 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 the NPRM, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (telephone (800) 647-5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

- 2. The FAA amends § 39.13 by removing Amendment 39-17755 (79 FR 10340; February 25, 2014) and adding the following new AD:

2016-04-05 B-N Group Ltd.: Amendment 39-18399; Docket No. FAA-2015-4803; Directorate Identifier 2015-CE-034-AD.

(a) Effective Date

This airworthiness directive (AD) becomes effective March 24, 2016.

(b) Affected ADs

This AD supersedes AD 2014-03-18, Amendment 39-17755 (79 FR 10340; February 25, 2014) ("AD 2014-03-18").

(c) Applicability

This AD applies to B-N Group Ltd. Models BN-2, BN-2A, BN-2A-2, BN-2A-3, BN-2A-6, BN-2A-8, BN-2A-9, BN-2A-20, BN-2A-21, BN-2A-26, BN-2A-27, BN-2B-20, BN-2B-21, BN-2B-26, BN-2B-27, BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3 airplanes, all serial numbers, certificated in any category.

(d) Subject

Air Transport Association of America (ATA) Code 76: Engine Controls.

(e) Reason

This AD was prompted by 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 describes the unsafe condition as possible damage of the cable sliding end assembly and installation of the incorrect end fitting on engine control cable assemblies. We are issuing this proposed AD to detect and correct damage of the cable sliding end assembly (cracking, distortion, corrosion) and incorrect end fittings on the engine control assemblies, which could lead to reduced engine control with consequent loss of control, and to incorporate revised service information with updated information on applicability and on the identity of parts to be inspected on some airplanes.

(f) Actions and Compliance

Unless already done, do the actions in paragraphs (f)(1) through (f)(6) of this AD:

(1) *For all airplanes except the Trislander Models BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3:* Within the next 6 months after April 1, 2014 (the effective date retained from AD 2014-03-18), do a one-time inspection of the engine control cable assemblies, part number (P/N) 137835, P/N 172449-1, P/N 172450, and P/N 172451, and surrounding areas for damage (cracking, distortion, corrosion); for the correct cable end-fitting; and to assure the wire locking is intact following Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 1, dated August 30, 2013; or Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 2, dated July 17, 2015.

(2) *For the Trislander Models BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3 airplanes:* Within the next 3 months after March 24, 2016 (the effective date of this AD), do a one-time inspection of the engine control cable assemblies, P/N 80468 and P/N NB-45-2883, and surrounding areas for damage (cracking, distortion, corrosion); for the correct cable end-fitting; and to assure the wire locking is intact following Britten-

Norman Aircraft Limited Service Bulletin No. SB 334, Issue 2, dated July 17, 2015.

(3) *For all airplanes except the Trislander Models BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3:* If no discrepancies are found during the inspection required in paragraph (f)(1) of this AD, before further flight, inspect the control linkages for proper adjustment and make any necessary changes following Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 1, dated August 30, 2013; or Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 2, dated July 17, 2015.

(4) *For the Trislander Models BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3 airplanes:* If no discrepancies are found during the inspection required in paragraph (f)(2) of this AD, before further flight, inspect the control linkages for proper adjustment and make any necessary changes following Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 2, dated July 17, 2015.

(5) *For all airplanes except the Trislander Models BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3:* If any discrepancies are found during the inspection required in paragraph (f)(1) of this AD and/or the control linkages cannot be properly adjusted as specified in paragraph (f)(3) of this AD, before further flight, replace the engine control cable assembly with a serviceable unit following Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 1, dated August 30, 2013; or Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 2, dated July 17, 2015.

(6) *For the Trislander Models BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3 airplanes:* If any discrepancies are found during the inspection required in paragraph (f)(2) of this AD and/or the control linkages cannot be properly adjusted as specified in paragraph (f)(4) of this AD, before further flight, replace the engine control cable assembly with a serviceable unit following Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 2, dated July 17, 2015.

(7) *For all airplanes except the Trislander Models BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3:* After April 1, 2014 (the effective date retained from AD 2014-03-18), do not install on any airplane engine control cable assemblies, P/N 137835, P/N 172449-1, P/N 172450, and P/N 172451, unless they are new or have been inspected as required in paragraphs (f)(1) and (f)(3) of this AD and found free of any discrepancies and have proper adjustment.

