

request comments on its proposal to implement portions of Title XI of the MMA, which amended provisions of the FD&C Act that govern the approval of 505(b)(2) applications and ANDAs. FDA also requested comment on its proposal to amend certain regulations regarding 505(b)(2) applications and ANDAs to facilitate compliance with and efficient enforcement of the FD&C Act. Comments on the proposed rule will inform FDA's rulemaking on ANDAs and 505(b)(2) applications.

The Agency has received requests for a 60-day extension of the comment period for the proposed rule. Each request conveyed concern that the current 90-day comment period does not allow sufficient time to develop a meaningful or thoughtful response to the proposed rule.

FDA has considered the requests and is extending the comment period for the proposed rule for 30 days, until June 8, 2015. The Agency believes that a 30-day extension of the comment period for the proposed rule allows adequate time for interested persons to submit comments without significantly delaying rulemaking on these important issues.

## II. Request for Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: April 17, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[REG-108214-15]

RIN 1545-BM69

### Exception From Passive Income for Certain Foreign Insurance Companies

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** This document contains proposed regulations that provide guidance regarding when a foreign insurance company's income is excluded from the definition of passive income under section 1297(b)(2)(B). The proposed regulations affect the U.S. shareholders of foreign corporations. This document also invites comments from the public on all aspects of the proposed rules and provides the opportunity for the public to request a public hearing.

**DATES:** Written or electronic comments and requests for a public hearing must be received by July 23, 2015.

**ADDRESSES:** Send submissions to: CC:PA:LPD:PR (REG-108214-15), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG-108214-15), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS REG-108214-15).

**FOR FURTHER INFORMATION CONTACT:** Concerning the proposed regulations, Josephine Firehock, (202) 317-4932; concerning submissions of comments or requests for a public hearing, Oluwafunmilayo (Funmi) Taylor at (202) 317-6901 (not toll-free numbers).

#### SUPPLEMENTARY INFORMATION:

#### Background and Explanation of Provisions

The Department of Treasury (Treasury) and the IRS are aware of situations in which a hedge fund establishes a purported foreign reinsurance company in order to defer and reduce the tax that otherwise would be due with respect to investment income. Such foreign corporations may be Passive Foreign Investment Companies (PFICs). For a description of the recent trends and legislative proposals to address the issue, see "Background and Data with Respect to Hedge Fund Reinsurance Arrangements," JCT (July 31, 2014) (2014 JCT Report); see also Notice 2003-34, 2003-23 IRB 990 (May 9, 2003).

Under section 1297 of the Internal Revenue Code (Code), a foreign corporation is a PFIC if either 75 percent or more of its gross income for the taxable year is passive income ("passive income test"), or on average 50 percent or more of its assets produce passive income or are held for the production of passive income ("passive asset test"). Section 1297(b)(1) generally defines the

term "passive income" to mean any income of a kind that would be "foreign personal holding company income" as defined in section 954(c). In general, an asset is characterized as passive if it generates (or is reasonably expected to generate in the reasonably foreseeable future) passive income as defined in section 1297(b). Assets that generate both passive and non-passive income in a taxable year are treated as partly passive and partly non-passive assets in proportion to the relative amounts of income generated by those assets in that year. See Notice 88-22, 1988-1 CB 489 (February 26, 1988).

For purposes of applying the passive income test, section 1297(b)(2)(B) provides that, except as provided in regulations, the term "passive income" does not include any income that is derived in the active conduct of an insurance business by a corporation which is predominantly engaged in an insurance business and which would be subject to tax under subchapter L as an insurance company if the corporation were a domestic corporation. As the terms "active conduct" and "insurance business" are not defined in section 1297, Treasury and the IRS are proposing regulations to clarify the circumstances under which investment income earned by a foreign insurance company is derived in the active conduct of an insurance business for purposes of determining whether the income is passive income, and thus the extent to which the company's assets are treated as passive assets for purposes of determining whether the company is a PFIC.

The proposed regulations provide that the term "active conduct" has the same meaning as in § 1.367(a)-2T(b)(3), except that officers and employees are not considered to include the officers and employees of related entities. The proposed regulations define the term "insurance business" to mean the business activity of issuing insurance and annuity contracts and the reinsuring of risks underwritten by insurance companies, together with investment activities and administrative services that are required to support or are substantially related to insurance contracts issued or reinsured by the foreign insurance company.<sup>1</sup> The regulations also provide that an

<sup>1</sup> Cf. Committee on Ways and Means U.S. House of Representatives, Supplemental Report, The Deficit Reduction Act of 1984, 98th Cong. 2d Sess., H.R. Rept. 98-432, part 2, at 531 (Mar. 5, 1984); Committee on Finance United States Senate, The Deficit Reduction Act of 1984, S. Rept. 98-169, vol. 1, at 1407-08 (April 2, 1984); H.R. Rept. 98-861, 98th Cong. 2d Sess. at 1045 (June 23, 1984) (Conference Report).

investment activity is any activity engaged in to produce income of a kind that would be foreign personal holding company income as defined in section 954(c). The proposed regulations further provide that investment activities will be treated as required to support or as substantially related to insurance or annuity contracts issued or reinsured by the foreign corporation to the extent that income from the activities is earned from assets held by the foreign corporation to meet obligations under the contracts.

