(c) Applicability

This AD applies to Safran Helicopter Engines, S.A. Arriel 2B, 2B1, 2C, 2C1, 2C2, 2D, 2E, 2S1, and 2S2 turboshaft engines with an engine accessory gearbox (AGB), part number 0292120650, with a machined front casing.

(d) Unsafe Condition

This AD was prompted by a report of an uncommanded in-flight shutdown (IFSD) of an Arriel 2S2 engine caused by rupture of the 41-tooth gear, which forms part of the bevel gear in the engine AGB. We are issuing this AD to prevent failure of the engine AGB, uncommanded IFSD, damage to the engine, and damage to the helicopter.

(e) Compliance

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

(1) Initial Wear Inspection

(i) For all affected engines, perform a wear inspection of the engine AGB cover before the engine AGB, module M01, exceeds 850 engine hours (EH) since new or since last overhaul (SLO), or within 50 EHs after April 14, 2016, or before the next flight after the effective date of this AD, whichever occurs latest.

(ii) Reserved.

(2) Repetitive Wear Inspection Intervals

(i) For Arriel 2E engines, repeat the engine AGB cover wear inspection within every 800 EH since last inspection (SLI).

(ii) For all affected engines, except for Arriel 2E engines, repeat the engine AGB cover wear inspection within every 600 EH SLI.

(3) Inspection Criteria

(i) Use paragraph 2.4.2 of Safran Helicopter Engines, S.A. Mandatory Service Bulletin (MSB) No. 292 72 2861, Version D, dated September 23, 2016, to do the inspections required by paragraphs (e)(1) and (e)(2) of this AD.

(ii) Reserved.

(4) Corrective Actions Based on the Results of the Most Recent Wear Inspection

(i) If the wear measured from the most recent wear inspection is 0.15 mm or less, no further action is required. However, you must still comply with the repetitive inspection requirements of paragraph (e)(2) of this AD.

(ii) If the most recent wear inspection was performed while the engine was in service, and the wear is greater than 0.15 mm, do the following:

(A) If the wear measured from the most recent wear inspection is greater than 0.15 mm, but 0.30 mm or less, remove the engine AGB from service within 200 EH SLI and replace with a part eligible for installation.

(B) If the wear measured from the most recent wear inspection is greater than 0.30 mm, but 0.40 mm or less, remove the engine AGB from service within 25 EH SLI and replace with a part eligible for installation.

(C) If the wear measured from the most recent wear inspection is greater than 0.40 mm, remove the engine AGB from service before further flight and replace with a part eligible for installation.

(iii) If the most recent wear inspection was performed on the engine during an engine shop visit, and the wear is greater than 0.15 mm, remove the engine AGB before further flight and replace with a part eligible for installation.

(f) Credit for Previous Action

If you have previously performed a wear inspection of the engine AGB cover prior to the effective date of this AD in accordance with the instructions given in Turbomeca MSB No. 292 72 2861, Version C, dated March 9, 2016, or Turbomeca MSB No. 292 72 2861, Version B, dated February 2, 2016, then you may take credit for that wear inspection as the ''most recent'' wear inspection for the purposes of paragraph (e)(4) of this AD.

(g) Definition

For the purpose of this AD, an engine shop visit is defined as the induction of an engine into the shop for maintenance involving the separation of any major mating engine flanges, except that the separation of engine flanges solely for the purposes of transportation without subsequent engine maintenance does not constitute an engine shop visit.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(i) Related Information

(1) For more information about this AD, contact Philip Haberlen, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA 01803; phone: 781–238–7770; fax: 781–238–7199; email: *philip.haberlen@faa.gov.*

(2) Refer to MCAI European Aviation Safety Agency AD 2016–0055R1, dated October 11, 2016, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov/document?D=FAA-2015-3753-0006.*

(j) 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) Safran Helicopter Engines, S.A. Mandatory Service Bulletin No. 292 72 2861, Version D, dated September 23, 2016.

(ii) Reserved.

(3) For Safran Helicopter Engines, S.A. service information identified in this AD, contact Safran Helicopter Engines, S.A. 40220 Tarnos, France; phone: 33 0 5 59 74 40 00; fax: 33 0 5 59 74 45 15.

(4) You may view this service information at FAA, Engine & Propeller Directorate, 1200 District Avenue, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(5) You may view this service information 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 Burlington, Massachusetts, on November 29, 2016.

Colleen M. D'Alessandro,

Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2016–31695 Filed 12–29–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 11 and 101

[Docket No. FDA–2011–F–0172]

RIN 0910–AG57

Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the compliance date for the final rule requiring disclosure of certain nutrition information for standard menu items in certain restaurants and retail food establishments. The final rule appeared in the **Federal Register** of December 1, 2014, and on May 5, 2016, we stated in the **Federal Register** that the enforcement of the final rule would begin on May 5, 2017. We are taking this action to clarify and confirm that the compliance date for the final rule is May 5, 2017.

DATES: *Effective date:* This final rule is effective December 30, 2016. *Compliance date:* Covered establishments must comply with the rule published December 1, 2014 (79 FR 71156) by May 5, 2017.

FOR FURTHER INFORMATION CONTACT: Ashley Rulffes, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371, email: *ashley.rulffes@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 1, 2014 (79 FR 71156), we published a final rule requiring disclosure of certain nutrition information for standard menu

items in certain restaurants and retail food establishments. The final rule, which is now codified at § 101.11 (21 CFR 101.11), implements provisions of section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(H)) and:

- Defines terms, including terms that describe criteria for determining whether an establishment is subject to the rule;
- establishes which foods are subject to the nutrition labeling requirements and which foods are not subject to these requirements;
- requires that calories for standard menu items be declared on menus and menu boards that list such foods for sale;
- requires that calories for standard menu items that are self-service or on display be declared on signs adjacent to such foods;
- requires that written nutrition information for standard menu items be available to consumers who ask to see it;
- requires, on menus and menu boards, a succinct statement concerning suggested daily caloric intake (succinct statement), designed to help the public understand the significance of the calorie declarations;
- requires, on menus and menu boards, a statement regarding the availability of the written nutrition information (statement of availability);
- establishes requirements for determination of nutrient content of standard menu items;
- establishes requirements for substantiation of nutrient content determined for standard menu items, including requirements for records that a covered establishment must make available to FDA within a reasonable period of time upon request; and
- establishes terms and conditions under which restaurants and similar retail food establishments not otherwise subject to the rule could elect to be subject to the requirements by registering with FDA.

In the preamble to the final rule (79 FR 71156 at 71239 through 71241), we stated that the rule would be effective on December 1, 2015, and also provided a compliance date of December 1, 2015, for covered establishments. The final rule (at § 101.11(a)) defines ''covered establishment'' as a restaurant or similar retail food establishment that is a part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership, *e.g.,* individual franchises) and offering for sale substantially the same menu items, as well as a restaurant or similar retail food establishment that is voluntarily registered to be covered under § 101.11(d).

II. Extending the Compliance Date

In the **Federal Register** of July 10, 2015 (80 FR 39675), in response to requests from affected entities, we announced our decision to extend the compliance date for the final rule to December 1, 2016. The final rule requirements are intended to ensure that consumers are provided accurate, clear, and consistent nutrition information for foods sold in covered establishments in a direct and accessible manner to enable consumers to make informed and healthful dietary choices. We stated in that extension that allowing adequate time for covered establishments to fully implement the final rule's requirements, as described in the requests, would help accomplish the primary objective of the final rule and is in the public interest.

On December 18, 2015, the President signed the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 747 of the Consolidated Appropriations Act states that none of the funds made available under the Consolidated Appropriations Act may be used to implement, administer, or enforce the final rule entitled ''Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments'' until 1 year after the date we publish a Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments.

In the **Federal Register** of May 5, 2016 (81 FR 27067), we announced the availability of the Level 1 guidance document and stated that enforcement of the final rule published December 1, 2014, would commence on May 5, 2017 (81 FR 27067 at 27068). While FDA made clear that we would not begin enforcing menu labeling requirements prior to May 5, 2017, we did not at that time formally make a change to the compliance date through rulemaking.

Therefore, through this final rule, we are clarifying and confirming that the compliance date for the final rule entitled ''Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments,'' codified at § 101.11, is May 5, 2017.

III. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this rule provides more flexibility by further extending the compliance date for the ''Food Labeling: Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments'' final rule (79 FR 71156) (menu labeling final rule), we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule would not result in an expenditure in any year that meets or exceeds this amount.

This rule extends the compliance date of the menu labeling final rule by approximately 5 months: From December 1, 2016, to May 5, 2017. The estimated costs and benefits accrued in any given year that the menu labeling rule is in effect, relative to the first year of compliance, does not change; however, because the compliance date is being extended by 5 months, the discounted value of both total costs and total benefits decreases. The principal benefit of this final rule will be the reduction in costs associated with extending the compliance date by 5 months. The principal cost of this final rule will be the reduction in benefits associated with extending the compliance date by 5 months. Extending the compliance date of the menu labeling final rule by 5 months reduces the annualized net benefits (discounted at 3 percent) approximately 3 percent, from $457 million to $442

million. While average annualized net benefits decrease by $15 million, they are still positive. We note that this extension of the compliance date will not have an actual effect on the cost or benefits of the menu labeling rule, because, under section 747 of the Consolidated Appropriations Act, 2016, FDA was not authorized to spend funds to ''implement, administer, or enforce'' the rule until May 5, 2017, a year after the date on which published a Level 1 guidance with respect to nutrition labeling of standard menu items in restaurants and similar retail food establishments. We are presenting the benefits and costs of the menu labeling final rule, which takes effect according to the dates in this rule.

The full analysis of economic impacts is available in the docket for this final rule (Ref. 1) and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

IV. Paperwork Reduction Act

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Analysis of Environmental Impact

We have determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VI. Reference

The following reference is on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at *https://www.regulations.gov.* FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

1. FDA, ''Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Extension of Compliance Date,'' 2015. Available at: *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/.*

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31597 Filed 12–29–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 888

[Docket No. FDA–2014–N–1205]

Orthopedic Devices; Reclassification of Pedicle Screw Systems, Henceforth To Be Known as Thoracolumbosacral Pedicle Screw Systems, Including Semi-Rigid Systems

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final order to reclassify pedicle screw systems, a preamendments class III device (regulated under product code NKB), into class II (special controls), renaming the device ''thoracolumbosacral pedicle screw systems''; reclassify dynamic stabilization systems, a subtype of pedicle screw systems regulated under product code NQP when used as an adjunct to fusion, into class II (special controls), renaming this device subtype ''semi-rigid systems''; and clarify the device identification of pedicle screw systems to more clearly delineate between rigid pedicle screw systems and semi-rigid systems. FDA is finalizing this action based on a reevaluation of information pertaining to the device type.

DATES: This order is effective on December 30, 2016. See further discussion in section V, ''Implementation Strategy.''

FOR FURTHER INFORMATION CONTACT: Constance P. Soves, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1437, Silver Spring, MD 20993, 301–796–6951, *Constance.Soves@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 (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 part 807 (21 Code of Federal Regulations (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 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.