DATES: Effective date confirmed: March 18, 2008.

FOR FURTHER INFORMATION CONTACT: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 18, 2007 (72 FR 59000), FDA solicited comments concerning the direct final rule for a 75-day period ending January 2, 2008. FDA stated that the effective date of the direct final rule would be on March 18, 2008, 75 days after the end of the comment period, unless any significant adverse comment was submitted to FDA during the comment period. FDA received two letters of comment on the direct final rule. However, neither of these constitutes significant adverse comment. Therefore, FDA is confirming the effective date of the direct final rule. The two comments received were from private industry and an individual. The comments received and FDA's responses to the comments are discussed as follows:

Both comments requested clarification of the change under the new 21 CFR 600.11(e)(4)(i)(B), the language for which was taken directly from the existing 21 CFR 600.11(e)(4). One comment asked whether the requirements under this section are intended to cover research and development. The comment also asked for the definition of ''microorganism'' and whether ''test'' refers to viral inactivation.

The new provision mirrors the last sentence in the existing provision. The requirements under 21 CFR 600.11(e)(4)(i)(B) apply to buildings and equipment used for the manufacture of biological products regulated by FDA, not for research and development. We do not believe it is necessary to define the term ''microorganism,'' as this is a generally understood term, and is used throughout 21 CFR part 600. The terms ''test'' and ''test procedures'' do not refer to manufacturing steps such as viral inactivation.

Another comment asked whether the industry practice of using biological indicators for equipment or materials sterilization qualification is consistent with the requirements in new 21 CFR 600.11(e)(4)(i)(B).

This direct final rule does not apply to microorganisms used as biological indicators for validation, qualification or monitoring of sterilization cycles. The rule does not change the requirements for those products set forth in 21 CFR 600.11(e)(2).

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby become effective on March 18, 2008.

Dated: February 29, 2008.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E8–4471 Filed 3–6–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9385]

RIN 1545–BG65

Diversification Requirements for Variable Annuity, Endowment, and Life Insurance Contracts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations concerning the diversification requirements of section 817(h) of the Internal Revenue Code (Code). The regulations expand the list of holders whose beneficial interests in an investment company, partnership, or trust do not prevent a segregated asset account from looking through to the assets of the investment company, partnership, or trust, to satisfy the requirements of section 817(h). The regulations also remove the sentence in § 1.817–5(a)(2) that provides that the payment required to remedy an inadvertent diversification failure must be based on the tax that would have been owed by the policyholders if they were treated as receiving the income on the contract. The regulations affect insurance companies that issue variable contracts and affect policyholders who purchase such contracts.

DATES: *Effective/applicability date:* These regulations are effective as of *March 7, 2008.*

FOR FURTHER INFORMATION CONTACT: James Polfer, (202) 622–3970 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

Section 817(d) defines a variable contract for purposes of part I of subchapter L of the Code (sections 801–818). For a contract to be a variable contract, it must provide for the allocation of all or a part of the amounts received under the contract to an account that, pursuant to state law or regulation, is segregated from the general asset accounts of the issuing insurance company. In addition, for a life insurance contract to be a variable contract, it must qualify as a life insurance contract for Federal income tax purposes, and the amount of the death benefits (or the period of coverage) must be adjusted on the basis of the investment return and the market value of the segregated asset account; for an annuity contract to be a variable contract, it must provide for the payment of annuities, and the amounts paid in, or the amount paid out, must reflect the investment return and the market value of the segregated asset account; for a contract that provides funding of insurance on retired lives to be a variable contract, the amounts paid in, or the amounts paid out, must reflect the investment return and the market value of the segregated asset account.

Section 817(h)(1) provides that a variable contract that is based on a segregated asset account is not treated as an annuity, endowment, or life insurance contract unless the segregated asset account is adequately diversified in accordance with regulations prescribed by the Secretary. If a segregated asset account is not adequately diversified for a calendar quarter, then the contracts supported by that segregated asset account are not treated as annuity, endowment, or life insurance contracts for that period and subsequent periods, even if the segregated asset account is adequately diversified in those subsequent periods. Under § 1.817–5(a), if a segregated asset account is not adequately diversified, income earned by that segregated asset account is treated as ordinary income received or accrued by the policyholders. Section 1.817–5(a)(2) provides conditions an issuer of a variable contract must satisfy in order to correct an inadvertent failure to diversify. Rev. Proc. 92–25, 1992–1 CB 741, see § 601.601(d)(2) of this chapter, sets forth in more detail the procedure by which an issuer may request the relief described in § 1.817–5(a)(2).

