

**INFORMATION** section for electronic access to the SECG.

**FOR FURTHER INFORMATION CONTACT:**

Vincent de Jesus, Center for Food Safety and Applied Nutrition (HFS-830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1774.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the **Federal Register** of April 28, 2014 (79 FR 23262), (see also Docket Nos. FDA-2007-0601, FDA-2004-N-0382, FDA-2005-P-0371, and FDA-2006-P-0224 (formerly Docket Nos. 2004N-0217, 2005P-0189, and 2006P-0137)), we issued a final rule prohibiting certain nutrient content claims for foods, including conventional foods and dietary supplements, that contain omega-3 fatty acids based on our determination that such nutrient content claims do not meet the requirements of the Federal Food, Drug, and Cosmetics Act. The final rule became effective January 1, 2016.

We examined the economic implications of the final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601-612) and determined that the final rule may have a significant economic impact on a substantial number of small entities. In compliance with section 212 of the Small Business Regulatory Enforcement Fairness Act (Pub. L. 104-121, as amended by Pub. L. 110-28), we are making available the SECG to explain the actions that a small entity must take to comply with the rule.

We are issuing the SECG consistent with our good guidance practices regulation (21 CFR 10.115(c)(2)). The SECG represents the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

**II. Electronic Access**

Persons with access to the Internet may obtain the SECG at either <http://www.fda.gov/FoodGuidances> or <http://www.regulations.gov>. Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: February 18, 2016.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF STATE**

**22 CFR Part 171**

**[Public Notice: 9448]**

**RIN 1400-AD78**

**Privacy Act; STATE-75, Family Advocacy Case Records**

**AGENCY:** Department of State.

**ACTION:** Final rule.

**SUMMARY:** The Department of State (the Department) finalizes its rule exempting portions of the Family Advocacy Case Records, State-75, from one or more provisions of the Privacy Act of 1974.

**DATES:** This rule is effective on February 23, 2016.

**FOR FURTHER INFORMATION CONTACT:** John Hackett, Director; Office of Information Programs and Services, A/GIS/IPS; Department of State, SA-2; 515 22nd Street NW., Washington, DC 20522-8001, or at [Privacy@state.gov](mailto:Privacy@state.gov).

**SUPPLEMENTARY INFORMATION:** The Department maintains the Family Advocacy Case Records system of records. The primary purpose of this system of records is to be utilized at post by members of the Family Advocacy Team and in the Department of State by the Family Advocacy Committee. The information may be shared within the Department on a need to know basis and in medical clearance determinations for overseas assignment of covered employees and family members, as well as for making determinations involving curtailment, medical evacuation, suitability, and security clearance.

The Department published a notice of proposed rulemaking (NPRM) on September 9, 2015, (80 FR 54256) proposing to amend 22 CFR part 171 to exempt portions of this system of records from the following subsections of the Privacy Act pursuant to subsections (k)(1) and (k)(2):

- 5 U.S.C. 552a(c)(3) (requiring that an accounting of certain disclosures be made available to an individual upon request);
- 5 U.S.C. 552a(d) (establishing requirements related to an individual's right to access and request amendment to certain records);
- 5 U.S.C. 552a(e)(1) (providing that an agency that maintains a system of records shall "maintain in its records only such information about an individual as is relevant and necessary to accomplish a purpose of the agency required to be accomplished by statute or by executive order of the President");
- 5 U.S.C. 552a(e)(4)(G) (requiring that an agency that maintains a system

of records publish in the **Federal Register** "the agency procedures whereby an individual can be notified at his request if the system of records contains a record pertaining to him");

- 5 U.S.C. 552a(e)(4)(H) (requiring that an agency that maintains a system of records publish in the **Federal Register** "the agency procedures whereby an individual can be notified at his request how he can gain access to any record pertaining to him contained in the system of records, and how he can contest its content");

- 5 U.S.C. 552a(e)(4)(I) (requiring that an agency that maintains a system of records publish in the **Federal Register** "the categories of sources of records in the system"); and

- 5 U.S.C. 552a(f) (requiring that an agency that maintains a system of records promulgate certain regulations).

STATE-75 is exempted under subsection (k)(1) to the extent that records within that system are subject to the provisions of 5 U.S.C. 552(b)(1), which covers materials that: (i) Are specifically authorized under criteria established by an Executive order to be kept secret in the interest of national defense and foreign policy, and (ii) are in fact properly classified pursuant to such Executive order. STATE-75 is exempted under subsection (k)(2) to the extent that records within that system are comprised of investigatory material compiled for law enforcement purposes, subject to the limitations set forth in subsection (k)(2). The subsection (k)(2) exemption is intended to prevent individuals who are the subject of investigation from frustrating the investigatory process, facilitate the proper functioning and integrity of law enforcement activities, prevent disclosure of investigative techniques, maintain the confidence of foreign governments in the integrity of the procedures under which privileged or confidential information may be provided, fulfill commitments made to sources to protect their identities and the confidentiality of information, and avoid endangering sources and law enforcement personnel.

For additional background, see the NPRM published on September 9, 2015, (80 FR 54256) and the system of records notice published on January 5, 2009 (74 FR 330). The Department received no public comments on these documents.

**List of Subjects in 22 CFR Part 171**

Privacy.

For the reasons stated in the preamble, 22 CFR part 171 is amended as follows:

**PART 171—[AMENDED]**

■ 1. The authority citation for part 171 continues to read as follows:

**Authority:** 5 U.S.C. 552, 552a; 22 U.S.C. 2651a; Pub. L. 95–521, 92 Stat. 1824, as amended; E.O. 13526, 75 FR 707; E.O. 12600, 52 FR 23781, 3 CFR, 1987 Comp., p. 235.

