

(d) *Limits*. The General Counsel will limit any authorization for testimony to the scope of the demand, and the scope of permissible production of records and information to that set forth in the written authorization.

(e) *Failure to meet requirements and exceptions*. USTR may oppose any demand or request that does not meet the requirements set forth in this subpart. The General Counsel may grant exceptions to the requirements in this subpart upon a showing of compelling need, to promote a significant interest of USTR or the United States, or for other good cause.

§ 2004.35 Processing demands and requests.

(a) The General Counsel will review a request or demand to produce or disclose records, information or testimony and determine whether, or under what conditions, to authorize the employee to testify regarding USTR matters or produce records and information. The General Counsel will notify the requester of the final determination, the reasons for the grant or denial of the demand or request, and any conditions on disclosure.

(b) When necessary, the General Counsel will coordinate with the U.S. Department of Justice to file appropriate motions, including motions to remove the matter to Federal court, to quash, or to obtain a protective order.

(c) The General Counsel will process demands and requests in the order in which they are received. Absent unusual circumstances and depending on the scope of the demand or request, the General Counsel will respond within 45 calendar days of the date USTR receives all information necessary to evaluate the demand or request.

§ 2004.36 Restrictions that apply to testimony.

(a) The General Counsel may impose conditions or restrictions on the testimony of USTR employees including, for example, limiting the scope of testimony or requiring the requester and other parties to the legal proceeding to agree that the testimony transcript will be kept under seal or will only be used or made available in the particular legal proceeding for which testimony was requested. The General Counsel also may require a copy of the testimony transcript at the requester's expense.

(b) USTR may offer the employee's written declaration in lieu of testimony.

(c) If authorized to testify pursuant to this subpart, an employee may testify as to relevant facts within his or her personal knowledge, but, unless

specifically authorized to do so by the General Counsel, the employee must not:

(1) Disclose classified, confidential or privileged information; or

(2) For a current USTR employee, testify as an expert or opinion witness with regard to any matter arising out of the employee's official duties or USTR's mission or functions, unless testimony is provided on behalf of the United States. A former employee can provide expert or opinion testimony where the testimony involves only general expertise gained while employed as a USTR employee.

§ 2004.37 Restrictions that apply to released records and information.

(a) The General Counsel may impose conditions or restrictions on the release of records and information, including requiring the parties to the legal proceeding to obtain a protective order or to execute a confidentiality agreement to limit access and further disclosure. The terms of a protective order or confidentiality agreement must be acceptable to the General Counsel. In cases where protective orders or confidentiality agreements already have been executed, USTR may condition the release of records and information on an amendment to the existing protective order or confidentiality agreement.

(b) If the General Counsel so determines, USTR may present original records for examination in response to a demand or request, but the records cannot be marked or altered or presented as evidence or otherwise used in a manner by which they could lose their status as original records. In lieu of original records, certified copies will be presented for evidentiary purposes. (See 28 U.S.C. 1733).

§ 2004.38 In the event of an adverse ruling.

(a) Notwithstanding USTR's rejection of a demand or request for records, information or testimony, if a court or other competent authority orders a USTR employee to comply with the demand, the employee promptly must notify the General Counsel of the order, and must respectfully decline to comply, citing *United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

(b) To seek reconsideration of USTR's rejection of a demand or request, or of any restrictions on receiving records, information or testimony, a requester must send a petition for reconsideration in accordance with § 2004.34(a) within 10 days of the date of the determination. The petition must contain a clear and concise statement of the basis for the reconsideration with supporting authorities. Determinations about

petitions for reconsideration are within the discretion of the United States Trade Representative or his/her designee, and are final.

(c) Pursuant to section 704 of the Administrative Procedure Act, 5 U.S.C. 704, a petition for reconsideration of a final determination under this section is a prerequisite to judicial review.

§ 2004.39 Fees.

(a) USTR may condition the production of records, information or an employee's appearance on advance payment of reasonable costs, which may include but are not limited to those associated with employee search time, copying, computer usage, and certifications.

(b) Witness fees will include fees, expenses and allowances prescribed by the rules applicable to the particular legal proceeding. If no fees are prescribed, USTR will base fees on the rule of the federal district court closest to the location where the witness will appear. Such fees may include but are not limited to time for preparation, travel and attendance at the legal proceeding.

Janice Kaye,

Chief Counsel for Administrative Law, Office of the U.S. Trade Representative.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 201, 207, 314, 514, 515, 601, 607, and 1271

[Docket No. FDA-2005-N-0464 (Formerly Docket No. 2005N-0403)]

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; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled "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" that appeared in the **Federal Register** of August 31, 2016 (81 FR 60169). That final rule amended current regulations

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.

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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)