The proposed regulations do not set forth a method to determine the portion of assets held to meet obligations under insurance and annuity contracts. Comments are requested on appropriate methodologies for determining the extent to which assets are held to meet obligations under insurance and annuity contracts.

The proposed regulations also do not define what it means to be “predominantly engaged” in an insurance business. Prior to 1984, the Code did not define an insurance company. Section 1.801–3(a) of the regulations, however, provides in relevant part that an insurance company is a company whose primary and predominant business activity during the taxable year is the issuing of insurance or annuity contracts or the reinsuring of risks underwritten by insurance companies.

In 1984, Congress enacted a definition of an “insurance company” that applied only to life insurance companies, and in 2004, a conforming amendment was made to apply the same definition to non-life insurance companies. See sections 816(a) and 831(c). Under this definition, in order for a corporation to be subject to tax as an insurance company under subchapter L, more than half of its business during the taxable year is required to be the issuing of insurance or annuity contracts or the reinsuring of risks underwritten by insurance companies. By requiring that more than half of the company’s business activity, rather than its predominant business activity, be insurance activity, the current subchapter L statutory rules adopt a stricter and more precise standard than the “primary and predominant” regulatory standard under prior law.<sup>2</sup>

<sup>2</sup> Committee on Ways and Means U.S. House of Representatives, Supplemental Report, The Deficit Reduction Act of 1984, 98th Cong. 2d Sess., H.R. Rept. 98–432, part 2, at 1402–3 (March 5, 1984); Committee on Finance United States Senate, The Deficit Reduction Act of 1984, 98th Cong. 2d Sess., S. Rpt. 98–169, vol. 1, at 525–6 (April 2, 1984); Committee on Ways and Means U.S. House of Representatives, Supplemental Report, The Deficit

Thus, any company taxable under subchapter L as an insurance company is necessarily predominantly engaged in an insurance business for purposes of section 1297(a)(2)(B).

#### Proposed Effective/Applicability Date

These regulations are proposed to apply on the date of publication of the Treasury decision adopting these rules as final regulations in the **Federal Register**.

#### Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. 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, this notice of proposed rulemaking has been submitted to the Chief Counsel of Advocacy of the Small Business Administration for comment on its impact on small business.

#### Comments and Requests for Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any comments that are submitted timely to the IRS as prescribed in this preamble under “Addresses.” Treasury and the IRS request comments on all aspects of the proposed rules. Comments specifically are requested with regard to how to determine the portion of a foreign insurance company’s assets that are held to meet obligations under insurance contracts issued or reinsured by the company. For example, assets could be considered as held to meet obligations under insurance or annuity contracts issued or reinsured by the corporation to the extent the corporation’s assets in the calendar year do not exceed a specified percentage of the corporation’s total insurance liabilities for the year (for example, the sum of the corporation’s “total reserves” (as defined in section 816(c)) plus (to the extent not included in total reserves) the items referred to in paragraphs (3),

Reduction Act of 1984, 98th Cong. 2d Sess., H.R. Rept. 98–432, part 2, at 1042–2 (March 5, 1984) (Conference Report); H.R. Rept. 108–457, Pension Funding Equity Act of 2004, 108th Cong. 2d Sess. at 52–53 (April 1, 2004).

(4), (5), and (6) of section 807(c)). Comments are requested with regard to what percentage would be appropriate. Also, comments are requested with regard to whether other methods would be more appropriate to determine the portion of assets that are held to meet obligations under insurance and annuity contracts.

All comments will be available at [www.regulations.gov](http://www.regulations.gov) or upon request. A public hearing will be scheduled if requested in writing by any person that timely submits comments. If a public hearing is scheduled, notice of the date, time, and place for the public hearing will be published in the **Federal Register**.

#### Drafting Information

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

#### List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

#### Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

#### PART 1—INCOME TAXES

■ **Par. 1.** The authority citation for part 1 is amended by adding an entry in numerical order to read in part as follows:

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

Section 1.1297–4 is also issued under 26 U.S.C. 1297(b)(2)(B) and 1298(g).

