

List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise.

Amendment to CBP Regulations

For the reasons set forth above, part 12 of Title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

§ 12.104g [Amended]

■ 2. In § 12.104g, paragraph (a), the table is amended in the entry for Colombia by adding, after the reference to “CBP Dec. 06–09”, the words “extended by CBP Dec. 11–06”.

Alan Bersin,

Commissioner, U.S. Customs and Border Protection.

Approved: March 9, 2011.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2011–5879 Filed 3–14–11; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Parts 312 and 314**

[Docket No. FDA–2011–N–0130]

Investigational New Drug Applications and Abbreviated New Drug Applications; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its investigational new drug application (IND) regulations and abbreviated new drug application regulations to correct inaccurate cross-references to the IND regulations and the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This

action is being taken to ensure accuracy and clarity in the Agency’s regulations.

DATES: This rule is effective March 15, 2011.

FOR FURTHER INFORMATION CONTACT:

Olivia A. Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, Rm. 6308, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3506.

SUPPLEMENTARY INFORMATION: FDA is amending its regulation in 21 CFR 312.83 to correct an inaccurate cross-reference to other sections of the IND regulations. FDA is amending its regulation in 21 CFR 314.94 to correct an inaccurate cross-reference to a section of the FD&C Act.

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 are unnecessary because this amendment to the regulations provides only technical changes to correct inaccurate cross-references to the IND regulations and the FD&C Act.

List of Subjects**21 CFR Part 312**

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 312 and 314 are amended as follows:

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

■ 1. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

§ 312.83 [Amended]

■ 2. Section 312.83 is amended by removing “312.34 and 312.35” and by adding in its place “312.305 and 312.320”.

PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

■ 3. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

§ 314.94 [Amended]

■ 4. Section 314.94 is amended in paragraph (a)(8)(iv) by removing “505(j)(4)(D)” and by adding in its place “505(j)(5)(F)”.

Dated: March 9, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–5946 Filed 3–14–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 301**

[TD 9516]

RIN 1545–BG73

Disclosure of Return Information in Connection With Written Contracts Among the IRS, Whistleblowers, and Legal Representatives of Whistleblowers

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations and removal of temporary regulations.

SUMMARY: This document contains final regulations relating to the disclosure of return information by an officer or employee of the Treasury Department, to a whistleblower and, if applicable, the legal representative of the whistleblower, to the extent necessary in connection with a written contract among the IRS, the whistleblower and, if applicable, the legal representative of the whistleblower, for services relating to the detection of violations of the internal revenue laws or related statutes. The final regulations will affect officers and employees of the Treasury Department who disclose return information to whistleblowers or their legal representatives in connection with written contracts among the IRS, whistleblowers and, if applicable, their legal representatives, for services relating to the detection of violations of the internal revenue laws or related statutes. The final regulations will also affect any whistleblower or legal representative of a whistleblower who receives return information in connection with a written contract among the IRS, the whistleblower and, if applicable, the legal representative of the whistleblower, for services relating to the detection of violations of the internal revenue laws or related statutes.

DATES: *Effective Date:* These final regulations are effective on March 15, 2011.

Applicability Date: For dates of applicability, see § 301.6103(n)–2(f).

FOR FURTHER INFORMATION CONTACT:

Helene R. Newsome, 202–622–7950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains final regulations implementing amendments to the Procedure and Administration Regulations (26 CFR part 301) under section 6103(n) relating to the disclosure of return information in connection with written contracts among the IRS, whistleblowers and, if applicable, their legal representatives.

The Tax Relief and Health Care Act of 2006, Public Law 109–432 (120 Stat. 2958), (the Act) was enacted on December 20, 2006. Section 406 of the Act amends section 7623, concerning the payment of awards to whistleblowers, and establishes a Whistleblower Office within the IRS that has responsibility for the administration of a whistleblower program. In connection with analyzing information provided by a whistleblower, or investigating a matter, the IRS may determine that it requires the assistance of the whistleblower, or the legal representative of the whistleblower. The Joint Committee on Taxation (the JCT) has noted that “[t]o the extent the disclosure of returns or return information is required [for the whistleblower or his or her legal representative] to render such assistance, the disclosure must be pursuant to an IRS tax administration contract.” Joint Committee on Taxation, *Technical Explanation of H.R. 6408, The “Tax Relief and Health Care Act of 2006,”* as Introduced in the House on December 7, 2006, at 89 (JCX–50–06), December 7, 2006. The JCT has further noted that “[i]t is expected that such disclosures will be infrequent and will be made only when the assigned task cannot be properly or timely completed without the return information to be disclosed.” *Id.*

Under section 6103(a), returns and return information are confidential unless the Internal Revenue Code authorizes disclosure. Section 6103(n) is the authority by which returns and return information may be disclosed pursuant to a tax administration contract. Section 6103(n) authorizes, pursuant to regulations prescribed by the Secretary, returns and return information to be disclosed to any person, for purposes of tax

administration, to the extent necessary in connection with: (1) The processing, storage, transmission, and reproduction of returns and return information; (2) the programming, maintenance, repair, testing, and procurement of equipment; and (3) the providing of other services.

