COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 140

Amendment to Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission; Receipt and Disposition of Foreign Gifts and Decorations

AGENCY: Commodity Futures Trading Commission.

ACTION: Final amendment.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is amending a provision of its regulations, 17 CFR 140.735–4 (1998), which sets forth the responsibilities of Commission members and employees concerning the receipt and disposition of gifts and decorations from foreign governments. The Commission adopted this regulation in 1982 to comply with the Foreign Gifts and Decorations Act, 5 U.S.C. 7342 (1994). The amendment clarifies the fact that gifts of travel expenses in excess of minimal value must be reported to and approved by the CFTC's Executive Director in accordance with the procedures set forth in the Commission's regulation whereas the receipt of travel benefits or expenses for services rendered need not be reported. The Commission is publishing this amendment in final form without soliciting comments pursuant to 5 U.S.C. 553(b)(3) because it involves a rule of agency procedure and does not alter current requirements. Therefore, notice and public procedure would be unnecessary.

EFFECTIVE DATE: June 16, 1998.

FOR FURTHER INFORMATION CONTACT: George Wilder, Office of General Counsel, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581, (202) 418–5120, or electronically at gwilder@cftc.gov.

SUPPLEMENTARY INFORMATION: The Commission amends its regulation concerning the receipt and disposition of foreign gifts and decorations to conform more clearly to the statutory provisions enacted by Congress. This amendment clarifies that an employee, which includes the spouse of a Commission member or employee, need not report his or her acceptance of travel benefits or expenses provided in exchange for services rendered. This situation is most likely to arise when the spouse of a Commission member or employee provides services to a foreign government or other organization described in Rule 140.735–4. In such circumstances, the acceptance of travel expenses will not trigger the reporting requirements of the Commission's regulation.

The Commission finds that this rule amendment relates solely to agency organization, procedure and practice. Therefore, the provisions of the Administrative Procedure Act, 5 U.S.C. 553, generally requiring notice of proposed rulemaking and opportunity for public comment, are not applicable. The Commission further finds that, because the amendment does not alter current requirements and only affects Commission members and employees who will be notified by internal means, there is good cause to make this amendment effective upon publication in the **Federal Register**.

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601–611 (1994 and Supp. II (1996)), requires that agencies, in proposing rules, consider the impact of those rules on small businesses. Section 3(a) of the RFA defines the term ''rule'' to mean ''any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of this title * * * for which the agency provides an opportunity for notice and public comment.'' 5 U.S.C. § 601(2). Since the amendment to the Commission's regulation was not effected pursuant to Section 553(b), it is not a ''rule'' as defined in the RFA, and the analysis and certification process required by that statue does not apply.

List of Subjects in 17 CFR Part 140

Organization and functions (Government agencies).

In consideration of the foregoing, the Commission amends Title 17, Part 140 of the Code of Federal Regulations as follows:

PART 140—ORGANIZATION, FUNCTIONS, AND PROCEDURES OF THE COMMISSION

Subpart C—Regulation Concerning Conduct of Members and Employees and Former Members and Employees of the Commission

1. The authority citation for Part 140 continues to read as follows:

Authority: 7 U.S.C. 4a (f) and (j), 12a(5), and 13.

2. Section 140.735–4 is amended by revising paragraphs (b)(3) and (c)(5) introductory text to read as follows:

§ 140.735–4 Receipt and disposition of foreign gifts and decorations.

* * * * *

(b) * * *

* * * * *

(3) Accept gifts of travel or gifts of expenses for travel, such as transportation, food and lodging, from foreign governments, other than those authorized in paragraph (c)(5) of this section; or

* * * * *

(c) * * *

* * * * *

(5) Commission members and employees are authorized to accept from a foreign government gifts of travel or gifts of expenses for travel taking place entirely outside the United States, such as transportation, food and lodging, of more than minimal value if the acceptance is approved by the Executive Director, upon a finding that it is consistent with the interests of the Commission. Either prior to or within 30 days after accepting each gift of travel or gift of travel expenses pursuant to this paragraph, the Commission member or employee concerned shall file a statement with the Executive Director containing the following information:

* * * * *

Dated: June 5, 1998.

Issued by the Commission.

Jean A. Webb,

Secretary of the Commission, Commodity Futures Trading Commission.

