

concerning who must register establishments and list human drugs, human drugs that are also biological products, and animal drugs. The final rule was published with an incorrect statement in the preamble about the rule's effect on establishments at which investigational drugs are manufactured. This document corrects that error.

DATES: Effective December 13, 2016.

FOR FURTHER INFORMATION CONTACT: David Joy, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6254, Silver Spring, MD 20993-0002, 301-796-2242.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 31, 2016 (81 FR 60169), FDA published the final rule "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs." The final rule published with an incorrect statement in the preamble about the rule's effect on establishments at which investigational drugs are manufactured. Under the amended regulations, manufacturers, repackers, relabelers, or salvagers who manufacture, repack, relabel, or salvage drugs solely for use in research, teaching, or chemical analysis and not for sale are exempt from the establishment registration requirement under 21 CFR 207.13(e) if they do not engage in other activities that require them to register.

In the **Federal Register** of August 31, 2016, in FR Doc. 2016-20471, the following correction is made: On page 60185, in the first column, in the third paragraph under "2. *When must initial registration information be provided?* (§ 207.21)," the following sentence is removed: "Accordingly, an establishment at which an investigational drug is manufactured is subject to the establishment registration requirement."

Dated: December 7, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-29774 Filed 12-12-16; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[TD 9796]

RIN 1545-BM94

Treatment of Certain Domestic Entities Disregarded as Separate From Their Owners as Corporations for Purposes of Section 6038A

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that treat a domestic disregarded entity wholly owned by a foreign person as a domestic corporation separate from its owner for the limited purposes of the reporting, record maintenance and associated compliance requirements that apply to 25 percent foreign-owned domestic corporations under section 6038A of the Internal Revenue Code.

DATES: *Effective date:* These regulations are effective December 13, 2016.

Applicability date: For dates of applicability, see §§ 1.6038A-1(n)(1) and (2) and 301.7701-2(e)(9).

FOR FURTHER INFORMATION CONTACT: Ronald M. Gootzeit, (202) 317-6937 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been previously reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)) under control number 1545-1191. The estimated average annual recordkeeping burden per recordkeeper is 10 hours. The estimated reporting burden is being reported under Form 5472 (OMB #1545-0123).

The collection of information in these final regulations is in §§ 1.6038A-2 and 1.6038A-3. This information will enhance the United States' compliance with international standards of transparency and exchange of information for tax purposes and will strengthen the enforcement of U.S. tax laws. The likely respondents are foreign-owned domestic entities that are disregarded as separate from their owners.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid control

number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Background and Explanation of Provisions

On May 10, 2016, the Department of the Treasury (Treasury Department) and the Internal Revenue Service (IRS) published in the **Federal Register** a notice of proposed rulemaking (REG-127199-15; 81 FR 28784) under sections 6038A and 7701 (the proposed regulations). The proposed regulations would treat a domestic disregarded entity wholly owned by a foreign person as a domestic corporation separate from its owner for the limited purposes of the reporting, record maintenance and associated compliance requirements that apply to 25 percent foreign-owned domestic corporations under section 6038A of the Internal Revenue Code. The proposed regulations would have applied to taxable years of the entities described in § 301.7701-2(c)(2)(vi) ending on or after the date that is 12 months after the date of publication of the Treasury decision adopting the proposed rules as final regulations in the **Federal Register**.

In addition to generally soliciting comments on all aspects of the proposed rules, the preamble to the proposed regulations specifically requested comments on possible alternative methods for reporting a domestic disregarded entity's transactions in cases in which the foreign owner of the domestic disregarded entity already has an obligation to report the income resulting from those transactions—for example, transactions resulting in income effectively connected with the conduct of a U.S. trade or business.

No written comments on the proposed regulations were received, and no public hearing was requested or held. However, these final regulations reflect a limited number of changes by the Treasury Department and the IRS to the proposed regulations.

