(d) Subject

Air Transport Association (ATA) of America Code 30, Ice and Rain Protection.

(e) Reason

This AD was prompted by reports of metallic debris found in the wing slat piccolo tubes; investigation revealed that the debris originated from the flow guide of the ball joint located downstream of the wing anti-ice valve. We are issuing this AD to address restricted airflow of the piccolo tubes, leading to insufficient wing anti-ice capability and significant undetected ice accretion on the wing, which could result in loss of control of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Repetitive Inspections and Corrective Actions

Within 25 months after the effective date of this AD: Perform a detailed inspection for discrepancies of the flow guide of the ball joint located downstream of the wing anti-ice valve, and do all applicable related investigative and corrective actions, in accordance with the Accomplishment Instructions of Dassault Aviation Service Bulletin F2000–441, dated June 20, 2017; or Dassault Aviation Service Bulletin F2000EX–413, dated July 10, 2017; as applicable. Repeat the detailed inspection thereafter at intervals not to exceed 25 months. Do all applicable corrective actions before further flight.

(h) No Reporting Requirement

Although the service information identified in paragraph (g) of this AD specifies to submit certain information to the manufacturer, this AD does not include that requirement.

(i) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, International Section, Transport Standards Branch, 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 International Section, send it to the attention of the person identified in paragraph (j)(2) of this AD. Information may be emailed to: *9-ANM-116-AMOC-REQUESTS@faa.gov.* 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.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, International Section, Transport Standards Branch, FAA; or the European Aviation Safety Agency (EASA); or Dassault Aviation's EASA Design Organization Approval (DOA). If approved by the DOA, the approval must include the DOA-authorized signature.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) EASA AD 2018–0022, dated January 29, 2018, for related information. This MCAI may be found in the AD docket on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2018–0496.

(2) For more information about this AD, contact Tom Rodriguez, Aerospace Engineer, International Section, Transport Standards Branch, FAA, 2200 South 216th Street, Des Moines, WA 98198; telephone and fax 206–231–3226.

(k) 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 this AD specifies otherwise.

(i) Dassault Aviation Service Bulletin F2000–441, dated June 20, 2017.

(ii) Dassault Aviation Service Bulletin F2000EX–413, dated July 10, 2017.

(3) For service information identified in this AD, contact Dassault Falcon Jet Corporation, Teterboro Airport, P.O. Box 2000, South Hackensack, NJ 07606; telephone 201–440–6700; internet *http://www.dassaultfalcon.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(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 Des Moines, Washington, on September 7, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–20630 Filed 9–26–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2017–1026; Product Identifier 2017–NM–097–AD; Amendment 39–19422; AD 2018–19–21]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: We are adopting a new airworthiness directive (AD) for all The Boeing Company Model 707 airplanes, and Model 720 and 720B series airplanes. This AD was prompted by fuel system reviews conducted by the manufacturer. This AD requires revising the maintenance or inspection program to include new airworthiness limitations. We are issuing this AD to address the unsafe condition on these products.

DATES: This AD is effective November 1, 2018.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of November 1, 2018.

ADDRESSES: For service information identified in this final rule, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone: 562–797–1717; internet: *https://www.myboeingfleet.com.* You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195. It is also available on the internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2017–1026.

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–2017–1026; or in person at Docket Operations between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this final rule, the regulatory evaluation, any comments received, and other information. The address for Docket Operations (phone: 800–647–5527) is Docket Operations, 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: Samuel Lee, Aerospace Engineer, Propulsion Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5262; fax: 562–627–5210; email: *samuel.lee@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 all The Boeing Company Model 707 airplanes, and Model 720 and 720B series airplanes. The NPRM published in the **Federal Register** on November 20, 2017 (82 FR 55057). The NPRM was prompted by fuel system reviews conducted by the manufacturer. The NPRM proposed to require revising the maintenance or inspection program to include new airworthiness limitations.

We are issuing this AD to detect and correct potential ignition sources inside fuel tanks caused by latent failures, alterations, repairs, or maintenance actions, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

Comments

We gave the public the opportunity to participate in developing this final rule. We have considered the comment received. Boeing supported the NPRM.