On March 25, 2008, temporary regulations (TD 9389) under section 6103(n) were published in the **Federal Register** (73 FR 15668) describing the circumstances under which officers and employees of the Treasury Department may disclose return information to whistleblowers and, if applicable, their legal representatives, in connection with written contracts for services relating to the detection of violations of the internal revenue laws or related statutes. A notice of proposed rulemaking (REG–114942–07) cross-referencing the temporary regulations was published in the **Federal Register** for the same day (73 FR 15687).

One written comment responding to the notice of proposed rulemaking was received. No public hearing was requested or held. After consideration of the comment, the regulations are adopted as proposed with only minor technical changes made.

The limitations applicable to section 6103(n) contracts as outlined in these regulations are not a limitation on the use of return information that may be disclosed to a whistleblower or the legal representative of a whistleblower during an award determination administrative proceeding and in an award determination appeal to the U.S. Tax Court.

Summary of Comment

The commentator recommended that § 301.6103(n)–2(b)(3) of the proposed regulations be revised to eliminate any requirement that a written contract be in place for a whistleblower to be provided with basic status information about the whistleblower’s claim for award under section 7623. The commentator drew a comparison with whistleblower claims under the False Claims Act and argued that the standard for the IRS to share status information with a whistleblower should not be the same as that required to share information from the actual returns of taxpayers. Unlike other statutory schemes, however, information regarding the status of a whistleblower’s claim with the IRS is “return information” as defined in section 6103(b)(2). Like returns (defined in section 6103(b)(1)), return information is confidential under section 6103(a) and may only be disclosed if authorized by a specific provision of the Code. In order to disclose status information to a

whistleblower, an exception to section 6103 must be applicable. Section 6103(n) provides authority for the IRS to make status information disclosures to a whistleblower. Because disclosures pursuant to section 6103(n) require a written tax administration contract, the final regulations do not adopt the commentator’s recommendation.

The commentator also recommended that § 301.6103(n)–2(d)(3) of the proposed regulations be revised to eliminate the inspection requirement. The commentator asserted that, by contrast, § 301.6103(n)–1, “Disclosure of returns and return information in connection with written contracts or agreements for the acquisition of property or services for tax administration purposes,” does not include such a requirement and argued that the requirement is unnecessary in that the regulations already provide for severe sanctions for any failure to comply with the terms of written contracts for services. In fact, § 301.6103(n)–1(e)(1) does indeed contain an inspection requirement. The final regulations retain the inspection requirement as consistent with the longstanding safeguard procedures that incorporate inspection as an integral part of the contracting process under section 6103(n).

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has 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 on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the proposed regulations preceding these regulations were submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information

The principal author of these regulations is Helene R. Newsome, Office of the Associate Chief Counsel (Procedure & Administration).

List of Subjects in 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 part 301 is amended as follows:

PART 301—PROCEDURE AND ADMINISTRATION

■ **Paragraph 1.** The authority citation for part 301 is amended by adding entries in numerical order to read as follows:

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

Section 301.6103(n)–2 also issued under 26 U.S.C. 6103(n). * * *

Section 301.6103(n)–2 also issued under 26 U.S.C. 6103(q). * * *

■ **Par. 2.** Section 301.6103(n)–2 is added to read as follows:

§ 301.6103(n)–2 Disclosure of return information in connection with written contracts among the IRS, whistleblowers, and legal representatives of whistleblowers.

(a) *General rule.* (1) Pursuant to the provisions of sections 6103(n) and 7623 of the Internal Revenue Code and subject to the conditions of this section, an officer or employee of the Treasury Department is authorized to disclose return information (as defined in section 6103(b)(2)) to a whistleblower and, if applicable, the legal representative of the whistleblower, to the extent necessary in connection with a written contract among the Internal Revenue Service (IRS), the whistleblower and, if applicable, the legal representative of the whistleblower, for services relating to the detection of violations of the internal revenue laws or related statutes.