(8) *For the Trislander Models BN2A MK. III, BN2A MK. III-2, and BN2A MK. III-3 airplanes:* After March 24, 2016 (the effective date of this AD), do not install on any airplane engine control cable assemblies P/N 80468 and/or P/N NB-45-2883, unless they are new or have been inspected as required in paragraphs (f)(2) and (f)(4) of this AD and found free of any discrepancies and have proper adjustment.

(g) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, Standards Office,

FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. Send information to ATTN: Raymond Johnston, Aerospace Engineer, FAA, Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4159; fax: (816) 329-3047; email: raymond.johnston@faa.gov. Before using any approved AMOC on any airplane to which the AMOC applies, notify your appropriate principal inspector (PI) in the FAA Flight Standards District Office (FSDO), or lacking a PI, your local FSDO.

(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.

(h) Related Information

Refer to MCAI European Aviation Safety Agency (EASA) AD No.: 2015-0184, dated September 1, 2015; for related information. The MCAI can be found in the AD docket on the Internet at: <http://www.regulations.gov/#/documentDetail;D=FAA-2015-4803-0001>.

(i) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(3) The following service information was approved for IBR on March 24, 2016 (the effective date of this AD).

(i) Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 2, dated July 17, 2015.

(ii) Reserved.

(4) The following service information was approved for IBR on April 1, 2014 (79 FR 10340; February 25, 2014).

(i) Britten-Norman Aircraft Limited Service Bulletin No. SB 334, Issue 1, dated August 30, 2013.

(ii) Reserved.

(5) For Britten-Norman service information identified in this AD, contact Britten-Norman Aircraft Limited, Commodore House, Mountbatten Business Centre, Millbrook Road East, Southampton SO15 1HY, United Kingdom; telephone: +44 20 3371 4000; fax: +44 20 3371 4001; email: info@bnaircraft.com; Internet: <http://www.britten-norman.com/customer-support/>.

(6) You may view this service information at FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call 816-329-4148. In addition, you can access this service information on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2015-4803.

(7) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on

the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Kansas City, Missouri, on February 10, 2016.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016-03307 Filed 2-17-16; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA-2011-N-0661]

Effective Date of Requirement for Premarket Approval for Total Metal-on-Metal Semi-Constrained Hip Joint Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

DATES: This order is effective on February 18, 2016.

FOR FURTHER INFORMATION CONTACT: Sergio M. de del Castillo, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1538, Silver Spring, MD 20993, 301-796-6419.

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 (Pub. L. 105-115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), the Medical Devices Technical Corrections Act (Pub. L. 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), among other amendments, established 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(d) 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 and devices found substantially equivalent by means of premarket notification (510(k)) procedures to such a preamendments device or to a device within that type (both the preamendments and substantially equivalent devices are referred to as preamendments class III devices) may be marketed without submission of a 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. Section 515(b)(1) of the FD&C Act directs FDA to issue an order requiring premarket approval for a preamendments class III device.

Although, under the FD&C Act, the manufacturer of a preamendments class

III device may respond to the call for PMAs by filing a PMA or a notice of completion of a PDP. In practice, the option of filing a notice of completion of a PDP has rarely been used. For simplicity, although the PDP option remains available to manufacturers in response to a final order under section 515(b) of the FD&C Act, this document will refer only to the requirement for the filing of, and obtaining approval of, a PMA.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA amended section 513(e) of the FD&C Act, changing the process for reclassifying a device from rulemaking to an administrative order. Section 608(b) of FDASIA amended section 515(b) of the FD&C Act, changing the process for requiring premarket approval for a preamendments class III device from rulemaking to an administrative order.

FDA is requiring PMAs for total metal-on-metal (MoM) semi-constrained hip joint systems (heretofore referenced as "MoM hips"), which include the following two specific preamendments class III devices: Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis; and hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis.

Section 515(b)(1) of the FD&C Act sets forth the process for issuing a final order. Specifically, prior to the issuance of a final order requiring premarket approval for a preamendments class III device, the following must occur: (1) Publication of a proposed order in the **Federal Register**; (2) a meeting of a device classification panel described in section 513(b) of the FD&C Act; and (3) consideration of comments from all affected stakeholders, including patients, payors, and providers. FDA published a proposed order to require PMAs for MoM hips in the **Federal Register** of January 18, 2013 (78 FR 4094), and convened a meeting of a device classification panel for MoM hips as discussed in the proposed order and in this document.

Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed order, consideration of any comments received, and a meeting of a device classification panel described in section 513(b) of the FD&C Act, issue a final order to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination.

A preamendments class III device may be commercially distributed without a PMA until 90 days after FDA issues a final order (a final rule issued