Clarification of Alternative Wire Types and Sleeving

Paragraph (h) of this AD allows alternative wire types and sleeving materials for certain wire types and sleeving materials identified in AWL No. 28–AWL–03. AWL No. 28–AWL–03 was originally mandated by AD 2008–04–11 R1, Amendment 39–16147 (74 FR 68505, December 28, 2009) (''AD 2008–04–11 R1''). Since the issuance of AD 2008–04–11 R1, which is terminated by this AD, we received numerous requests for approval of alternative methods of compliance (AMOCs) from operators and supplemental type certificate (STC) holders (or applicants) to allow the installation of the alternative wire types and sleeving. We evaluated certain attributes of those alternative wire types and sleeving for each installation, and issued numerous AMOC approvals for AD 2008–04–11 R1, based on our determination that the installation of those wire types and sleeving would provide an acceptable level of safety. The alternative wire types and sleeving specified in paragraph (h) of this AD were previously approved as an AMOC for AD 2008–04–11 R1. Although paragraph (h) of this AD provides certain allowances, it does not provide approval of alternative wire types and sleeving that are installed as part of an aircraft design change. Each applicant for any design change is responsible to show that the installation of alternative wire types and sleeving identified in paragraphs (h)(l) and (h)(2) of this AD complies with all applicable regulatory requirements. This responsibility includes, but is not limited to, substantiation of compliance with flammability requirements, and substantiation to show that sleeve installation, including the selection of sleeve thickness, is adequate to protect wires from chafing for the life of installation.

Conclusion

We reviewed the relevant data, considered the comment received, and determined that air safety and the public interest require adopting this final rule 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 for addressing the unsafe condition; and
- Do not add any additional burden upon the public than was already proposed in the NPRM.

Related Service Information Under 1 CFR Part 51

We reviewed Boeing 707/720 Airworthiness Limitations (AWLs), D6–7552–AWL, dated October 2016, which addresses fuel systems ignition prevention and impact-resistant fuel tank access doors. 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.

Costs of Compliance

We estimate that this AD affects 9 airplanes of U.S. registry. We estimate the following costs to comply with this AD:

We have determined that revising the maintenance or inspection program takes an average of 90 work-hours per operator, although we recognize that this number may vary from operator to operator. In the past, we have estimated that this action takes 1 work-hour per airplane. Since operators incorporate maintenance or inspection program changes for their affected fleet(s), we have determined that a per-operator estimate is more accurate than a per-airplane estimate. Therefore, we estimate the total cost per operator to be $7,650 (90 work-hours × $85 per work-hour).

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.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes and associated appliances to the Director of the System Oversight Division.

Regulatory Findings

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 that this AD:

(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),

(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.

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 adding the following new airworthiness directive (AD):

2018–19–21 The Boeing Company: Amendment 39–19422; Docket No. FAA–2017–1026; Product Identifier 2017–NM–097–AD.

(a) Effective Date

This AD is effective November 1, 2018.

(b) Affected ADs

This AD affects the ADs specified in paragraphs (b)(1) and (b)(2) of this AD.

(1) AD 2008–04–11 R1, Amendment 39–16147 (74 FR 68505, December 28, 2009) (''AD 2008–04–11 R1'').

(2) AD 2013–24–07, Amendment 39–17681 (78 FR 72550, December 3, 2013) (''AD 2013–24–07'').

(c) Applicability

This AD applies to all The Boeing Company airplanes, certificated in any category, identified in paragraphs (c)(1) and (c)(2) of this AD.

(1) Model 707–100 long body, –200, –100B long body, –100B short body, –300, –300B, –300C, and –400 series airplanes.

(2) Model 720 and 720B series airplanes.

(d) Subject

Air Transport Association (ATA) of America Code 28, Fuel.

(e) Unsafe Condition

This AD was prompted by fuel system reviews conducted by the manufacturer. We are issuing this AD to detect and correct potential ignition sources inside fuel tanks caused by latent failures, alterations, repairs, or maintenance actions, which, in combination with flammable fuel vapors, could result in fuel tank explosions and consequent loss of the airplane.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Revision of Maintenance or Inspection Program

Within 60 days after the effective date of this AD, revise the maintenance or inspection program, as applicable, to incorporate the information in Section A, including Subsections A.1, A.2, and Appendix A, as specified in Boeing 707/720 Airworthiness Limitations (AWLs), D6–7552–AWL, dated October 2016; except as provided in paragraph (h) of this AD. The initial compliance times for the AWL tasks are within the applicable compliance times specified in paragraphs (g)(1) through (g)(5) of this AD.