■ **Par. 2.** Section 1.1297–4 is added to read as follows:

#### § 1.1297–4 Exception from the definition of passive income for certain foreign insurance company income.

(a) *Income derived in the active conduct of an insurance business.* For purposes of section 1297, the term *passive income* does not include income earned by a foreign corporation that would be subject to tax under subchapter L if it were a domestic corporation, but only to the extent the income is derived in the active conduct of an insurance business.

(b) *Definitions.* The following definitions apply for purposes of paragraph (a) of this section—

(1) *Active conduct.* The term *active conduct* has the same meaning as in § 1.367(a)–2T(b)(3), except that officers and employees are not considered to

include the officers and employees of related entities as provided in § 1.367(a)-2T(b)(3).

(2) *Insurance business.* The term *insurance business* means the business of issuing insurance and annuity contracts and the reinsuring of risks underwritten by insurance companies, together with those investment activities and administrative services that are required to support or are substantially related to insurance and annuity contracts issued or reinsured by the foreign corporation. For purposes of the preceding sentence—

(i) An investment activity is any activity engaged in by the foreign corporation to produce income of a kind that would be foreign personal holding company income as defined in section 954(c); and

(ii) Investment activities are required to support or are substantially related to insurance and annuity contracts issued or reinsured by the foreign corporation to the extent that income from the activities is earned from assets held by the foreign corporation to meet obligations under the contracts.

(c) *Effective/applicability date.* These regulations apply beginning [EFFECTIVE DATE OF FINAL RULE].

**John M. Dalrymple,**

*Deputy Commissioner for Services and Enforcement.*

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[EPA-R01-OAR-2014-0796; EPA-R01-OAR-2014-0862; FRL-9926-73-Region 1]

#### Approval and Promulgation of Air Quality Implementation Plans; New Hampshire; Nonattainment New Source Review and Prevention of Significant Deterioration Program

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA) is proposing to conditionally approve the New Hampshire November 15, 2012 State Implementation Plan (SIP) revisions that are intended to ensure that the State's Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) programs are consistent with the federal PSD and NNSR program requirements. In a letter dated March 20, 2015, the New Hampshire

Department of Environmental Services (NH DES) committed to revising its regulations no later than one year from the date when EPA publishes a notice of final conditional approval, and to submitting the revised regulations to EPA for approval into the SIP. EPA is also proposing to fully approve a July 1, 2003 SIP revision that clarifies two definitions related to New Hampshire's permitting programs. These actions are being taken in accordance with the Clean Air Act (CAA).

**DATES:** Written comments must be received on or before May 26, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID Number EPA-R01-OAR-2014-0796 by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *Email:* [mcdonnell.ida@epa.gov](mailto:mcdonnell.ida@epa.gov)

3. *Fax:* (617) 918-0653

4. *Mail:* "Docket Identification Number EPA-R01-OAR-2014-0796", Ida McDonnell, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Permits, Toxics, and Indoor Programs Unit, 5 Post Office Square—Suite 100, (Mail code OEP05-2), Boston, MA 02109-3912.

5. *Hand Delivery or Courier.* Deliver your comments to: Ida McDonnell, Manager, Air Permits, Toxics, and Indoor Programs Unit, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, 5 Post Office Square—Suite 100, (mail code OEP05-2), Boston, MA 02109-3912. Such deliveries are only accepted during the Regional Office's normal hours of operation. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

*Instructions:* Direct your comments to Docket ID No. EPA-R01-OAR-2014-0796. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *www.regulations.gov*, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *www.regulations.gov*, or email, information that you consider to be CBI or otherwise protected. The *www.regulations.gov* Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you

provide it in the body of your comment. If you send an email comment directly to EPA without going through *www.regulations.gov* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

*Docket:* All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy at Office of Ecosystem Protection, U.S. Environmental Protection Agency, EPA New England Regional Office, Air Permits, Toxics and Indoor Programs Unit, 5 Post Office Square—Suite 100, Boston, MA. EPA requests that if at all possible, you contact the contact listed in the **FOR FURTHER INFORMATION CONTACT** section to schedule your inspection. The Regional Office's official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding legal holidays.

In addition, copies of the state submittal and EPA's proposed approval and technical support document are also available for public inspection during normal business hours, by appointment at the Air Resources Division, New Hampshire Department of Environmental Services, 6 Hazen Drive, P.O. Box 95, Concord, NH 03302-0095.

**FOR FURTHER INFORMATION CONTACT:** Brendan McCahill, U.S. Environmental Protection Agency, EPA New England Regional Office, Office of Ecosystem Protection, Air Permits, Toxics, and Indoor Programs Unit, 5 Post Office Square—Suite 100, (mail code OEP05-2), Boston, MA 02109-3912, telephone number (617) 918-1652, Fax number (617) 918-0652, email [mccahill.brendan@EPA.GOV](mailto:mccahill.brendan@EPA.GOV).