

II. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so it is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Classification of these devices into class II will relieve manufacturers of the device of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs. The agency, therefore, certifies that the final rule will not have a significant impact on a substantial number of small entities. In addition, this final rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act is not required.

IV. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the 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.

V. Paperwork Reduction Act of 1995

This final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

VI. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Veridex, LLC, dated December 24, 2003.

List of Subjects in 21 CFR Part 866

Biologics, Laboratories, Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 866 is amended as follows:

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 866.6020 is added to subpart G to read as follows:

§ 866.6020 Immunomagnetic circulating cancer cell selection and enumeration system.

(a) *Identification.* An immunomagnetic circulating cancer cell selection and enumeration system is a device that consists of biological probes, fluorochromes, and other reagents; preservation and preparation devices; and a semiautomated analytical instrument to select and count circulating cancer cells in a prepared sample of whole blood. This device is intended for adjunctive use in monitoring or predicting cancer disease progression, response to therapy, and for the detection of recurrent disease.

(b) *Classification.* Class II (special controls). The special control for this device is FDA's guidance document entitled "Class II Special Controls Guidance Document: Immunomagnetic

Circulating Cancer Cell Selection and Enumeration System." See § 866.1(e) for availability of this guidance document.

Dated: April 26, 2004.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9127]

RIN 1545–BC47

Reduction of Tax Attributes Due to Discharge of Indebtedness

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final regulations regarding the reduction of tax attributes under sections 108 and 1017 of the Internal Revenue Code. These final regulations affect taxpayers that realize income from the discharge of indebtedness that is excluded from gross income pursuant to section 108.

DATES: *Effective Date:* These final regulations are effective May 10, 2004.

Applicability Date: These final regulations apply to discharges of indebtedness occurring on or after May 10, 2004.

FOR FURTHER INFORMATION CONTACT: Theresa M. Kolish (202–622–7530) of the Office of Associate Chief Counsel (Corporate) (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

On July 18, 2003, the IRS and Treasury Department promulgated temporary regulations providing guidance regarding the application of the attribute reduction rules of sections 108 and 1017. Those temporary regulations clarified that, in the case of a transaction described in section 381(a) that ends a year in which the distributor or transferor corporation excludes income from the discharge of indebtedness from gross income under section 108(a)(excluded COD income), any tax attributes to which the acquiring corporation succeeds, including the basis of property acquired by the acquiring corporation in the transaction, must reflect the reductions required by

sections 108 and 1017. For this purpose, all attributes listed in section 108(b)(2) of the distributor or transferor corporation immediately prior to the transaction described in section 381(a), including the basis of property, but after the determination of tax for the year of the discharge, are available for reduction under section 108(b)(2).

The temporary regulations were published in the **Federal Register** (68 FR 42590) for July 18, 2003, and a notice of proposed rulemaking (Reg-113112-03) cross-referencing the temporary regulations was published in the **Federal Register** for the same day (68 FR 42652). No public hearing was requested or held. One written comment was received. The following paragraphs describe the written comment received and the changes made to the temporary regulations in these final regulations.

The comment received argued that the rules of the temporary regulations are contrary to the relevant provisions of the Internal Revenue Code. The IRS and Treasury Department continue to believe that the rules of sections 108(b)(4)(A) and 1017 merely prescribe an ordering of calculations and that the rules of the temporary regulations are consistent with the policies underlying sections 108 and 1017 and the corporate reorganization provisions, including "deferring, but eventually collecting within a reasonable period, tax on ordinary income realized from debt discharge." S. Rep. No. 96-1035, at 10 (1980).

The IRS and Treasury Department, however, have become aware that taxpayers are taking the position that the rules of the temporary regulations do not apply in certain cases to reduce the attributes to which the acquiring corporation succeeded as a result of certain transactions described in section 381(a). Therefore, these final regulations make certain modifications to the rules of the temporary regulations to ensure that, to the extent possible, the transferor corporation's excluded COD income is applied to reduce attributes in a manner that will effect a deferral, rather than a permanent elimination, of income. In that regard, the final regulations apply in cases in which the taxpayer realizes excluded COD income either during or after the taxable year in which the taxpayer is the distributor or transferor of assets in a transaction described in section 381(a). In addition, it provides that the basis of stock or securities of the acquiring corporation received by the taxpayer in exchange for the transferred assets in the transaction described in section 381(a) is not available for reduction under section 108(b)(2).

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 these 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 notice of proposed rulemaking preceding these regulations 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 regulations is Theresa M. Kolish, Office of Associate Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Final Amendments to the Regulations

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

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 is amended by removing the entry for "1.108-7T" and continues to read, in part, as follows:

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

■ **Par. 2.** Section 1.108-7T is redesignated as § 1.108-7 and amended as follows:

- 1. The language "(temporary)" is removed from the section heading.
 - 2. Paragraphs (c) and (e) are revised.
- The revisions read as follows:

§ 1.108-7 Reduction of attributes.

* * * * *

(c) *Transactions to which section 381 applies.* If a taxpayer realizes COD income that is excluded from gross income under section 108(a) either during or after a taxable year in which the taxpayer is the distributor or transferor of assets in a transaction described in section 381(a), any tax attributes to which the acquiring corporation succeeds, including the basis of property acquired by the acquiring corporation in the transaction, must reflect the reductions required by section 108(b). For this purpose, all

attributes listed in section 108(b)(2) immediately prior to the transaction described in section 381(a), but after the determination of tax for the year of the distribution or transfer of assets, including basis of property, will be available for reduction under section 108(b)(2). However, the basis of stock or securities of the acquiring corporation, if any, received by the taxpayer in exchange for the transferred assets shall not be available for reduction under section 108(b)(2).