(1) AWL No. 28–AWL–01, External Wires Over Center Fuel Tank, as specified in Boeing 707/720 Airworthiness Limitations (AWLs), D6–7552–AWL, dated October 2016. The initial compliance time for accomplishment of the actions specified by AWL No. 28–AWL–01 is specified in paragraph (g)(1)(i) or (g)(1)(ii) of this AD, as applicable.

(i) For airplanes that have been previously inspected as specified in 28–AWL–01 as of the effective date of this AD: Conduct the inspection within 120 months after the most recent inspection.

(ii) For airplanes that have not been inspected as specified in 28–AWL–01 as of the effective date of this AD: Conduct the inspection within 12 months after the effective date of this AD.

(2) AWL No. 28–AWL–18, AC Fuel Boost Pump Bonding Installation, as specified in Boeing 707/720 Airworthiness Limitations (AWLs), D6–7552–AWL, dated October 2016. The initial compliance time for accomplishment of the actions specified by AWL No. 28–AWL–18 is specified in paragraph (g)(2)(i) or (g)(2)(ii) of this AD, as applicable.

(i) For airplanes that have been previously inspected as specified in 28–AWL–18 as of the effective date of this AD: Conduct the inspection within 72 months after the most recent inspection.

(ii) For airplanes that have not been inspected as specified in 28–AWL–18 as of the effective date of this AD: Conduct the inspection within 12 months after the effective date of this AD.

(3) AWL No. 28–AWL–19, Fuel Valve Bonding Jumper Installation—Engine Fuel Shutoff, Defuel, Reserve Tank Transfer, Fuel Dump, and Fuel Manifold Valves, as specified in Boeing 707/720 Airworthiness Limitations (AWLs), D6–7552–AWL, dated October 2016. The initial compliance time for accomplishment of the actions specified by AWL No. 28–AWL–19 is specified in paragraph (g)(3)(i) or (g)(3)(ii) of this AD, as applicable.

(i) For airplanes that have been previously inspected as specified in 28–AWL–19 as of the effective date of this AD: Conduct the inspection within 72 months after the most recent inspection.

(ii) For airplanes that have not been inspected as specified in 28–AWL–19 as of the effective date of this AD: Conduct the inspection within 12 months after the effective date of this AD.

(4) AWL No. 28–AWL–21, Dry Bay Fuel Manifold Assembly—Bonding Jumper Installation, as specified in Boeing 707/720 Airworthiness Limitations (AWLs), D6–7552–AWL, dated October 2016. The initial compliance time for accomplishment of the actions specified by AWL No. 28–AWL–21 is specified in paragraph (g)(4)(i) or (g)(4)(ii) of this AD, as applicable.

(i) For airplanes that have been previously inspected as specified in 28–AWL–21 as of the effective date of this AD: Conduct the inspection within 72 months after the most recent inspection.

(ii) For airplanes that have not been inspected as specified in 28–AWL–21 as of the effective date of this AD: Conduct the inspection within 12 months after the effective date of this AD.

(5) AWL No. 28–AWL–23, Reserve Tank Transfer Piping Assembly—Bonding Jumper Installation, as specified in Boeing 707/720 Airworthiness Limitations (AWLs), D6–7552–AWL, dated October 2016. The initial compliance time for accomplishment of the actions specified by AWL No. 28–AWL–23 is specified in paragraph (g)(5)(i) or (g)(5)(ii) of this AD, as applicable.

(i) For airplanes that have been previously inspected as specified in 28–AWL–23 as of the effective date of this AD: Conduct the inspection within 72 months after the most recent inspection.

(ii) For airplanes that have not been inspected as specified in 28–AWL–23 as of the effective date of this AD: Conduct the inspection within 12 months after the effective date of this AD.

(h) Additional Acceptable Wire Types and Sleeving

As an option, when accomplishing the actions required by paragraph (g) of this AD, the changes specified in paragraphs (h)(1) and (h)(2) of this AD are acceptable.

(1) Where AWL No. 28–AWL–03 identifies wire types BMS 13–48, BMS 13–58, and BMS 13–60, the following wire types are acceptable: MIL–W–22759/16, SAE AS22759/16 (M22759/16), MIL–W–22759/32, SAE AS22759/32 (M22759/32), MIL–W–22759/34, SAE AS22759/34 (M22759/34), MIL–W–22759/41, SAE AS22759/41 (M22759/41), MIL–W–22759/86, SAE AS22759/86 (M22759/86), MIL–W–22759/87, SAE AS22759/87 (M22759/87), MIL–W–22759/92 and SAE AS22759/92 (M22759/92); and MIL–C–27500 and NEMA WC 27500 cables constructed from these military or SAE specification wire types identified above.

(2) Where AWL No. 28–AWL–03 identifies TFE–2X Standard wall for wire sleeving, the following sleeving materials are acceptable: Roundit 2000NX and Varglas Type HO, HP, or HM.

(i) No Alternative Actions and Intervals

Except as provided in paragraph (h) of this AD, after the maintenance or inspection program has been revised as required by paragraph (g) 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 (k) of this AD.

(j) Terminating Action for Other ADs

(1) Accomplishment of the actions required by paragraph (g) of this AD terminates all requirements of AD 2008–04–11 R1.

(2) Accomplishment of the actions required by paragraph (g) of this AD terminates the requirements of paragraph (h) of AD 2013–24–07.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Los Angeles ACO Branch, 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 certification office, send it to the attention of the person identified in paragraph (l) of this AD. Information may be emailed to: *9-AWP-LAACO-ADS@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, Los Angeles ACO Branch, 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.

(l) Related Information

For more information about this AD, contact Samuel Lee, Aerospace Engineer, Propulsion Section, FAA, Los Angeles ACO Branch, 3960 Paramount Boulevard, Lakewood, CA 90712–4137; phone: 562–627–5262; fax: 562–627–5210; email: *samuel.lee@faa.gov.*

(m) 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 707/720 Airworthiness Limitations (AWLs), D6–7552–AWL, dated October 2016. (Subsection A.2 of this document includes pages 33 and 34, which are not identified in the Table of Contents.)

(ii) Reserved.

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone: 562–797–1717; internet: *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Transport Standards Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(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 Des Moines, Washington, on September 10, 2018.

Michael Kaszycki,

Acting Director, System Oversight Division, Aircraft Certification Service.

[FR Doc. 2018–20631 Filed 9–26–18; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 884

[Docket No. FDA–2017–N–6538]

Obstetrical and Gynecological Devices; Reclassification of Single-Use Female Condom, To Be Renamed Single-Use Internal Condom

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is issuing a final order to reclassify single-use female condoms, renaming the device to ''single-use internal condom,'' a postamendments class III device (regulated under product code MBU), into class II (special controls) subject to premarket notification (510(k)). FDA is also identifying the special controls that the Agency believes are necessary to provide a reasonable assurance of safety and effectiveness of the device. FDA is finalizing this reclassification on its own initiative based on new information. FDA is also amending the existing device identification for ''female condom,'' a preamendments class III device (product code OBY), by renaming the device ''multiple-use female condom,'' to distinguish it from the ''single-use internal condom.'' This order reclassifies single-use internal condoms from class III to class II and reduces regulatory burden because these types of devices will no longer be required to submit a premarket approval application (PMA), but can instead submit a less burdensome 510(k) before marketing their device.

DATES: This order is effective October 29, 2018.

FOR FURTHER INFORMATION CONTACT: Monica Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G215, Silver Spring, MD 20993, 240–402–2791, *monica.garcia@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, establishes 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).

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)(1) 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 postamendments device that has been initially classified in class III under section 513(f)(1) of the FD&C Act may be reclassified into class I or class II under section 513(f)(3) of the FD&C Act. Section 513(f)(3) of the FD&C Act provides that FDA acting by order can reclassify the device into class I or class II on its own initiative, or in response to a petition from the manufacturer or importer of the device. To change the classification of the device, the proposed new class must have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

Reevaluation of the data previously before the Agency is an appropriate basis for subsequent action where the reevaluation is made in light of newly available regulatory authority (see *Bell* v. *Goddard,* 366 F.2d 177, 181 (7th Cir. 1966); *Ethicon, Inc.* v. *FDA,* 762 F. Supp. 382, 388–391 (D.D.C. 1991)), or in light of changes in ''medical science'' (*Upjohn Co.* v. *Finch,* 422 F.2d 944, 951 (6th Cir. 1970)). Whether data before the Agency are old or new, the ''new information'' to support reclassification under section 513(f)(3) must be ''valid