
(i) Retained Replacement, With No Changes


(1) Within 12,000 flight hours on the seat or 4 years, whichever occurs later after the seat manufacturing date or after the backrest link replacement.


(j) Retained Credit for Previous Actions, With No Changes

This paragraph restates the credit provided in paragraph (j) of AD 2014–20–11, Amendment 39–17984 (79 FR 60322, October 7, 2014), with no changes. This paragraph provides credit for actions required by paragraphs (g), (h), and (i) of this AD, if those actions were performed before October 22, 2014 (the effective date AD 2014–20–11), Amendment 39–17984 (79 FR 60322, October 7, 2014), using the service information specified in paragraphs (j)(1), (j)(2), or (j)(3) of this AD.

(1) Sicma Aero Seat Service Bulletin 90–25–012, Issue 3, dated October 3, 2001, which is not incorporated by reference in this AD.

(2) Sicma Aero Seat Service Bulletin 90–25–012, Issue 4, dated December 19, 2001, which is not incorporated by reference in this AD.


(k) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) Alternative Methods of Compliance (AMOCs): The Manager, Boston 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 ACO, send it to ATTN: Ian Lucas, Aerospace Engineer, Boston ACO, ANE–150, FAA, Engine and Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7757; fax: 781–238–7170; email: ian.lucas@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. The AMOC approval letter must specifically reference this AD.

(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, Boston ACO, FAA; or the European Aviation Safety Agency (EASA).

(l) Related Information


(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(4) and (m)(5) of this AD.

(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 this AD specifies otherwise.

(3) The following service information was approved for IBR on October 22, 2014 (79 FR 60322, October 7, 2014).


(ii) Reserved.

(4) For service information identified in this AD, contact Zodiac Seats France, 7, Rue Lucien Coupet, 36100 ISSOUDUN, France; telephone +33 (0) 2 54 03 39 39; fax +33 (0) 2 54 03 39 00; email customerservices@sicma.zodiac.com; Internet http://www.sicma.zodiacaerospace.com/en/.

(5) You may view this service information at the 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.

(6) 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 202–741–6036, or go to: http://www.archives.gov/federal-register/cfr/ibr-locations.html.
is one that explains: (1) Why the direct final rule is inappropriate, including challenges to the rule’s underlying premise or approach; or (2) why the direct final rule will be ineffective or unacceptable without a change. In determining whether a comment necessitates withdrawal of this direct final rule, NASA will consider whether it warrants a substantive response in a notice and comment process.

Background
On January 18, 2011, President Obama signed E.O. 13563, Improving Regulations and Regulatory Review, directing agencies to develop a plan for a retrospective analysis of existing regulations. NASA developed its plan and published it on the Agency’s open Government Web site at http://www.nasa.gov/open/. The Agency conducted an analysis of its existing regulations to comply with the Order and determined that subpart 1216.2, Floodplain and Wetlands Management, should be repealed.

Subpart 1216.2 was promulgated January 4, 1979, [44 FR 1089] in response to Executive Order (E.O.) 11988, Floodplain Management, and E.O. 11990, Protection of Wetlands. Neither E.O. mandates that these requirements be codified in the CFR. For example, E.O. 11988 subsection 2(d) states in pertinent part “. . . each agency shall issue or amend existing regulations and procedures . . .;” and E.O. 11990 section 6 states in pertinent part “. . . agencies shall issue or amend their existing procedures . . .” Therefore, this subpart will be repealed because it is now captured in NASA Interim Directive (NID) 8500.100, Floodplain and Wetlands Management. NID 8500.100 is accessible at http://nodi3.gsfc.nasa.gov/OPD_docs/NID_8500_100.pdf.

Statutory Authority
The National Aeronautics and Space Act (the Space Act), 51 U.S.C. 20113 (a), authorizes the Administrator of NASA to make, promulgate, issue, rescind, and amend rules and regulations governing the manner of its operations and the exercise of the powers vested in it by law.

Regulatory Analysis
Executive Order 12866, Regulatory Planning and Review and Executive Order 13563, Improvement Regulation and Regulation Review

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits of reducing costs, harmonizing rules, and promoting flexibility. This rule has been designated as “not significant” under section 3(f) of E.O. 12866.

Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 et seq.) requires an agency to prepare an initial regulatory flexibility analysis to be published at the time the proposed rule is published. This requirement does not apply if the agency “certifies that the rule will not, if promulgated, have a significant economic impact on a substantial number of small entities” (5 U.S.C. 603). This rule removes two subparts from Title 14 of the CFR that are already reflected in existing NASA internal requirements and, therefore, does not have a significant economic impact on a substantial number of small entities.

Review Under the Paperwork Reduction Act

This direct final rule does not contain any information collection requirements subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.).

Review Under E.O. 13132

E.O. 13132, “Federalism,” 64 FR 43255 (August 4, 1999) requires regulations be reviewed for Federalism effects on the institutional interest of states and local governments, and if the effects are sufficiently substantial, preparation of the Federal assessment is required to assist senior policy makers. The amendments will not have any substantial direct effects on state and local governments within the meaning of the E.O. Therefore, no Federalism assessment is required.

List of Subjects in 14 CFR Part 1216

Flood plains.

PART 1216—ENVIRONMENTAL POLICY

Accordingly, under the authority of the National Aeronautics and Space Act, as amended (51 U.S.C. 20113), NASA amends 14 CFR part 1216 by removing and reserving subpart 1216.2, consisting of §§ 1216.200 through 1216.205.

Cheryl E. Parker,
NASA Federal Register Liaison Officer.
[FR Doc. 2015–12914 Filed 5–27–15; 8:45 am]
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2015–N–1297]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Vibrator for Climax Control of Premature Ejaculation

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the vibrator for climax control of premature ejaculation into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the classification of the vibrator for climax control of premature ejaculation. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective May 28, 2015. The classification was applicable on March 20, 2015.

FOR FURTHER INFORMATION CONTACT: Tuan Nguyen, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G118, Silver Spring, MD 20993–0002, 301–796–5174, tuan.nguyen@fda.hhs.gov.

SUPPLEMENTAL INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order.