(a) Effective Date

This AD is effective December 26, 2014.

(b) Affected ADs

This AD supersedes AD 2013–15–09, Amendment 39–17525 (78 FR 49111, August 13, 2013).

(c) Applicability

This AD applies to all Pratt & Whitney Division (PW) PW4074, PW4074D, PW4077, PW4077D, PW4084D, PW4090, and PW4090–3 turbofan engine models with second-stage high-pressure turbine (HPT) air seal, part number (P/N) 54L041, 50L960, or 50L976, installed.

(d) Unsafe Condition

This AD was prompted by additional reports of cracking in the second-stage HPT air seal. We are issuing this AD to prevent failure of the second-stage HPT air seal, which could lead to uncontained engine failure and damage to the airplane.

(e) Compliance

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

(1) At the next piece-part exposure after the effective date of this AD, do the following:

(i) Remove from service second-stage HPT air seals, P/Ns 50L960, 50L976, and 54L041.

(ii) Perform a fluorescent-penetrant inspection (FPI) of the second-stage HPT air seal, P/N 54L041, for a through-crack in the front forward fillet radius.

(iii) If a through-crack in the front forward fillet radius is found, remove the first-stage HPT hub, second-stage HPT hub, and second-stage HPT blade retaining plate from service. Do not reinstall the first-stage HPT hub, second-stage HPT hub, or second-stage HPT blade retaining plate into any engine.

(2) For engines with second-stage HPT air seals, P/N 54L041, installed, perform initial and repetitive inspections for cracks on-wing until the part is removed from the engine as follows:

(i) Perform an initial eddy current inspection (ECI) for cracks before reaching 2,200 cycles since new, within 1,000 cycles-in-service after September 17, 2013, or before further flight, whichever occurs later.

(ii) Thereafter, repeat the ECI every 1,200 cycles since last inspection, or fewer, depending on the results of the inspection.

(iii) Use section 4.0 of the appendix of PW Alert Service Bulletin (ASB) No. PW4G–112–A72–330, Revision 2, dated July 11, 2013, to perform the inspection and use paragraph 8 of the Accomplishment Instructions of PW ASB No. PW4G–112–A72–330, Revision 2, dated July 11, 2013, to disposition the results of the inspection.

(f) Installation Prohibition

(1) After the effective date of this AD, do not install any second-stage HPT air seal, P/N 54L041, P/N 50L960, or P/N 50L976, into any engine.

(2) After the effective date of this AD, do not install any spare first-stage HPT hub, second-stage HPT hub, or second-stage HPT blade retaining plate that was previously mated in service to a second-stage HPT air seal, P/N 54L041, that was found to have a through-crack in the front forward fillet radius, into any engine.

(g) Definitions

For the purpose of this AD:

(1) Piece-part exposure is when the second-stage HPT air seal is removed from the engine and fully disassembled.

(2) A through-crack is a crack that has propagated through the thickness of the part and can be seen on both the inner diameter and outer diameter of the front forward fillet radius.

(h) Credit for Previous Actions

(1) If you performed an ECI of the second-stage HPT air seal before the effective date of this AD, using PW ASB No. PW4G–112–A72–330, Revision 1, dated February 14, 2013, or an earlier version, you have met the requirements of paragraph (e)(2)(i) of this AD.

(2) If you performed an in-shop FPI of the second-stage HPT air seal before the effective date of this AD, you have met the requirements of paragraph (e)(2)(i) of this AD.

(i) 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.*

(j) Related Information

(1) For more information about this AD, contact Jo-Ann Theriault, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7105; fax: 781–238–7199; email: *jo-ann.theriault@faa.gov.*

(2) PW Service Bulletin (SB) No. PW4G–112–72–332, Revision 3, dated June 25, 2014, which is not incorporated by reference in this AD, can be obtained from PW, using the contact information in paragraph (k)(3) of this AD. This SB provides guidance on how to replace the second-stage HPT air seal with an air seal that is more resistant to low cycle fatigue cracks.

(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 the AD specifies otherwise.

(3) The following service information was approved for IBR on September 17, 2013 (78 FR 49111, August 13, 2013).

(i) Pratt & Whitney (PW) Alert Service Bulletin No. PW4G–112–A72–330, Revision 2, dated July 11, 2013.

(ii) Reserved.

(4) For PW service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: 860–565–8770; fax: 860–565–4503.

(5) You may view this service information at FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call 781–238–7125.

(6) 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 December 22, 2014.

Colleen M. D'Alessandro,

Assistant Directorate Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2014–30283 Filed 12–23–14; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. FDA–2009–F–0303]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Advantame

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; response to objections.

SUMMARY: The Food and Drug Administration (FDA or we) is responding to objections we received on the final rule that amended the food additive regulations to provide for the safe use of advantame as a non-nutritive sweetener and flavor enhancer in foods generally, except in meat and poultry. After reviewing the objections to the final rule, we have concluded that they do not provide a basis for modifying or revoking the regulation. We are also confirming the effective date of May 21, 2014, for the final rule.

DATES: The effective date of the final rule published on May 21, 2014 (79 FR 29078), is confirmed: May 21, 2014.

FOR FURTHER INFORMATION CONTACT: Felicia M. Ellison, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–1264.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 21, 2009 (74 FR 35871), we announced that a food additive petition (FAP 9A4778), had been filed by Ajinomoto Co., Inc., c/o Ajinomoto Corporate Services LLC, 1120 Connecticut Ave. NW., suite 1010, Washington, DC 20036. The petition

proposed to amend the food additive regulations in part 172, *Food Additives Permitted for Direct Addition to Food for Human Consumption* (21 CFR part 172), to provide for the safe use of advantame as a non-nutritive sweetener in tabletop applications and powdered beverage mixes. Subsequently, in a letter dated August 24, 2012, the petitioner informed us that FAP 9A4778 had been transferred from Ajinomoto Corporate Services LLC to Ajinomoto North America, Inc., One Parker Plaza, 400 Kelby St., Fort Lee, NJ 07024.

In an amended document published in the **Federal Register** of October 26, 2012 (77 FR 65340), we announced that Ajinomoto Co., Inc., c/o Ajinomoto North America, Inc., One Parker Plaza, 400 Kelby St., Fort Lee, NJ 07024, had amended its food additive petition to provide for the safe use of advantame as a non-nutritive sweetener and flavor enhancer in foods generally, except in meat and poultry.

In response to FAP 9A4778, we issued a final rule in the **Federal Register** on May 21, 2014 (79 FR 29078), permitting the safe use of advantame as a non-nutritive sweetener and flavor in foods generally, except in meat and poultry. This regulation is codified at § 172.803. We based our decision on data contained in the petition and in our files. In the preamble to the final rule (79 FR 29078 at 29079–29084), we outlined the basis for our decision and stated that objections to the final rule and requests for a hearing were due within 30 days of the publication date (*i.e.,* by June 20, 2014).

II. Objections and Requests for a Hearing

Section 409(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 348(f)(1)) provides that, within 30 days after publication of an order relating to a food additive regulation, any person adversely affected by such order may file objections, ''specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections.''

Under 21 CFR 171.110, objections and requests for a hearing are governed by part 12 (21 CFR part 12) of FDA's regulations. Under § 12.22(a), each objection must meet the following conditions: (1) Must be submitted on or before the 30th day after the date of publication of the final rule; (2) must be separately numbered; (3) must specify with particularity the provision of the regulation or proposed order objected to; (4) must specifically state each objection on which a hearing is requested; failure to request a hearing on an objection constitutes a waiver of the right to a hearing on that objection; and (5) must include a detailed description and analysis of the factual information to be presented in support of the objection if a hearing is requested; failure to include a description and analysis for an objection constitutes a waiver of the right to a hearing on that objection.

Following publication of the final rule permitting the use of advantame as a non-nutritive sweetener and flavor enhancer in foods generally, except meat and poultry, we received 12 submissions with objections to the rule within the 30-day objection period. The majority of these submissions were letters expressing concern regarding one or more of the following issues: (1) Labeling of products containing advantame, and (2) advantame being mistaken for aspartame. A few of the letters also expressed general opposition to the final rule, or objected to the rule based on adverse effects believed to have been caused by aspartame, and not advantame. None of these letters requested a hearing, nor provided evidence in support of any of these objections that could be considered factual information (§ 12.22(a)(5)). Therefore, these objections do not justify the modification or revocation of the regulation. We will not discuss these submissions further.

There was one submission that raised a specific objection. The letter was from the Natural Resources Defense Council (NRDC) (letter to Docket No. FDA–2009–F–0303, June 20, 2014). The letter from NRDC did not request a hearing on their objection. Therefore, NRDC has waived its right to a hearing on their objection (see § 12.22(a)(4)). The only remaining question under § 12.24(a) is whether NRDC's objection, and the information submitted in support of the objection, establish that the regulation authorizing the use of advantame should be modified or revoked. As discussed in detail in section III, we have concluded that NRDC has not established a basis for modification or revocation of the regulation authorizing the use of advantame.

III. Analysis of Objection

The objection raised by NRDC asserts that FDA did not comply with section 409 of the FD&C Act in our evaluation of the advantame petition because, they claim, we did not conduct a fair evaluation of the data before the Agency as required by section 409(c)(3) of the FD&C Act and did not consider the relevant safety factors as required by section 409(c)(5). Specifically, NRDC states that advantame and the sweetener aspartame are structurally related and that FDA has stated that ''advantame actually contains a small amount of aspartame.'' NRDC asserts that when we were considering potential effects of advantame, we considered the health effects of aspartame but did not consider the potential impacts of advantame on the hypothalamus despite having evidence that aspartame significantly altered that part of the brain. In support of their claim, NRDC cites five animal studies that they state are in FDA's possession and indicate aspartame affects the hypothalamus. NRDC requests that since the brain tissues from the key advantame animal studies were preserved, FDA should withdraw its approval of advantame until those tissues are examined for alteration of the hypothalamus and the implications on a child's developing brain are fully considered. In addition, NRDC claims that we did not comply with Executive Order 13045 regarding protection of children from environmental health risks and safety risks by not assessing the safety of advantame on a child's brain development.

The issue of whether aspartame poses a risk of hypothalamic adverse effects, including endocrine dysfunction, was thoroughly addressed in the Commissioner's final decision on aspartame published in the **Federal Register** on July 24, 1981 (46 FR 38285). In that decision, the Commissioner affirmed the safety of aspartame as a nutritive sweetener and concluded that there is a reasonable certainty that human consumption of aspartame at projected consumption levels will not pose a risk to the brain, including endocrine function. We are not aware of any new relevant evidence to the contrary. NRDC has not provided any evidence that the effects on the hypothalamus in the aspartame studies they cited are toxicologically significant at the expected levels of intake of aspartame and, further, they have not provided evidence of the relevancy of this information to the safety of advantame.

We disagree with NRDC's characterization of the relationship between advantame and aspartame. While advantame is structurally related to aspartame, and aspartame is used as one of the starting chemicals in the manufacture of advantame, which is what FDA was referring to in the language quoted by NRDC, the two sweeteners are chemically different and are metabolized differently in the human body. When aspartame is consumed, it is metabolized into its two

constituent amino acids, phenylalanine and aspartic acid, and a small amount of methanol. By contrast, the primary metabolite of advantame is the de-esterified form of advantame, namely N-[N-[3-(3-hydroxy-4-methoxyphenyl)propyl]-α-aspartyl]-L-phenylalanine. Because chemically these two sweeteners are different compounds, FDA's safety decision on advantame was based solely on studies conducted on advantame. Therefore, we did not consider the health effects of aspartame in our safety decision on advantame.