* * * * *

(e) *Effective date.* This section applies to discharges of indebtedness occurring on or after May 10, 2004.

■ **Par. 3.** Section 1.1017-1 is amended by revising paragraph (b)(4) to read as follows:

§ 1.1017-1 Basis reductions following a discharge of indebtedness.

* * * * *

(b) * * *

(4) *Transactions to which section 381 applies.* If a taxpayer realizes COD income that is excluded from gross income under section 108(a) either during or after a taxable year in which the taxpayer is the distributor or transferor of assets in a transaction described in section 381(a), the basis of property acquired by the acquiring corporation in the transaction must reflect the reductions required by section 1017 and this section. For this purpose, the basis of property of the distributor or transferor corporation immediately prior to the transaction described in section 381(a), but after the determination of tax for the year of the distribution or transfer of assets, will be available for reduction under section 108(b)(2). However, the basis of stock or securities of the acquiring corporation, if any, received by the taxpayer in exchange for the transferred assets shall not be available for reduction under section 108(b)(2). See § 1.108-7. This paragraph (b)(4) applies to discharges of indebtedness occurring on or after May 10, 2004.

■ **Par. 4.** In § 1.1017-1T, paragraph (b)(4) is removed and the entry for paragraphs (a) through (b)(3) is revised to read as follows:

§ 1.1017-1T Basis reductions following a discharge of indebtedness (temporary).

(a) through (b)(4) [Reserved]. For further guidance, see § 1.1017-1(a) through (b)(4).

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Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Approved: May 4, 2004.

Gregory F. Jenner,

Acting Assistant Secretary of the Treasury.

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DEPARTMENT OF THE TREASURY**Internal Revenue Service****26 CFR Part 1**

[TD 9128]

RIN 1545-BB73

Real Estate Mortgage Investment Conduits; Application of Section 446 With Respect to Inducement Fees

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulation.

SUMMARY: This document contains final regulations relating to the proper timing and source of income from fees received to induce taxpayers to become the holders of noneconomic residual interests in Real Estate Mortgage Investment Conduits (REMICs).

DATES: *Effective Date:* These regulations are effective May 11, 2004.

Applicability Dates: For dates of applicability of the final regulations, see §§ 1.446-6(g) and 1.863-1(f).

FOR FURTHER INFORMATION CONTACT: For information concerning accounting for inducement fees relating to noneconomic REMIC residual interests, contact John W. Rogers III at (202) 622-3950 (not a toll-free number). For information concerning the source of REMIC inducement fee income, contact Bethany Ingwalson at (202) 622-3850 (not a toll-free number).

SUPPLEMENTARY INFORMATION:**Background**

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under sections 446(b)(relating to general rules for methods of accounting), 860C (relating to other definitions and special rules applicable to REMICs), and 863(a)(relating to special rules for determining source) of the Internal Revenue Code of 1986 (Code). On July 21, 2003, the IRS and

Treasury Department published a notice of proposed rulemaking (REG-162625-02) in the **Federal Register** (68 FR 43055).

In the notice of proposed rulemaking the IRS and Treasury Department requested comments on the proper method of accounting to be used by taxpayers for inducement fee income. No written or electronic comments were received from the public in response to the notice of proposed rulemaking. No requests to speak at the public hearing were received, and, accordingly, the hearing was canceled. Therefore, these final regulations adopt without substantive changes the proposed regulations set out in the notice of proposed rulemaking.

Explanation of Provisions

Final regulations governing REMICs, issued in 1992, contain rules governing the transfer of noneconomic residual interests. Those regulations do not, however, contain rules that address the transferee's treatment of the fee received to induce the transferee to become the holder of a noneconomic residual interest. Following release of the final REMIC regulations, the IRS and the Treasury Department received requests for guidance on the proper method of accounting to be used by taxpayers for inducement fee income. These regulations provide rules relating to the proper timing and source of income from an inducement fee received in connection with becoming the holder of a noneconomic residual interest in a REMIC.

The notice of proposed rulemaking published on July 21, 2003, stated that, to clearly reflect income, an inducement fee must be included in income over a period that is reasonably related to the period during which the applicable REMIC is expected to generate taxable income or net loss allocable to the holder of the noneconomic residual interest. The notice of proposed rulemaking further stated that an inducement fee generally may not be taken into account in a single tax year. The notice of proposed rulemaking also set forth two safe harbor methods of accounting for inducement fees and contained a rule clarifying that an inducement fee is income from sources within the United States. The final regulations adopt these provisions without substantive change. For further information on the rationale for the rules set out in these final regulations, see the preamble for the proposed regulations in the notice of proposed rulemaking.

The effective date provision of § 1.446-6(g) contained in the notice of

proposed rulemaking stated that these regulations would become effective upon publication of the final regulations in the **Federal Register**. The notice of proposed rulemaking specifically requested comments on whether the applicability of these regulations should be limited to transactions arising on or after their effective date and whether some delay in the effective date of these regulations is warranted. No comments were received from the public in response to this request. In finalizing these regulations, the IRS and Treasury Department have determined not to limit the applicability of these regulations to transactions arising on or after the effective date of the final regulations or to delay the effective date. The effective date provision in § 1.446-6(g), therefore, is also adopted without substantive change.

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 these regulations, and because these 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 notice of proposed rulemaking preceding these regulations 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 regulations is John W. Rogers III, Office of Associate Chief Counsel (Financial Institutions & Products). 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.

Adoption of Amendments to the Regulations

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

PART 1—INCOME TAXES

■ **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 * * *