

does not make any changes to existing requirements, and thus, does not impose any new costs on facilities, the agency certifies that this final rule will not have a significant impact on a substantial number of small entities. Full analysis of the effect of the registration requirement on small entities is provided in the analysis of economic impacts set out in the preceding analysis of economic impacts and in the preamble to the interim final rule at 68 FR 58894 at 58954.

V. Unfunded Mandates

Section 202 of the Unfunded Mandates Reform Act of 1995 (Public Law 104-4) requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$115 million, using the most current (2003) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any one-year expenditure that would meet or exceed this amount.

VI. Federalism Analysis

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 concludes that the final 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.

VII. The Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The title, description, and respondent description of the information collection provisions and an estimate of the annual reporting burden were provided in the interim final rule issued October 10, 2003 (68 FR 58894). Included in the estimate was the time for reviewing instructions,

searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information. The final rule requires no new information collection. Individuals and organizations may submit comments on the burden estimates or on any other aspect of these information collection provisions, including suggestions for reducing the burden, and should direct them to the contact person identified in the **FOR FURTHER INFORMATION CONTACT** section of this document. The information collection provisions in this final rule have been approved under OMB control number 0910-0502. This approval expires October 31, 2006. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

VIII. Analysis of Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

List of Subjects

21 CFR Part 1

Cosmetics, Drugs, Exports, Food labeling, Imports, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

PART 1—GENERAL ENFORCEMENT REGULATIONS

PART 20—PUBLIC INFORMATION

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the interim rule amending 21 CFR parts 1 and 20, which was published at 68 FR 58894 (October 10, 2003) and amended at 69 FR 29428 (May 24, 2004), is adopted as a final rule without change.

Dated: August 28, 2005.

Michael Chertoff,

Secretary of Homeland Security.

Dated: September 20, 2005.

Michael O. Leavitt,

Secretary of Health and Human Services.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9226]

RIN 1545-BD27

Stock Held by Foreign Insurance Companies

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations relating to the determination of income of foreign insurance companies that is effectively connected with the conduct of a trade or business within the United States. The regulations provide that the exception to the asset-use test for stock shall not apply in determining whether the income, gain, or loss from portfolio stock held by foreign insurance companies constitutes effectively connected income.

DATES: *Effective Date:* These regulations are effective on October 3, 2005.

FOR FURTHER INFORMATION CONTACT: Sheila Ramaswamy, (202) 622-3870 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On June 25, 2004, a notice of proposed rulemaking (REG-117307-04) was published in the **Federal Register** (69 FR 35543). No requests for a public hearing were received, and no public hearing was held. The IRS received one written comment in response to the notice of proposed rulemaking. After consideration of the comment, the proposed regulation is adopted without change.

Explanation of Provisions and Summary of Comments

This Treasury decision adopts the language of the proposed regulation without change.

The IRS received one comment in response to the proposed regulation. The commentator requested further clarification regarding what constitutes

an insurance company for federal income tax purposes. The IRS believes the issue of what constitutes an insurance company is outside the scope of this regulation, which solely relates to the application of the asset-use test to stock held by foreign insurance companies.

The commentator also expressed concern about the interaction of the proposed regulation with § 1.864-5(a), which provides, generally, that foreign source income, such as a foreign-source dividend or gain, cannot constitute U.S. effectively connected income in circumstances in which a U.S.-source dividend or gain would not constitute U.S. effectively connected income. Accordingly, the commentator is concerned that the rule in the regulations will also expand the category of foreign-source dividends or gains that may constitute effectively connected income. That is true and the Treasury Department and the IRS believe this is the appropriate result.

The IRS invited comments whether the 10 percent threshold provided in the proposed regulation was an appropriate standard for determining whether stock is a portfolio investment. The commentator stated that it was possible for insurance companies to make a strategic investment in a corporation at a level below 10 percent of the vote or value of the corporation, such as by purchasing a special class of shares that conveyed the power to elect directors. The commentator recommended creating a rebuttable presumption of portfolio status.

We do not believe that treating the 10 percent threshold as a rebuttable presumption is appropriate. The 10 percent threshold provides a reasonable method for identifying portfolio stock held by a branch of a foreign life insurance company.

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 provisions of the Regulatory Flexibility Act (5 U.S.C. chapter 6) do 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 this regulation is Sheila Ramaswamy, Office of Associate Chief Counsel (International). 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.

Proposed Amendment to the Regulations

■ Accordingly, 26 CFR part 1 is 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.** In § 1.864-4, paragraph (c)(2)(iii)(b) is revised to read as follows:

§ 1.864-4 U.S. source income effectively connected with U.S. business.

* * * * *

(c) * * *

(2) * * *

(iii) * * *

(b) *Stock held by foreign insurance companies.* This paragraph (c)(2)(iii) shall not apply to stock of a corporation (whether domestic or foreign) held by a foreign insurance company unless the foreign insurance company owns 10 percent or more of the total voting power or value of all classes of stock of such corporation. For purposes of this section, section 318(a) shall be applied in determining ownership, except that in applying section 318(a)(2)(C), the phrase “10 percent” is used instead of the phrase “50 percent.”

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Mark E. Matthews,

Deputy Commissioner for Services and Enforcement.

Approved: August 9, 2005.

Eric Solomon,

Acting Deputy Assistant Secretary for Tax Policy.

[FR Doc. 05-19622 Filed 9-30-05; 8:45 am]

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EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

29 CFR Part 1610

RIN 3046-AA75

Freedom of Information Act Fee Schedule

AGENCY: Equal Employment Opportunity Commission.

ACTION: Final rule.

SUMMARY: The Equal Employment Opportunity Commission (EEOC or the Commission) is adopting revisions to its Freedom of Information Act (FOIA) fee schedule. The updated schedule of fees reflects increases in the direct costs incurred by the Commission in responding to requests for records.

DATES: October 3, 2005.

FOR FURTHER INFORMATION CONTACT: Thomas J. Schlageter, Assistant Legal Counsel, or Michelle Zinman, Senior General Attorney at (202) 663-4640 (voice) or (202) 663-7026 (TTY). This notice of final rule is also available in the following formats: large print, Braille, audiotape and electronic file on computer disk. Requests for this notice of final rule in an alternative format should be made to EEOC's Publication Center at 1-800-669-3362.

SUPPLEMENTARY INFORMATION: On July 1, 2005, at 70 FR 38060-01, the EEOC published a notice of proposed rulemaking proposing to amend the sections of 29 CFR part 1610 that concern the fees assessed to persons who seek agency records under the FOIA. The changes comply with the Office of Management and Budget's Uniform Freedom of Information Act Fee Schedule and Guidelines, 52 FR 10012 (1987). Comments from the public were due on or before August 31, 2005. No comments were received. Therefore, EEOC is adopting the proposed revisions, without change, as its final rule.

Regulatory Procedures

Executive Order 12866

Pursuant to Executive Order 12866, EEOC has determined that the regulation will not have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State or local tribal governments or communities. Therefore, a detailed cost-benefit assessment of the regulation is not required.