First, it was and remains the intent of the Treasury Department and the IRS that the generally applicable exceptions to the requirements of section 6038A should not apply to a domestic disregarded entity that is wholly owned by a foreign person. Accordingly, the proposed regulations provided that the exceptions to the record maintenance requirements in § 1.6038A-1(h) and (i)

for small corporations and *de minimis* transactions would not apply to these entities. The proposed regulations did not address the additional exception provided in § 1.6038A-2(e)(3), under which a reporting corporation is not required to file Form 5472, Information Return of a 25% Foreign-Owned U.S. Corporation or a Foreign Corporation Engaged in a U.S. Trade or Business (Under Sections 6038A and 6038C of the Internal Revenue Code), with respect to a related foreign corporation when a U.S. person that controls the related foreign corporation files a Form 5471, Information Return of U.S. Persons With Respect to Certain Foreign Corporations, containing required information with respect to reportable transactions between the reporting corporation and the related foreign corporation for the taxable year. Similarly, the proposed regulations did not address the additional exception provided in § 1.6038A-2(e)(4), under which a reporting corporation is not required to file Form 5472 with respect to a related foreign corporation that qualifies as a foreign sales corporation for a taxable year for which the foreign sales corporation files Form 1120-FSC, U.S. Income Tax Return of a Foreign Sales Corporation. Upon final consideration of the proposed regulations, the Treasury Department and the IRS have concluded that, consistent with the scope and intent of the proposed regulations, the reporting requirements of the proposed regulations should apply without regard to the exceptions generally applicable under § 1.6038A-2(e)(3) and (4). The exceptions in § 1.6038A-2(e)(3) and (4) are revised accordingly in the final regulations.

Second, to facilitate entities' compliance with the requirements of section 6038A, including the obligation of reporting corporations to file Form 5472, the final regulations provide that these entities have the same taxable year as their foreign owner if the foreign owner has a U.S. return filing obligation. If the foreign owner has no U.S. return filing obligation, then for ease of tax administration, the final regulations provide that the taxable year of these entities is the calendar year unless otherwise provided in forms, instructions, or published guidance.

Third, the Treasury Department and the IRS have concluded that for ease of administration, these regulations should apply to taxable years of entities beginning on or after January 1, 2017, and ending on or after December 13, 2017. The proposed regulations would have applied to taxable years ending on or after the date that is 12 months after

the date of publication of the final regulations in the **Federal Register**, without regard to the date on which the taxable year began. This Treasury decision adopts the proposed regulations as so amended and with other minor clarifications for readability.

Special Analyses

Certain IRS regulations, including these, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory assessment is not required. Pursuant to the Regulatory Flexibility Act (5 U.S.C. chapter 6), it is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. Accordingly, a regulatory flexibility analysis is not required. This certification is based on the fact that these regulations will primarily affect a small number of foreign-owned domestic entities that do not themselves otherwise have a U.S. return filing requirement, and that the requirement to file a return for these entities will not impose a significant burden on them. Pursuant to section 7805(f), the proposed regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small entities.

Drafting Information

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

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 301

Employment taxes, Estate taxes, Excise taxes, Gift taxes, Income taxes, Penalties, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 301 are amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by revising the entries for §§ 1.6038A-1 and 1.6038A-2 to read in part as follows:

Authority: 26 U.S.C. 7805 * * *
Section 1.6038A-1 also issued under 26 U.S.C. 6001.
Section 1.6038A-2 also issued under 26 U.S.C. 6001.

* * * * *

■ **Par. 2.** Section 1.6038A-0 is amended by adding an entry for § 1.6038A-2(b)(9) to read as follows:

§ 1.6038A-0 Table of contents.

* * * * *

§ 1.6038A-2 Requirement of return.

* * * * *

(b) * * *

(9) Examples.

* * * * *

■ **Par. 3.** Section 1.6038A-1 is amended as follows:

- 1. Add a sentence at the end of paragraph (c)(1).
- 2. Revise the first sentence of paragraph (h).
- 3. Revise the first sentence of paragraph (i)(1).
- 4. Add a sentence at the end of paragraph (n)(1).
- 5. Add a sentence at the end of paragraph (n)(2).

The additions and revisions read as follows:

§ 1.6038A-1 General requirements and definitions.

* * * * *

(c) * * *

(1) * * * A domestic business entity that is wholly owned by one foreign person and that is otherwise classified under § 301.7701-3(b)(1)(ii) of this chapter as disregarded as an entity separate from its owner is treated as an entity separate from its owner and classified as a domestic corporation for purposes of section 6038A. See § 301.7701-2(c)(2)(vi) of this chapter.