[FR Doc. 98–15720 Filed 6–15–98; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 10

[Docket No. 98N–0361]

Administrative Practices and Procedures; Internal Review of Agency Decisions

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing the review of agency decisions by inserting a statement that sponsors, applicants, or manufacturers of drugs (including biologics) or devices may request review of a scientific controversy by an appropriate scientific advisory panel, or an advisory committee. This action is being taken to clarify the availability of review of scientific controversies by such advisory panels and committees.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a companion proposed rule. If any significant adverse comment is received, FDA will withdraw the direct final rule and will follow its usual procedures for notice-and-comment rulemaking based on the companion proposed rule.

DATES: The regulation is effective October 29, 1998. Submit written comments by August 31, 1998. If a timely significant adverse comment is received, FDA will publish a document of significant adverse comment in the **Federal Register** by September 29, 1998. If no timely significant adverse comment is received, FDA will publish a document in the **Federal Register** by September 29, 1998, to confirm the effective date of October 29, 1998.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Suzanne M. O'Shea, Office of the Chief Mediator and Ombudsman (HF–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3390.

SUPPLEMENTARY INFORMATION:

I. Discussion

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115). Section 404 of FDAMA amends the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et seq.*) by adding a new provision, Dispute Resolution (section 562 of the act (21 U.S.C. 360bbb-1)). Under the dispute resolution provision, FDA is to determine the existence of procedures for sponsors, applicants, and manufacturers of drugs (including biologics) or devices to request review of scientific controversies. Where such procedures do not exist, FDA is directed to issue a regulation establishing a procedure by which a sponsor, applicant, or manufacturer of a drug or device may request review of a scientific controversy, including review by an appropriate scientific advisory panel as described in section 505(n) of the act[1] (21 U.S.C. 355(n)), or an advisory committee as described in section 515(g)(2)(B) of the act (21 U.S.C. 360e(g)(2)(B)).

FDA procedures currently provide mechanisms for sponsors, applicants, or manufacturers of drugs and devices to request review of all scientific controversies. Agency regulations and policy statements contain numerous procedures for obtaining review of scientific controversies affecting regulated products, including some that provide for review by an FDA advisory panel or committee. Moreover, any interested person[2] may obtain review of any agency decision by raising the matter with the supervisor of the employee who made the decision. If the issue is not resolved at the supervisor's level, the interested person may request that the matter be reviewed at the next higher supervisory level. This process may continue through the agency's chain of command (§ 10.75 (21 CFR 10.75)).

Notwithstanding the existence of these dispute resolution provisions, FDA is amending § 10.75 in light of FDAMA, to clarify that sponsors, applicants, or manufacturers of a drug or device subject to the act, or a product covered by the Public Health Service Act (42 U.S.C. 262), may request review of scientific controversies by an appropriate scientific advisory committee. FDA recommends that sponsors, applicants, and manufacturers continue to use established mechanisms for obtaining review of scientific controversies prior to seeking review by an advisory panel or committee. FDA recognizes however, that in appropriate circumstances, review by such an advisory committee may provide FDA with useful advice and recommendations about how the agency may best resolve a controversy.

II. Rulemaking Procedures

FDA described its procedures for direct final rulemaking in the **Federal Register** of November 21, 1997 (62 FR 62466). This action is appropriate for direct final rulemaking because it is a noncontroversial amendment to FDA's regulations that is in accord with FDAMA. Furthermore, FDA anticipates no significant adverse comments. Consistent with FDA's procedures for direct final rulemaking, FDA will withdraw this direct final rule if it receives any significant adverse comment. If this direct final rule is withdrawn, FDA will consider all comments received to develop a final rule using the usual notice and comment rulemaking procedures, based on the companion proposed rule published in the proposed rules section of this issue of the **Federal Register**.

FDA is providing a period of 75 days for comment on this direct final rule, to run concurrently with the comment period for the companion proposed rule. This comment period begins on June 16, 1998, and ends on August 31, 1998. If FDA receives a significant adverse comment, the agency will publish a document of significant adverse comment in the **Federal Register** to withdraw the direct final rule by September 29, 1998. If FDA receives no significant adverse comment during the comment period, it will publish a document in the **Federal Register** by September 29, 1998, to confirm the October 29, 1998, effective date of this direct final rule.

A significant adverse comment is defined as a comment that explains why the rule would be inappropriate, including challenges to the rule's underlying premise or approach, or would be ineffective or unacceptable without a change. In determining whether a significant adverse comment is sufficient to terminate a direct final rulemaking, FDA will consider whether the comment raises an issue serious enough to warrant a substantive response in a notice-and-comment process. Comments that are frivolous, insubstantial, or outside the scope of the rule will not be considered significant or adverse under this procedure. For example, a comment requesting inclusion of consumer representatives on an FDA advisory committee will not be considered a significant adverse comment because it is outside the scope of this rule. A comment suggesting a change in addition to that proposed by the rule would not be considered a significant adverse comment, unless, as explained by the comment, the rule would be ineffective without change.