Congress enacted the diversification requirements of section 817(h) to ''discourage the use of tax-preferred variable annuity and variable life insurance primarily as investment vehicles.'' H.R. Conf. Rep. No. 98–861, at 1055 (1984). In section 817(h)(1), Congress granted the Secretary broad regulatory authority to develop rules to carry out this intent. Congress directed that these standards be imposed because ''by limiting a customer's ability to

select specific investments underlying a variable contract, [adequate diversification] will help ensure that a customer's primary motivation in purchasing the contract is more likely to be the traditional economic protections provided by annuities and life insurance.'' S. Prt. 98–169, Vol. I at 546 (1984). A primary directive from Congress to Treasury in enacting the standards was to ''deny annuity or life insurance treatment for investments that are publicly available to investors.'' H.R. Conf. Rep. No. 98–861, at 1055 (1984).

Section 817(h)(4) provides a look-through rule under which taxpayers do not treat the interest in a regulated investment company (RIC) or trust as a single asset of the segregated asset account but rather apply the diversification tests by taking into account the assets of the RIC or trust. Section 817(h) further provides that the look-through rule applies only if all of the beneficial interests in a RIC or trust are held by one or more insurance companies (or affiliated companies) in their general account or segregated asset accounts, or by fund managers (or affiliated companies) in connection with the creation or management of the RIC or trust.

Under § 1.817–5(f)(1), if look-through treatment is available, a beneficial interest in a RIC, real estate investment trust, partnership, or trust that is treated under sections 671 through 679 as owned by the grantor or another person (''investment company, partnership or trust'') is not treated as a single investment of a segregated asset account for purposes of testing diversification. Instead, a pro rata portion of each asset of the investment company, partnership, or trust is treated as an asset of the segregated asset account. Section 1.817–5(f)(2)(i) provides that the look-through rule applies to any investment company, partnership, or trust if (1) all the beneficial interests in the investment company, partnership, or trust are held by one or more segregated asset accounts of one or more insurance companies; and (2) public access to the investment company, partnership, or trust is available exclusively through the purchase of a variable contract (except as otherwise permitted in § 1.817–5(f)(3)).

Under § 1.817–5(f)(3), look-through treatment is not prevented by reason of beneficial interests in an investment company, partnership, or trust that are

(1) Held by the general account of a life insurance company or a corporation related to a life insurance company, but only if the return on such interests is computed in the same manner as the return on an interest held by a segregated asset account is computed, there is no intent to sell such interests to the public, and a segregated asset account of such life insurance company also holds or will hold a beneficial interest in the investment company, partnership, or trust;

(2) Held by the manager, or a corporation related to the manager, of the investment company, partnership or trust, but only if the holding of the interests is in connection with the creation or management of the investment company, partnership or trust, the return on such interest is computed in the same manner as the return on an interest held by a segregated asset account is computed, and there is no intent to sell such interests to the public;

(3) Held by the trustee of a qualified pension or retirement plan; or

(4) Held by the public, or treated as owned by the policyholders pursuant to Rev. Rul. 81–225, see § 601.601(d)(2) of this chapter, but only if (A) the investment company, partnership or trust was closed to the public in accordance with Rev. Rul. 82–55, 1982–1 CB 12, see § 601.601(d)(2) of this chapter, or (B) all the assets of the segregated asset account are attributable to premium payments made by policyholders before September 26, 1981, to premium payments made in connection with a qualified pension or retirement plan, or to any combination of such premium payments.

On July 31, 2007, the Treasury Department and the IRS published a notice of proposed rulemaking (REG–118719–07) under section 817 in the **Federal Register** (72 FR 41651). The proposed regulations would expand the list of holders whose beneficial interests in an investment company, partnership, or trust do not prevent a segregated asset account from looking through to the assets of the investment company, partnership, or trust, to satisfy the requirements of section 817(h). The proposed regulations also would remove the sentence in § 1.817–5(a)(2) that provides that the payment required to remedy an inadvertent diversification failure must be based on the tax that would have been owed by the policyholders if they were treated as receiving the income on the contract. One written comment was received in response to the notice of proposed rulemaking, and no public hearing was requested or held. After consideration of the comment, the proposed regulations are adopted as final regulations with the change discussed below.

Summary of Comment and Explanation of Revisions

Comment on the Proposed Regulation

A. Amendment to § 1.817–5(a)(2) (Remedy for Inadvertent Nondiversification)

The regulations remove the sentence in § 1.817–5(a)(2) that provides that the payment required to remedy an inadvertent diversification failure must be based on the tax that would have been owed by the policyholders if they were treated as receiving the income on the contract.

The commentator supports the removal of the sentence. The commentator also suggested that the correction procedures under section 817(h) should be modified to (1) provide flexibility to more appropriately address various fact patterns, (2) encourage taxpayers to establish compliance practices and procedures, (3) promote compliance by providing limited fees for voluntary corrections, (4) provide for fees and sanctions in graduated steps to ensure that there is always an incentive for prompt correction, and (5) provide for sanctions that are reasonable in light of the nature, extent, and severity of the violation. The Treasury Department and the IRS will consider these comments in the course of evaluating what steps, if any, to take in response to submissions received concerning correction procedures more generally under Notice 2007–15, 2007–7 I.R.B. 503 (February 12, 2007).