Regarding concerns about possible effects of advantame on the hypothalamus, the hypothalamus is involved with endocrine control via the pituitary gland. Therefore, any long-lasting hypothalamic changes would affect the pituitary gland. For this reason, we recommend in our guidance ''Toxicological Principles for the Safety Assessment of Direct Food Additives and Color Additives Used in Food'' that the pituitary gland from subchronic and long-term animal studies be assessed for treatment-related changes. Consistent with our guidance, the pituitary gland was one of the organs evaluated in the animal studies on advantame that were considered in the final rule, and there was no evidence of toxicologically significant changes.

As previously noted, NRDC has requested that we withdraw our approval of advantame until we examine the brain tissues from the key advantame animal studies that were preserved for alteration of the hypothalamus and fully consider the implications on a child's developing brain. NRDC has claimed that several studies on a different substance showed effects on the hypothalamus, but has not provided any information to support its view that additional histopathological examination of brain tissue samples is necessary to establish the safety of advantame. During our evaluation of the advantame petition, we thoroughly reviewed all of the data provided by the petitioner on the safety of advantame, including the results from a two-generation study in rats, a chronic (52-week) dog study, a 104-week mouse carcinogenicity study, and a combined 104-week rat carcinogenicity feeding study with in utero and chronic (52-week) phases, which included extensive histological evaluations of the brain, including the hypothalamus. In evaluating these studies, we applied the appropriate safety factors to extrapolate the findings from these animal studies to humans as required by section 409(c)(5) of the FD&C Act. We also considered the potential intake of advantame at both the mean and 90th percentile of consumption for various age groups, including children. Based on this exposure and toxicological information, the estimated levels of daily intake for even high consumers of advantame were far below (approximately 200 times) the acceptable daily intake level, establishing that advantame is safe for the general population, including children.

NRDC's objection to the advantame final rule does not provide any new evidence or identify any evidence that we overlooked in our evaluation that would call into question FDA's determination of safety for advantame. Moreover, NRDC has not provided a basis for concluding that the information we evaluated is inadequate to support a finding that the use of advantame as a non-nutritive sweetener in food is safe. Therefore, this objection does not provide a basis for us to reconsider our decision to issue the final rule on advantame.

IV. Summary and Conclusion

Section 409 of the FD&C Act requires that a food additive be shown to be safe before marketing. Under 21 CFR 170.3(i), a food additive is ''safe'' if ''there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use.'' In our May 21, 2014, final rule approving the use of advantame, we concluded that the data presented by the petitioner to establish safety of the additive demonstrate that advantame is safe for its intended use in food.

The petitioner has the burden to demonstrate the safety of the additive to gain FDA approval. However, once we make a finding of safety, the burden shifts to an objector, who must come forward with evidence that calls into question our conclusion (see section 409(f)(1) of the FD&C Act). After evaluating the objection from NRDC, we have concluded that the objection does not provide any basis for us to reconsider our decision to issue the final rule permitting the use of advantame as a non-nutritive sweetener and flavor enhancer in foods generally, except meat and poultry. Accordingly, we are not making any changes in response to the objection.

Therefore, we have determined that the final rule should not be modified or revoked based on the objections. Thus, we are confirming May 21, 2014, as the effective date of the regulation.

Dated: December 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30144 Filed 12–23–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 860

[Docket No. FDA–2013–N–1529]

Medical Device Classification Procedures; Reclassification Petition: Content and Form; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations for petitioning for device reclassification to update mailing addresses for the petitions. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective December 24, 2014.

FOR FURTHER INFORMATION CONTACT: Nancy Pirt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4438, Silver Spring, MD 20993–0002, 301–796–6254.

SUPPLEMENTARY INFORMATION: FDA is updating mailing addresses for device reclassification petitions (21 CFR 860.123). For devices regulated by the Center for Devices and Radiological Health, the room number is now 4438. In addition, the Center for Biologics Evaluation and Research has moved to a new location at FDA's White Oak Campus. The address remains the same for the Center for Drug Evaluation and Research. The regulations are being amended to ensure clarity and to improve the accuracy and readability of the regulations.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment and a delayed effective date are unnecessary because these corrections are nonsubstantive.

List of Subjects in 21 CFR Part 860

Administrative practice and procedure, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under