* * * * *

(h) * * * A reporting corporation (other than an entity that is a reporting corporation as a result of being treated as a corporation under § 301.7701-2(c)(2)(vi) of this chapter) that has less than \$10,000,000 in U.S. gross receipts for a taxable year is not subject to §§ 1.6038A-3 and 1.6038A-5 for that taxable year. * * *

(i) * * *

(1) * * * A reporting corporation (other than an entity that is a reporting corporation as a result of being treated as a corporation under § 301.7701-2(c)(2)(vi) of this chapter) is not subject to §§ 1.6038A-3 and 1.6038A-5 for any taxable year in which the aggregate value of all gross payments it makes to and receives from foreign related parties with respect to related party transactions (including monetary

consideration, nonmonetary consideration, and the value of transactions involving less than full consideration) is not more than \$5,000,000 and is less than 10 percent of its U.S. gross income. * * *

* * * * *

(n) * * *

(1) * * * However, § 1.6038A-1 as it applies to entities that are reporting corporations as a result of being treated as a corporation under § 301.7701-2(c)(2)(vi) of this chapter applies to taxable years of such reporting corporations beginning after December 31, 2016, and ending on or after December 13, 2017.

(2) * * * Section 1.6038A-2 as it applies to entities that are reporting corporations as a result of being treated as a corporation under § 301.7701-2(c)(2)(vi) of this chapter applies to taxable years of such reporting corporations beginning after December 31, 2016, and ending on or after December 13, 2017.

* * * * *

■ **Par. 4.** Section 1.6038A-2 is amended as follows:

- 1. Revise the second sentence of paragraph (a)(2).
- 2. Revise paragraph (b)(3)(vii).
- 3. Remove the word “and” at the end of paragraph (b)(3)(ix).
- 4. Remove the undesignated paragraph following paragraph (b)(3)(x).
- 5. Remove the period at the end of paragraph (b)(3)(x) and add “; and” in its place.
- 6. Add paragraphs (b)(3)(xi) and (b)(9).
- 7. Add a sentence at the end of paragraph (d).
- 8. Revise the first sentence of paragraph (e)(3).
- 9. Revise paragraph (e)(4).

The additions and revisions read as follows:

§ 1.6038A-2 Requirements of return.

(a) * * *

(2) * * * However, if neither party to the transaction is a United States person as defined in section 7701(a)(30) (which, for purposes of section 6038A, includes an entity that is a reporting corporation as a result of being treated as a corporation under § 301.7701-2(c)(2)(vi) of this chapter) and the transaction—

* * * * *

(b) * * *

(3) * * *

(vii) Amounts loaned and borrowed (except open accounts resulting from sales and purchases reported under other items listed in this paragraph (b)(3) that arise and are collected in full in the ordinary course of business), to be

reported as monthly averages or outstanding balances at the beginning and end of the taxable year, as the form shall prescribe;

* * * * *

(xi) With respect to an entity that is a reporting corporation as a result of being treated as a corporation under § 301.7701-2(c)(2)(vi) of this chapter, any other transaction as defined by § 1.482-1(i)(7), such as amounts paid or received in connection with the formation, dissolution, acquisition and disposition of the entity, including contributions to and distributions from the entity.

* * * * *

(9) *Examples.* The following examples illustrate the application of paragraph (b)(3) of this section:

Example 1. (i) In year 1, W, a foreign corporation, forms and contributes assets to X, a domestic limited liability company that does not elect to be treated as a corporation under § 301.7701-3(c) of this chapter. In year 2, W contributes funds to X. In year 3, X makes a payment to W. In year 4, X, in liquidation, distributes its assets to W.

(ii) In accordance with § 301.7701-3(b)(1)(ii) of this chapter, X is disregarded as an entity separate from W. In accordance with § 301.7701-2(c)(2)(vi) of this chapter, X is treated as an entity separate from W and classified as a domestic corporation for purposes of section 6038A. In accordance with paragraphs (a)(2) and (b)(3) of this section, each of the transactions in years 1 through 4 is a reportable transaction with respect to X. Therefore, X has a section 6038A reporting and record maintenance requirement for each of those years.

Example 2. (i) The facts are the same as in *Example 1* of this paragraph (b)(9) except that, in year 1, W also forms and contributes assets to Y, another domestic limited liability company that does not elect to be treated as a corporation under § 301.7701-3(c) of this chapter. In year 1, X and Y form and contribute assets to Z, another domestic limited liability company that does not elect to be treated as a corporation under § 301.7701-3(c) of this chapter. In year 2, X transfers funds to Z. In year 3, Z makes a payment to Y. In year 4, Z distributes its assets to X and Y in liquidation.

(ii) In accordance with § 301.7701-3(b)(1)(ii) of this chapter, Y and Z are disregarded as entities separate from each other, W, and X. In accordance with § 301.7701-2(c)(2)(vi) of this chapter, Y, Z and X are treated as entities separate from each other and W, and are classified as domestic corporations for purposes of section 6038A. In accordance with paragraph (b)(3) of this section, each of the transactions in years 1 through 4 involving Z is a reportable transaction with respect to Z. Similarly, W’s contribution to Y and Y’s contribution to Z in year 1, the payment to Y in year 3, and the distribution to Y in year 4 are reportable transactions with respect to Y. Moreover, X’s contribution to Z in Year 1, X’s funds transfer to Z in year 2, and the distribution to X in

year 4 are reportable transactions with respect to X. Therefore, Z has a section 6038A reporting and record maintenance requirement for years 1 through 4; Y has a section 6038A reporting and record maintenance requirement for years 1, 3, and 4; and X has a section 6038A reporting and record maintenance requirement in years 1, 2, and 4 in addition to its section 6038A reporting and record maintenance described in *Example 1* of this paragraph (b)(9).

* * * * *

(d) * * * In the case of an entity that is a reporting corporation as a result of being treated as a corporation under § 301.7701-2(c)(2)(vi) of this chapter, Form 5472 must be filed at such time and in such manner as the Commissioner may prescribe in forms or instructions.

(e) * * *

(3) * * * A reporting corporation (other than an entity that is a reporting corporation as a result of being treated as a corporation under § 301.7701-2(c)(2)(vi) of this chapter) is not required to make a return of information on Form 5472 with respect to a related foreign corporation for a taxable year for which a U.S. person that controls the foreign related corporation makes a return of information on Form 5471 that is required under section 6038 and this section, if that return contains information required under § 1.6038-2(f)(11) with respect to the reportable transactions between the reporting corporation and the related corporation for that taxable year. * * *

(4) *Transactions with a foreign sales corporation.* A reporting corporation (other than an entity that is a reporting corporation as a result of being treated as a corporation under § 301.7701-2(c)(2)(vi) of this chapter) is not required to make a return of information on Form 5472 with respect to a related corporation that qualifies as a foreign sales corporation for a taxable year for which the foreign sales corporation files Form 1120-FSC.

* * * * *

PART 301—PROCEDURE AND ADMINISTRATION

■ **Par. 5.** The authority citation for part 301 continues to read in part as follows:

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

■ **Par. 6.** Section 301.7701-2 is amended by revising the last sentence of paragraph (a) and adding paragraphs (c)(2)(vi) and (e)(9) to read as follows:

§ 301.7701-2 Business entities; definitions.

(a) * * * But see paragraphs (c)(2)(iii) through (vi) of this section for special rules that apply to an eligible entity that

is otherwise disregarded as an entity separate from its owner.

* * * * *

(c) * * *

(2) * * *

(vi) *Special rule for reporting under section 6038A—(A) In general.* An entity that is disregarded as an entity separate from its owner for any purpose under this section is treated as an entity separate from its owner and classified as a corporation for purposes of section 6038A if—

(1) The entity is a domestic entity; and

(2) One foreign person has direct or indirect sole ownership of the entity.

(B) *Definitions—(1) Indirect sole ownership.* For purposes of paragraph (c)(2)(vi)(A)(2) of this section, indirect sole ownership means ownership by one person entirely through one or more other entities disregarded as entities separate from their owners or through one or more grantor trusts, regardless of whether any such disregarded entity or grantor trust is domestic or foreign.

(2) *Entity disregarded as separate from its owner.* For purposes of paragraph (c)(2)(vi)(B)(1) of this section, an entity disregarded as an entity separate from its owner is an entity described in paragraph (c)(2)(i) of this section.

(3) *Grantor trust.* For purposes of paragraph (c)(2)(vi)(B)(1) of this section, a grantor trust is any portion of a trust that is treated as owned by the grantor or another person under subpart E of subchapter J of chapter 1 of the Code.