B. Expansion of List of Permitted Investors Under § 1.817–5(f)(3)

The regulations expand the list of permitted investors in § 1.817–5(f)(3) to include (i) qualified tuition programs as defined in section 529, (ii) trustees of pension or retirement plans established and maintained outside of the United States primarily for the benefit of individuals substantially all of whom are nonresident aliens, and (iii) an account which, pursuant to Puerto Rican law or regulation, is segregated from the general asset accounts of the life insurance company that owns the account, provided the requirements of section 817(d) and (h) are satisfied.

The commentator supports such an expansion of the list of permitted investors and urged that the list be further expanded to include segregated asset accounts of any foreign insurer that makes an election under section 953(d) to be treated as a domestic corporation for U.S. tax purposes. A general rule to this effect would be beyond the scope of the proposed regulations and may require a more

specific examination of the manner in which such accounts are segregated under the applicable foreign law. Accordingly, such an expansion is not provided in these regulations, but the Treasury Department and IRS will consider the issue for possible future published guidance.

The commentator also urged that guidance is needed concerning (1) what steps must be taken to verify that an entity is a permitted investor, and (2) what happens if, despite verification efforts, the entity in question was never a permitted investor or subsequently loses its status as such. The Treasury Department and IRS are aware of this issue, but have concluded it is beyond the scope of the proposed regulations and at this time might better be addressed by Internal Revenue Bulletin guidance or by letter ruling. Accordingly, the issue is not addressed in these final regulations, but the Treasury Department and IRS will consider the issue for possible future published guidance.

Finally, the commentator suggested that the language of the amendment that expands the list of permitted investors to include certain Puerto Rican accounts should be clarified to eliminate confusion. Specifically, in the notice of proposed rulemaking, the proviso clause of the amendment stated that such an account will be a permitted investor ''provided the requirements of section 817(d) and (h) are satisfied.'' The commentator expressed concern that the language of the amendment as written in the notice of proposed rulemaking could be read to present an issue of circularity (that is, to be a permitted investor, the account must satisfy section 817(h), but to satisfy section 817(h), the account must be a permitted investor.) To eliminate this potential confusion, the final regulations state that, solely for purposes of § 1.817–5(f)(3)(vi), the requirement under section 817(d)(1) that the account be segregated pursuant to State law or regulation shall be disregarded and § 1.817–5(f)(1) shall be applied without regard to the Puerto Rican segregated asset account.

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 Internal Revenue Code, the notice of proposed rulemaking preceding this regulation was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these final regulations is James Polfer, Office of the Associate Chief Counsel (Financial Institutions and Products), Internal Revenue Service. However, personnel from other offices of the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

■ Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAX

■ **Paragraph 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 1.817–5 also issued under 26 U.S.C. 817(h).

■ **Par. 2.** Section 1.817–5 is amended as follows:

■ 1. The last sentence of paragraph (a)(2)(iii) is removed.

■ 2. Paragraph (f)(3)(iii) is revised.

■ 3. Paragraph (f)(3)(iv) is redesignated as paragraph (f)(3)(vii).

■ 4. New paragraphs (f)(3)(iv) through (vi) are added.

■ The revisions and additions read as follows:

§ 1.817–5 Diversification requirements for variable annuity, endowment, and life insurance contracts.

* * * * *

(f) * * *

(3) * * *

(iii) Held by the trustee of a qualified pension or retirement plan;

(iv) Held by a qualified tuition program as defined in section 529;

(v) Held by the trustee of a pension plan established and maintained outside of the United States, as defined in section 7701(a)(9), primarily for the benefit of individuals substantially all of whom are nonresident aliens, as defined in section 7701(b)(1)(B);

(vi) Held by an account which, pursuant to Puerto Rican law or regulation, is segregated from the general asset accounts of the life insurance company that owns the account, provided the requirements of section 817(d) and (h) are satisfied. Solely for purposes of this paragraph (f)(3)(vi), the requirement under section 817(d)(1) that the account be segregated pursuant to State law or regulation shall be disregarded and § 1.817–5(f)(1) shall be applied without regard to the Puerto Rican segregated asset account; or

* * * * *

Linda E. Stiff,

Deputy Commissioner for Services and Enforcement.

Approved: February 29, 2008.

Eric Solomon,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. E8–4577 Filed 3–6–08; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9383]

RIN 1545–BH21

Guidance Under Section 1502; Amendment of Matching Rule for Certain Gains on Member Stock

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations concerning the treatment of certain intercompany gain with respect to consolidated group member stock. These amendments provide for the redetermination of an intercompany gain as excluded from gross income in certain member stock transactions. These regulations affect corporations filing consolidated returns. The text of these temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

DATES: *Effective Date:* These regulations are effective on *March 7, 2008.*

Applicability Date: For dates of applicability, see § 1.1502–13T(c)(6)(ii)(C)(*2*) and (f)(7)(ii).

FOR FURTHER INFORMATION CONTACT: John F. Tarrant or Ross E. Poulsen, (202) 622–7790 (not a toll-free number).

SUPPLEMENTARY INFORMATION: