

e. The introductory language of paragraph (b) and paragraph (c) of § 139.201;

f. Paragraphs (a) and (b) of § 139.203;

g. Paragraph (b) of § 139.205;

h. The introductory language of § 139.301;

i. The introductory language, the second and third sentences of paragraph (c), and the second sentence of paragraph (d) of § 139.303;

j. The introductory language of paragraph (a) and paragraphs (a)(1) through (a)(6) of § 139.305;

k. The introductory language of paragraph (a) and paragraphs (a)(1) through (a)(3) of § 139.307;

l. The introductory language of paragraphs (a) and (b) and paragraphs (b)(1) through (b)(4) of § 139.309;

m. The introductory language of paragraphs (a) and (b); paragraphs (b)(2) and (3); the first and second sentences of paragraph (c); and paragraphs (d), (e), and (g) of § 139.311;

n. Paragraph (a) and the introductory language of paragraph (b) of § 139.313;

o. The first and second sentences of the introductory language of paragraph (f), paragraph (f)(2), and paragraphs (i) and (k) of § 139.317;

p. Paragraphs (a) and (b); the introductory language of paragraphs (d) through (g); paragraphs (g)(1) and (2); the first, second, and third sentences of paragraph (g)(3); the introductory language of paragraph (h); the introductory language of paragraph (h)(2); paragraphs (h)(2)(i) and (ii); the introductory language of paragraph (i); the second and third sentences of paragraph (i)(2); paragraph (i)(3); the second and third sentences of paragraph (i)(4); paragraph (i)(5); and paragraphs (j), (k), and (m) of § 139.319;

q. The first and second sentences of paragraphs (a) and (b), paragraph (c) in two places, paragraph (d), the introductory language of paragraph (e), the first and second sentences of paragraph (e)(1), paragraph (e)(2), and the first and second sentences of paragraphs (f) and (g) of § 139.321;

r. The first and second sentences of the introductory language of paragraph (a); paragraph (e); the first and third sentences of paragraph (f); the introductory language of paragraph (g); and paragraphs (h), (i), and (k) of § 139.325;

s. The introductory language of paragraphs (a), (b), (b)(3), and (c) of § 139.327;

t. The introductory language and the second sentences of paragraph (f)(1) and (2) of § 139.329;

u. The first sentence of § 139.331;

v. The introductory language of § 139.333;

w. The introductory language of paragraph (a) of § 139.335;

x. Paragraph (a) and the introductory language of paragraphs (b) through (e) of § 139.337;

y. The introductory language and paragraph (d) of § 139.339;

z. The introductory language of paragraph (a) of § 139.341; and

aa. Section 139.343.

Issued in Washington, DC, on April 27, 2004.

Donald P. Byrne,

Assistant Chief Counsel for Regulations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

[Docket No. 2004D-0065]

Guidance for Industry: Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2); Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability of guidance.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a revised guidance entitled "Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2)." The guidance responds to various questions raised about section 307 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and the agency's implementing regulation, which require the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States.

DATES: Submit written or electronic comments on the agency guidance at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or to the Prior Notice Help Desk at 1-800-216-7331 or 301-575-0156, or FAX: 301-210-0247. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document. Submit written comments on the guidance to the Division of Dockets Management (HFA-

305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

FOR FURTHER INFORMATION CONTACT:

