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]

BILLING CODE 4164–01–P

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

authority delegated to the Commissioner of Food and Drugs, 21 CFR part 860 is amended as follows:

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

■ 1. The authority citation for 21 CFR part 860 continues to read as follows:

Authority: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

■ 2. Revise § 860.123(b)(1) to read as follows:

§ 860.123 Reclassification petition: Content and form.

* * * * *

(b) * * *

(1) For devices regulated by the Center for Devices and Radiological Health, addressed to the Food and Drug Administration, Center for Devices and Radiological Health, Regulations Staff, 10903 New Hampshire Ave., Bldg. 66, Rm. 4438, Silver Spring, MD 20993–0002; for devices regulated by the Center for Biologics Evaluation and Research, addressed to the Food and Drug Administration, Center for Biologics Evaluation and Research, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G112, Silver Spring, MD 20993–0002; for devices regulated by the Center for Drug Evaluation and Research, addressed to the Food and Drug Administration, Center for Drug Evaluation and Research, Central Document Control Room, 5901–B Ammendale Rd., Beltsville, MD 20705–1266, as applicable.

* * * * *

Dated: December 18, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–30141 Filed 12–23–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9707]

RIN 1545–BM08

Filing of Form 5472

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations concerning the manner of filing Form 5472, ''Information Return of a 25% Foreign-Owned U.S. Corporation or a Foreign Corporation Engaged in a U.S. Trade or Business.'' The final regulations affect certain 25-percent foreign-owned domestic corporations and certain foreign corporations that are engaged in a trade or business in the United States that are required to file Form 5472.

DATES: *Effective date:* These regulations are effective on December 24, 2014. *Applicability date:* For dates of applicability, see §§ 1.6038A–1(n)(2) and (n)(3) and 1.6038A–2(g).

FOR FURTHER INFORMATION CONTACT: Anand Desai at (202) 317–6939 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On June 6, 2014, the Department of the Treasury (Treasury Department) and the IRS published a notice of proposed rulemaking (REG–114942–14) in the **Federal Register** (79 FR 32687, 2014–26 IRB 1117) under sections 6038A and 6038C of the Internal Revenue Code (Code) (proposed regulations). The proposed regulations proposed removing a provision for timely filing Form 5472 separately from an income tax return that is untimely filed (''untimely filed return provision''). As a result, Form 5472 would be required to be filed in all cases only with the filer's income tax return for the taxable year by the due date (including extensions) of that return. No public hearing was requested or held. The Treasury Department and the IRS received two written comments on the proposed regulations, which are available at *www.regulations.gov*. After consideration of the comments, this Treasury decision adopts the proposed regulations, without substantive change, as final regulations.

Summary of Comments

One comment recommended that the ''untimely filed return provision'' be retained because the IRS may not timely receive the information required by Form 5472 if the untimely filed return provision is removed. The comment also recommended conforming changes to permit the filing of Form 5471, ''Information Return of U.S. Persons With Respect to Certain Foreign Corporations,'' and Form 8865, ''Return of U.S. Persons With Respect to Certain Foreign Partnerships,'' separately from an income tax return that is untimely filed.

The Treasury Department and the IRS decline to adopt this comment. The Treasury Department and the IRS have determined that tax administration generally is more efficient when forms (for example, Form 5471, Form 5472, and Form 8865) are filed with the filer's timely filed income tax return.

The second comment addressed issues unrelated to the proposed regulatory change. The final regulations do not incorporate the suggestions contained in this comment, which are outside the scope of the proposed regulations.

Special Analyses

It has been determined that these regulations are not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because the regulations do not impose a collection of information, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Anand Desai, Office of Associate Chief Counsel (International). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805 * * *

■ **Par. 2.** Section 1.6038A–1 is amended by revising the third sentence of, and adding a new fourth sentence to, paragraph (n)(2), and adding a third sentence to paragraph (n)(3), to read as follows:

§ 1.6038A–1 General requirements and definitions.

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(n) * * *