III. Analysis of Impacts

A. 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.

B. Economic Impact

In accordance with Executive Order 12866, FDA has carefully analyzed the economic effect of this rule and has determined that it is not a major rule as defined by the Executive Order.

[1] FDA understands the term ''scientific advisory panel'' to mean a public advisory committee as discussed in 21 CFR part 14.

[2] An interested person, as defined in 21 CFR 10.3, is a person who submits a petition or comment or objection or otherwise asks to participate in an informal or formal administrative proceeding or court action. This definition of interested person includes a sponsor, applicant, or manufacturer of a drug or device.

FDA, in accordance with the Regulatory Flexibility Act, has considered the effect that this rule will have on small entities, including small businesses, and has determined that no significant economic impact on a substantial number of small entities will derive from this action.

IV. Paperwork Reduction Act of 1995

The direct 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.

V. Request for Comments

Interested persons may, on or before August 31, 1998, submit to the Dockets Management Branch (address above) written comments regarding this rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. The comment period for the direct final rule runs concurrently with that of the companion proposed rule. Any comments received under the companion proposed rule will be considered as comments regarding this direct final rule. Likewise, any comment submitted under the direct final rule will be considered as comments to the companion proposed rule in the event the direct final rule is withdrawn.

List of Subjects in 21 CFR Part 10

Administrative practice and procedure, News media.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and authority delegated to the Commissioner of Food and Drugs, 21 CFR part 10 is amended as follows:

PART 10—ADMINISTRATIVE PRACTICES AND PROCEDURES

1. The authority citation for 21 CFR part 10 is revised to read as follows:

Authority: 5 U.S.C. 551–558, 701–706; 15 U.S.C. 1451–4161; 21 U.S.C. 141–149, 321–397, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264.

2. Section 10.75 is amended by adding a sentence at the end of paragraph (b) to read as follows:

§ 10.75 Internal agency review of decisions.

* * * * *

(b) * * * A sponsor, applicant, or manufacturer of a drug or device regulated under the act or the Public Health Service Act (42 U.S.C. 262), may request review of a scientific controversy by an appropriate scientific advisory panel as described in section 505(n) of the act, or an advisory committee as described in section 515(g)(2)(B) of the act.

* * * * *

Dated: June 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–15815 Filed 6–15–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 31

[TD 8771]

RIN 1545–AW29

Federal Employment Tax Deposits—De Minimis Rule

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Temporary and final regulations.

SUMMARY: This document contains temporary and final regulations relating to the deposit of Federal employment taxes. The regulations change the de minimis deposit rule for quarterly and annual return periods. The regulations affect taxpayers required to make deposits of Federal employment taxes. The text of the 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 of this issue of the **Federal Register**.

DATES: *Effective date:* These regulations are effective June 16, 1998.

Applicability date: For dates of applicability, see § 31.6302–1T(f)(4).

FOR FURTHER INFORMATION CONTACT: Vincent Surabian (202) 622–4940 (not a toll-free call).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

This document contains amendments to 26 CFR part 31, Employment Taxes and Collection of Income Tax at Source. Section 31.6302–1(f)(4) provides that if the total amount of accumulated employment taxes for the quarter is less than $500 and the amount is fully deposited or remitted with a timely filed return for the quarter, the amount deposited or remitted will be deemed to be timely deposited.

The temporary regulations change the $500 threshold to $1,000. In addition, the regulations replace the term ''quarter'' with the term ''return period'' since some employment taxes are reported on an annual basis (Forms 943, 945, and CT–1) rather than quarterly (Form 941). Thus, a taxpayer that has accumulated employment taxes of less than $1,000 for a return period (quarterly or annual, as the case may be) does not have to make deposits but may remit its full liability with a timely filed return for the return period.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 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 Internal Revenue Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Drafting Information: The principal author of these regulations is Vincent Surabian, Office of Assistant Chief Counsel (Income Tax & Accounting). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 31

Employment taxes, Income taxes, Penalties, Pensions, Railroad retirement, Reporting and recordkeeping requirements, Social security, Unemployment compensation.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 31 is amended as follows:

PART 31—EMPLOYMENT TAXES AND COLLECTION OF INCOME TAX AT SOURCE

Paragraph 1. The authority citation for part 31 is amended by adding an entry in numerical order to read as follows:

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

§ 31.6302–1T also issued under 26 U.S.C. 6302 (a) and (c). * * *