

The Regulatory Flexibility Act requires agencies to examine regulatory alternatives for small entities, if the rule may have a significant economic impact on a substantial number of small entities. Since we have determined that the possible compliance costs to any sponsor would be extremely small, if they occur at all, we are certifying that the final rule would not have a significant economic impact on a substantial number of small entities. No further small business analysis is required.

V. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the final rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VI. Paperwork Reduction Act of 1995

The information collected in § 500.88 has been approved by the Office of Management and Budget (OMB) under OMB control number 0910-0032. This final rule amends § 500.88 but does not substantively modify the information collection. Therefore, clearance by OMB under the Paperwork Reduction Act of 1995 is not required.

VII. Reference

The following reference has been placed on display in the Dockets Management Branch (see ADDRESSES) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. U.S. Department of Justice, "The Food and Drug Administration's Discretion to Approve Methods of Detection and to Define the Term 'No Residue' Pursuant to the Federal Food, Drug, and Cosmetic Act: Memorandum Opinion for the Assistant Administrator and General Counsel Environmental Protection Agency and the General Counsel Department of Health and Human Services," October 13, 1995.

List of Subjects in 21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs).

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner

of Food and Drugs, 21 CFR part 500 is amended as follows:

PART 500—GENERAL

1. The authority citation for 21 CFR part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371.

§ 500.80 [Amended]

2. Section 500.80 *Scope of this subpart* is amended in paragraph (a) in the third sentence by removing the phrase "provides an operational definition of no residue and".

§ 500.82 [Amended]

3. Section 500.82 *Definitions* is amended in paragraph (b) as follows:

- a. By alphabetically adding "*Limit of detection (LOD)* means the lowest concentration of analyte that can be confirmed by the approved regulatory method.";

- b. By removing from the definition of "*Marker residue*" the phrase "permitted concentration" and by adding in its place " S_m ";

- c. By removing from the definition of "*Preslaughter withdrawal period or milk discard time*" the phrase "for the residue of carcinogenic concern in the edible product to deplete to the concentration that will satisfy the operational definition of no residue" and by adding in its place "at which no residue is detectable in the edible product using the approved regulatory method (i.e., the marker residue is below the LOD)";

- d. By removing from the definition of " R_m " the phrase "in the last tissue to deplete to its permitted concentration"; and

- e. By removing the definition of " S_m " and by adding in its place " S_m means the concentration of residue in a specific edible tissue corresponding to a maximum lifetime risk of cancer in the test animals of 1 in 1 million".

4. Section 500.84 is amended by revising the section heading and paragraph (c)(2) and by adding two sentences at the end of paragraph (c)(1) and adding paragraph (c)(3) to read as follows:

§ 500.84 Conditions for approval of the sponsored compound.

* * * * *

(c) * * *

(1) * * * Because the total diet is not derived from food-producing animals, FDA will make corrections for food intake. FDA will designate as S_m the concentration of residue in a specific edible tissue corresponding to a maximum lifetime risk of cancer in test animals of 1 in 1 million.

(2) From the appropriate residue chemistry data FDA will calculate the R_m as described in § 500.86(c). The sponsor must provide a regulatory method in accordance with § 500.88(b). FDA will calculate the LOD of the method from data submitted by the sponsor under § 500.88. The LOD must be less than or equal to R_m .

(3) FDA will conclude that the provisions of this subpart are satisfied when no residue of the compound is detectable (that is, the marker residue is below the LOD) using the approved regulatory method under the conditions of use of the sponsored compound, including any required preslaughter withdrawal period or milk discard time.

5. Section 500.88 is amended by revising paragraphs (b) and (c) to read as follows:

§ 500.88 Regulatory method.

* * * * *

(b) The regulatory method must be able to confirm the identity of the marker residue in the target tissue at a minimum concentration corresponding to the R_m . FDA will determine the LOD from the submitted analytical method validation data.

(c) FDA will publish in the **Federal Register** the complete regulatory method for ascertaining the marker residue in the target tissue in accordance with the provisions of sections 409(c)(3)(A), 512(d)(1)(I), and 721(b)(5)(B) of the act.

Dated: December 17, 2002.

Margaret M. Dotzel,

Assistant Commissioner for Policy.

[FR Doc. 02-32216 Filed 12-20-02; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9033]

RIN 1545-BB36

Section 6038—Returns Required With Respect to Controlled Foreign Partnerships

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulation.

SUMMARY: This document contains final and temporary regulations relating to controlled foreign partnerships. This document requires that the United States partner must follow the filing requirements that are specified in the

instructions for Form 8865. The text of the temporary regulation also serves as the text of the proposed regulation set forth in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective December 23, 2002.

