(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 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 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


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.
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 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. This document corrects that error.

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]

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