**§ 171.36 [Amended]**

■ 2. Section 171.36 is amended by adding an entry, in alphabetical order, for “Family Advocacy Case Records, State–75” to the lists in paragraphs (b)(1) and (2)

**Joyce A. Barr,**

*Assistant Secretary for Administration, U.S. Department of State.*

[FR Doc. 2016–03630 Filed 2–22–16; 8:45 am]

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**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 1**

[TD 9752]

RIN 1545–BM54

**Reporting of Specified Foreign Financial Assets**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations.

**SUMMARY:** This document contains final regulations providing guidance regarding the requirements for certain domestic entities to report specified foreign financial assets to the Internal Revenue Service. These regulations set forth the conditions under which a domestic entity will be considered a specified domestic entity required to undertake such reporting. These regulations affect certain domestic corporations, partnerships, and trusts.

**DATES:** *Effective date:* These regulations are effective on February 23, 2016.

*Applicability date:* For dates of applicability, see §§ 1.6038D–2(g) and 1.6038D–6(e).

**FOR FURTHER INFORMATION CONTACT:** Joseph S. Henderson, (202) 317–6942 (not a toll-free number).

**SUPPLEMENTARY INFORMATION:****Background**

Section 6038D was enacted by section 511 of the Hiring Incentives to Restore Employment (HIRE) Act, Public Law 111–147 (124 Stat. 71). Section 6038D(a) requires certain individuals to report information about specified foreign financial assets. Section 6038D(f)

provides that, to the extent provided by the Secretary in regulations or other guidance, section 6038D shall apply to any domestic entity which is formed or availed of for purposes of holding, directly or indirectly, specified foreign financial assets, in the same manner as if the entity were an individual.

On December 19, 2011, the Department of the Treasury (Treasury Department) and the Internal Revenue Service (IRS) published temporary regulations (the “2011 temporary regulations”) (TD 9567) and a notice of proposed rulemaking by cross-reference to temporary regulations (REG–130302–10) in the **Federal Register** (76 FR 78553 and 76 FR 78594, respectively) addressing the reporting requirements under section 6038D. The notice of proposed rulemaking also included proposed § 1.6038D–6, which set forth the conditions under which a domestic entity will be considered a specified domestic entity and, therefore, required to report specified foreign financial assets in which it holds an interest. Corrections to the 2011 temporary regulations were published on February 21, 2012, in the **Federal Register** (77 FR 9845). Corrections to proposed § 1.6038D–6 were published on February 21, 2012, and February 22, 2012, in the **Federal Register** (77 FR 9877 and 77 FR 10422, respectively). The 2011 temporary regulations were issued as final regulations (TD 9706; 79 FR 73817) on December 12, 2014 (the “2014 final regulations”). The Treasury Department and the IRS did not adopt proposed § 1.6038D–6 (REG–144339–14) as a final regulation at that time.

The Treasury Department and the IRS received written comments on proposed § 1.6038D–6. All comments are available at [www.regulations.gov](http://www.regulations.gov) or upon request. Because no requests to speak were received, no public hearing was held. After consideration of the comments received, the Treasury Department and the IRS adopt proposed § 1.6038D–6 as a final regulation with the modifications described herein.

**Summary of Comments and Explanation of Revisions***I. Organizational Changes Regarding the Reporting Threshold*

Proposed §§ 1.6038D–6(b)(1)(i) and 1.6038D–6(c)(1) provide that, in order to be treated as a specified domestic entity, an entity must have an interest in specified foreign financial assets (excluding assets excepted under § 1.6038D–7T) that exceeds the reporting threshold in § 1.6038D–2T(a)(1). Under the proposed regulations, a domestic entity applies

the reporting threshold in § 1.6038D–2T(a)(1) to determine whether it is a specified domestic entity. In making this determination, the proposed regulations require a corporation or partnership to take into account the aggregation rules in proposed § 1.6038D–6(b)(4)(i). Proposed §§ 1.6038D–6(b)(1)(i) and 1.6038D–6(c)(1), however, suggested that a specified domestic entity is required to again apply § 1.6038D–2T(a)(1) to determine whether it has a reporting requirement.

The Treasury Department and the IRS did not intend for domestic entities to apply the reporting threshold described in § 1.6038D–2(a)(1) twice in order to determine their section 6038D reporting responsibilities. Therefore, these final regulations eliminate the requirement to apply § 1.6038D–2(a)(1) as part of determining whether an entity is a specified domestic entity. Instead, a domestic entity that meets the definition of a specified domestic entity, which under these final regulations is determined without regard to whether the reporting threshold in § 1.6038D–2(a)(1) is met, applies the reporting threshold under § 1.6038D–2(a)(1) once, as part of determining whether it has a filing obligation. The aggregation rule for corporations and partnerships and the rule excluding assets excepted under § 1.6038D–7 from the reporting threshold have been moved to § 1.6038D–2(a)(6). These changes are organizational and no change is intended to the substantive reporting requirements for a specified domestic entity.

*II. Elimination of Principal Purpose Test*

Proposed § 1.6038D–6(b)(1)(iii) provides that a corporation or partnership is treated as formed or availed of for purposes of holding, directly or indirectly, specified foreign financial assets if either: (1) At least 50 percent of the corporation or partnership’s gross income or assets is passive; or (2) at least 10 percent of the corporation or partnership’s gross income or assets is passive and the corporation or partnership is formed or availed of by a specified individual with a principal purpose of avoiding section 6038D (the principal purpose test). Under proposed § 1.6038D–6(b)(1)(iii), all facts and circumstances are taken into account to determine whether a specified individual has a principal purpose of avoiding section 6038D.

The Treasury Department and the IRS believe that a 50-percent passive assets or income threshold appropriately captures situations in which specified individuals may use a domestic