(2) The IRS shall have the discretion to determine whether to enter into a written contract pursuant to section 7623 with the whistleblower and, if applicable, the legal representative of the whistleblower, for services described in paragraph (a)(1) of this section.

(b) *Limitations.* (1) Disclosure of return information in connection with a written contract for services described in paragraph (a)(1) of this section shall be made only to the extent the IRS deems it necessary in connection with the reasonable or proper performance of the contract. Disclosures may include, but are not limited to, disclosures to accomplish properly any purpose or activity of the nature described in section 6103(k)(6) and the regulations thereunder.

(2) If the IRS determines that the services of a whistleblower and, if applicable, the legal representative of the whistleblower, as described in paragraph (a)(1) of this section, can be performed reasonably or properly by disclosure of only parts or portions of

return information, then only the parts or portions of the return information shall be disclosed.

(3) Upon written request by a whistleblower, or a legal representative of a whistleblower, with whom the IRS has entered into a written contract for services as described in paragraph (a)(1) of this section, the Director of the Whistleblower Office, or designee of the Director, may inform the whistleblower and, if applicable, the legal representative of the whistleblower, of the status of the whistleblower's claim for award under section 7623, including whether the claim is being evaluated for potential investigative action, or is pending due to an ongoing examination, appeal, collection action, or litigation. The information may be disclosed only if the IRS determines that the disclosure would not seriously impair Federal tax administration.

(4) Return information disclosed to a whistleblower and, if applicable, a legal representative of a whistleblower, under this section, shall not be further disclosed or otherwise used by the whistleblower or a legal representative of a whistleblower, except as expressly authorized in writing by the IRS.

(c) *Penalties.* Any whistleblower, or legal representative of a whistleblower, who receives return information under this section, is subject to the civil and criminal penalty provisions of sections 7431, 7213, and 7213A for the unauthorized inspection or disclosure of the return information.

(d) *Safeguards.* (1) Any whistleblower, or the legal representative of a whistleblower, who receives return information under this section, shall comply with all applicable conditions and requirements as the IRS may prescribe from time to time for the purposes of protecting the confidentiality of the return information and preventing any disclosure or inspection of the return information in a manner not authorized by this section (prescribed requirements).

(2) Any written contract for services as described in paragraph (a)(1) of this section shall provide that any whistleblower and, if applicable, the legal representative of a whistleblower, who has access to return information under this section, shall comply with the prescribed requirements.

(3) Any whistleblower, or the legal representative of a whistleblower, who may receive return information under this section, shall agree in writing, before any disclosure of return information is made, to permit an inspection of the whistleblower's or the legal representative's premises by the IRS relative to the maintenance of the

return information disclosed under these regulations and, upon completion of services as described in the written contract with the IRS, to dispose of all return information by returning the return information, including any and all copies or notes made, to the IRS, or to the extent that it cannot be returned, by destroying the information in a manner consistent with prescribed requirements.

(4) If the IRS determines that any whistleblower, or the legal representative of a whistleblower, who has access to return information under this section, has failed to, or does not, satisfy the prescribed requirements, the IRS, using the procedures described in the regulations under section 6103(p)(7), may take any action it deems necessary to ensure that the prescribed requirements are or will be satisfied, including—

(i) Suspension of further disclosures of return information by the IRS to the whistleblower and, if applicable, the legal representative of the whistleblower, until the IRS determines that the conditions and requirements have been or will be satisfied; and

(ii) Suspension or termination of any duty or obligation arising under the contract with the IRS.

(e) *Definitions.* For purposes of this section—

(1) The term *Treasury Department* includes the IRS and the Office of the Chief Counsel for the IRS.

(2) The term *whistleblower* means an individual who provides information to the IRS regarding violations of the tax laws or related statutes and submits a claim for an award under section 7623 with respect to the information.

(3) The term *legal representative* means any individual who is a member in good standing in the bar of the highest court of any state, possession, territory, commonwealth, or the District of Columbia, and who has a written power of attorney executed by the whistleblower.

(f) *Effective/applicability date.* This section is applicable on March 15, 2011.

§ 301.6103(n)–2T [Removed]

■ **Par. 3.** Section 301.6103(n)–2T is removed.

Steven T. Miller,

Deputy Commissioner for Services and Enforcement.

Approved: March 9, 2011.

Michael Mundaca,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2011–6111 Filed 3–14–11; 8:45 am]

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