Applicability Date: For dates of applicability, see §§ 1.6038–3(l) and 1.6038–3T(l).

FOR FURTHER INFORMATION CONTACT:

Tasheaya Warren, (202) 622–3860 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in these regulations has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget under control number 1545–1617. Responses to this collection of information are mandatory.

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

For further information concerning this collection of information, and where to submit comments on the collection of information and the accuracy of the estimated burden, and suggestions for reducing this burden, please refer to the preamble to the cross-referencing notice of proposed rulemaking published in the Proposed Rules section of this issue of the **Federal Register**.

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

In 1997, Congress amended section 6038 to require information reporting by certain United States persons with direct and indirect interests in controlled foreign partnerships (CFPs). Treas. Reg. § 1.6038–3 was published in 1999 (TD 8850, 64 FR 72545 (1999)) (the “1999 Final Regulations”) and provides guidance regarding the reporting requirements under section 6038 with respect to CFPs. A United States person required to report under section 6038 with respect to a CFP must file Form 8865, Return of U.S. Persons With Respect To Certain Foreign

Partnerships. In addition to the reporting obligation imposed on certain partners in foreign partnerships under section 6038, section 6031 requires certain foreign partnerships to file Form 1065, U.S. Return of Partnership Income or Form 1065–B, U.S. Return for Electing Large Partnerships.

Treas. Reg. § 1.6038–3(j)(1) provides that if a foreign partnership completes and files Form 1065 and a United States partner is required to file Form 8865 with respect to that partnership, the United States partner must attach to its Form 8865 copies of the Form 1065 schedules filed by the partnership instead of completing the Form 8865 schedules that are equivalent to Form 1065 schedules. This rule was added to the 1999 Final Regulations to reduce the burden imposed by those regulations where there is an overlap between section 6038 and section 6031. However, this rule does not directly address the filing requirements for Form 8865, when a United States partner files electronically its income tax return (including any attachments such as Form 8865).

Explanation of Provisions

To facilitate revisions to the filing requirements for Form 8865 (such as electronic filing of Form 8865), the temporary regulation amends Treas. Reg. § 1.6038–3 to provide that a United States partner must follow the filing requirements that are specified in the instructions for Form 8865 when the United States partner must file Form 8865 and the partnership completes and files Form 1065 or Form 1065–B. As a transitional matter, for the next filing season it is anticipated that the instructions for Form 8865 will continue to provide for the existing filing procedure pursuant to which a United States partner attaches certain schedules from Form 1065 or Form 1065–B to its Form 8865 as well as provide for an alternative electronic filing procedure for Form 8865.

The final regulation also makes two revisions to the 1999 Final Regulations. If a U.S. person is required to file Form 8865, Treas. Reg. § 1.6038–3(g)(1) provides that a U.S. person must submit any information that Form 8865 or its accompanying instructions require to be submitted. The final regulation clarifies the requirement under Treas. Reg. § 1.6038–3, as reflected in the Form 8865 instructions, that the United States partner must include the foreign partnership’s name, address and taxpayer identification number on Form 8865. The final regulation also corrects a cross reference in Treas. Reg. § 1.6038–3(b)(9) (Example 1).

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 has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to this regulation. For the applicability of the Regulatory Flexibility Act (5 U.S.C. chapter 6) refer to the Special Analyses section of the preamble to the cross-reference notice of proposed rulemaking published in the Proposed Rules section of this issue of the **Federal Register**. Pursuant to section 7805(f) of the Internal Revenue Code, this temporary regulation will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small businesses.

Drafting Information

The principal author of this regulation is Tasheaya Warren, Office of the Associate Chief Counsel (International). However, other personnel from the IRS and Treasury Department participated in its development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 continues to read in part as follows:

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

Par. 2. Section 1.6038–3 is amended as follows:

1. The last sentence in paragraph (b)(9) *Example 1* is revised.
 2. Paragraphs (g)(1)(i) through (g)(1)(v) are redesignated as paragraphs (g)(1)(ii) through (g)(1)(vi), respectively.
 3. New paragraph (g)(1)(i) is added.
 4. Paragraphs (j) and (l) are revised.
- The revisions and addition read as follows:

§ 1.6038–3 Information returns required of certain United States persons with respect to controlled foreign partnerships (CFPs).

* * * * *

(b) * * *

(9) * * *

Example 1. Sole U.S. partner does not own more than a fifty-percent interest. * * *

See also § 1.6046A-1(f)(1) regarding the overlap between sections 6038B and 6046A).

* * * * *

(g) * * * (1) * * *

(i) The name, address, and taxpayer identification number (if any) of the foreign partnership of which the person qualified as a controlling fifty-percent partner or a controlling ten-percent partner;

* * * * *

(j) [Reserved]. For further guidance, see § 1.6038-3T(j).