(C) *Taxable year.* The taxable year of an entity classified as a corporation for section 6038A purposes pursuant to paragraph (c)(2)(vi)(A) of this section is—

(1) The same as the taxable year of the foreign person described in paragraph (c)(2)(vi)(A)(2) of this section, if that foreign person has a U.S. income tax or information return filing obligation for its taxable year; or

(2) The calendar year, if paragraph (c)(2)(vi)(C)(1) of this section does not apply, unless otherwise provided in forms, instructions, or published guidance.

* * * * *

(e) * * *

(9) *Reporting required under section 6038A.* Paragraph (c)(2)(vi) of this section applies to taxable years of entities beginning after December 31,

2016, and ending on or after December 13, 2017.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: November 15, 2016.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2016–29641 Filed 12–12–16; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

31 CFR Part 22

RIN 1505–AC45

Regulation Regarding Nondiscrimination on the Basis of Race, Color, or National Origin in Programs or Activities Receiving Federal Financial Assistance From the Department of the Treasury

AGENCY: Department of the Treasury.

ACTION: Final rule.

SUMMARY: This final rule provides for the enforcement of Title VI of the Civil Rights Act of 1964, as amended (“Title VI”) to the end that no person in the United States shall on the grounds of race, color, or national origin be denied participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity that receives federal financial assistance from the Department of the Treasury. The promulgation of this final regulation will provide guidance to the Department’s recipients of federal financial assistance in complying with the provisions of Title VI and will also promote consistent and appropriate enforcement of Title VI by the Department’s components. Through this final rule, the Department also notifies beneficiaries of its programs offering financial assistance of the protections against discrimination based on race, color, and national origin.

DATES: Effective January 12, 2017.

FOR FURTHER INFORMATION CONTACT:

Mariam G. Harvey, Director, Office of Civil Rights and Diversity, Department of the Treasury, (202) 622–0316 (voice), by mail to Mariam G. Harvey, Director, Office of Civil Rights and Diversity, 1500 Pennsylvania Avenue NW., Washington, DC 20220; or facsimile (202) 622–0367.

SUPPLEMENTARY INFORMATION:

I. Purpose of the Regulatory Action

The purpose of this final rule is to provide for the enforcement of Title VI of the Civil Rights Act of 1964, as

amended (42 U.S.C. 2000d, *et seq.*), as it applies to programs or activities receiving assistance from the Department of the Treasury. Specifically, the statute states that “[n]o person in the United States shall, on the grounds of race, color, or national origin be denied participation in, be denied the benefits of, or be otherwise subjected to discrimination under any program or activity that receives federal financial assistance.” 42 U.S.C. 2000d. Each federal agency subject to Title VI is required to issue regulations implementing Title VI. 28 CFR 42.403. The Department of the Treasury is issuing Title VI regulations for the first time. Under Treasury’s Title VI implementing regulations, Treasury-funded programs are prohibited from taking acts, including permitting actions, that discriminate based on the statutorily protected classes. The regulations further provide for Treasury procedures to ensure compliance, including a hearing procedure.

Prior to this rule, the Department was requiring recipients of financial assistance to sign assurances of compliance with Title VI. With the issuance of this final rule, the Department will continue to require assurance of compliance and strengthen its civil rights compliance requirements.

II. Background

A. Treasury’s July 13, 2015, Proposed Rule

On July 13, 2015, at 80 FR 39977, Treasury published its proposed rule implementing Title VI. Each federal agency subject to Title VI is required to issue regulations implementing Title VI. 42 U.S.C. 2000d to 2000d–7; 28 CFR 42.403. The comment period for the proposed rule ended on September 11, 2015.

III. Public Comments and Treasury’s Response

A. The Public Comments Generally

The public posted six comments to the Notice of Proposed Rulemaking implementing Title VI. Three comments were from public interest groups. One comment was from a city government office. Two individuals also commented, but one of the comments was nonresponsive. All public comments can be viewed at <http://www.regulations.gov/#!docketBrowser;rpp=25;po=0;dt=PS%25BPR;D=TREAS-DO-2015-0006>.

The comments can be grouped in two main subjects: Data collection and coverage of Low Income Housing Credits (LIHTCs).