* * * * *

(l) *Effective date.* Except as otherwise provided, this section shall apply for tax years of a foreign partnership ending on or after December 31, 2000. For tax years of a foreign partnership prior to December 23, 2002, see § 1.6038-3(j) in effect prior to these amendments (see 26 CFR part 1 revised April 1, 2002).

Par. 3. Section 1.6038-3T is added to read as follows:

§ 1.6038-3T Information returns required of certain United States persons with respect to controlled foreign partnership (CFPs) (temporary).

(a) Through (i)(2) [Reserved]. For further guidance, see § 1.6038-3(a) through (i)(2).

(j) *Overlap with section 6031.* A partner may be required to file Form 8865 under this section and the foreign partnership in which it is a partner may also be required to file a Form 1065 or Form 1065-B under section 6031(e) for the same partnership tax year. For cases where a United States person is a controlling fifty-percent partner or a controlling ten-percent partner with respect to a foreign partnership, and that foreign partnership completes and files Form 1065 or Form 1065-B, the instructions for Form 8865 will specify the filing requirements that address this overlap in reporting obligations.

(k) [Reserved]. For further guidance, see § 1.6038-3(k).

(l) *Effective date.* This section shall apply to tax years of a foreign partnership ending on or after December 23, 2002. The applicability of this section expires on December 20, 2005.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 4. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

Par. 5. In § 602.101, paragraph (b) is amended by adding the following entry in numerical order to the table to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	* * * * *
1.6038-3T	1545-1617
* * * * *	* * * * *

Robert E. Wenzel,

Deputy Commissioner of Internal Revenue.

Approved: December 5, 2002.

Pamela F. Olson,

Assistant Secretary of the Treasury.

[FR Doc. 02-32152 Filed 12-20-02; 8:45 am]

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LIBRARY OF CONGRESS

Copyright Office

37 CFR Part 201

[Docket No. 2002-5A]

Notice of Termination

AGENCY: Copyright Office, Library of Congress.

ACTION: Interim rule.

SUMMARY: The Copyright Office is announcing an interim regulation governing the form, content, and manner of service of notices of termination of transfers or licenses of copyright that were granted in or after 1978. Such notices may be served, for the first time, commencing January 1, 2003. The interim regulation is based on a proposed regulation recently published in the **Federal Register**.

EFFECTIVE DATE: January 1, 2003.

FOR FURTHER INFORMATION CONTACT:

David O. Carson, General Counsel.
Telephone: (202) 707-8380. Telefax:
(202) 707-8366.

SUPPLEMENTARY INFORMATION: On December 20, 2002, the Copyright Office published a proposed regulation governing the form, content, and manner of service of notices of termination to terminate transfers or licenses of copyright that were granted in or after 1978. Such notices of termination are permitted pursuant to 17 U.S.C. 203, and may be served, for the first time, commencing January 1, 2003.

Because the comment period for the proposed regulations will extend into 2003, and because it is necessary to have in place a regulation governing the form, content, and manner of service of these notices of termination on January 1, 2003, so that persons entitled to serve such notices will know the requirements for the notices, the Office is announcing this interim regulation. The regulation will be in effect only until the Office has had the opportunity to consider the comments received in response to the notice of proposed rulemaking, and to publish a final regulation.

The interim regulation is identical to the proposed regulation with one exception. The proposed regulation amends § 201.10(b)(1)(i) of the Copyright Office regulations to require that a notice of termination pursuant to section 17 U.S.C. 304 must identify whether the termination is made under section 304(c) or section 304(d). Because this proposed amendment would change established practice with respect to terminations under section 304(c), and because we do not believe it would be prudent to change the requirements for section 304 notices of termination on such short notice, that proposed amendment is not included in the interim regulation.

Because it is necessary to have such a regulation in place by January 1, 2003, the Register of Copyrights finds that notice and public procedure are impracticable and contrary to public interest and that good cause exists for publication of this interim regulation less than 30 days before its effective date and without first seeking public comment.

The entire text of § 201.10, as amended, may be found on the Copyright Office Web site at <http://www.copyright.gov/docs/203.html>.

List of Subjects in 37 CFR Part 201

Copyright.

In consideration of the foregoing, 37 CFR part 201 is amended as follows:

PART 201—GENERAL PROVISIONS

1. The authority citation for part 201 continues to read as follows:

Authority: 17 U.S.C. 702.

2. Section 201.10 is amended as follows:

(a) By revising the section heading and the first sentence of the introductory text.

(b) By revising paragraph (b)(1) introductory text.

(c) By revising paragraph (b)(1)(v).

(d) By revising paragraph (b)(1)(vii)(B).