Domenic Veneziano, Office of Regulatory Affairs, Office of Regional Operations, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 866-521-2297.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 10, 2003 (68 FR 58974), FDA issued an interim final rule (IFR) to implement section 307 of the Bioterrorism Act. The prior notice regulation requires the submission to FDA beginning on December 12, 2003, of prior notice of food, including animal feed, that is imported or offered for import into the United States. On December 16, 2003, FDA issued the first edition of a guidance entitled "Prior Notice of Imported Food Questions and Answers (Edition 1)." This guidance entitled "Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2)" is a revision of the guidance published on December 16, 2003, and responds to additional questions about the prior notice IFR. It is intended to help the industry better understand and comply with the regulation in 21 CFR part 1, subpart I. FDA is issuing this guidance entitled "Questions and Answers Regarding the Interim Final Rule on Prior Notice of Imported Food (Edition 2)" as a level 1 guidance. Consistent with FDA's good guidance practices regulation (§ 10.115(g)(2) (21 CFR 10.115)(g)(2)), the agency will accept comments, but it is implementing the guidance document immediately, in accordance with § 10.115(g)(2), because the agency has determined that prior public participation is not feasible or appropriate. As noted, the Bioterrorism Act requires prior notice submission to FDA starting on December 12, 2003. Clarifying the provisions of the IFR will facilitate timely and accurate prior notice submissions and thus, assist in the implementation of the IFR. FDA continues to receive a large number of questions regarding the prior notice IFR, and is responding to these inquiries under § 10.115 as promptly as possible, using a question-and-answer format. The agency believes that it is reasonable to maintain all responses to questions concerning prior notice of imported food in a single document that is periodically updated as the agency receives and responds to additional

questions. The following four indicators will be employed to help users of the guidance identify revisions: (1) The guidance will be identified as a revision of a previously issued document, (2) the revision date of the guidance will appear on its cover, (3) the edition number of the guidance will be included in its title, and (4) questions and answers that have been revised or added to the original guidance will be identified as such in the body of the guidance.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, 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. The guidance and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.cfsan.fda.gov/guidance.html>.

Dated: April 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-10023 Filed 4-29-04; 11:01 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9123]

RIN 1545-AY17

Electing Mark to Market for Marketable Stock

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide procedures for certain United States persons holding marketable stock in a passive foreign investment company (PFIC) to elect mark to market treatment for that stock under section 1296 of the Internal Revenue Code and related provisions of sections 1291 and 1295. These final regulations affect United States persons owning marketable stock in a PFIC.

DATES: *Effective Date:* These regulations are effective May 3, 2004.

Applicability Date: For dates of applicability, see §§ 1.1291-1(j), 1.1295-1(k), and 1.1296-1(j).

FOR FURTHER INFORMATION CONTACT:

Alexandra K. Helou, (202) 622-3840 (not a toll free number).

SUPPLEMENTARY INFORMATION:

Background

On July 31, 2002, the IRS published in the **Federal Register** a notice of proposed rulemaking (REG-112306-00; 2002-44 I.R.B. 767) under section 1296 and related provisions of the Internal Revenue Code (Code). Two written comments were received in response to the notice of proposed rulemaking. No public hearing was requested or held on the notice of proposed rulemaking. After consideration of the comments, the proposed regulations are adopted as final regulations with the modifications discussed below.

Summary of Public Comments and Explanation of Changes

A. Deferral of Post-October PFIC Losses by Regulated Investment Companies (RICs) Under Section 852(b)(10)

One commentator recommended that the regulations provide guidance regarding the determination of post-October "net reduction in value" of PFIC stock held by a RIC under section 852(b)(10). Section 852(b)(10) provides that taxable income of a RIC (other than a RIC to which an election under section 4982(e)(4) applies) shall be computed without regard to any net reduction in value occurring after October 31 of the taxable year of any stock of a PFIC with respect to which an election under section 1296(k) is in effect and that any such reduction shall be treated as occurring on the first day of the following taxable year.

To address concerns relating to a RIC's post-October period, the commentator provided three recommendations. First, that the regulations clarify whether the deferral of post-October PFIC losses under section 852(b)(10) is elective or mandatory; second, that RICs be permitted to defer their post-October losses under rules similar to those that apply to foreign currency gains and losses under § 1.852-11; and third, that RICs be allowed to include actual post-October dispositions of PFIC stock when computing losses eligible for deferral.

The IRS and Treasury have considered these recommendations and determined that the issues raised with respect to section 852(b)(10) are issues under the RIC tax provisions that are

beyond the scope of this regulations project.

B. Situations Arising From Different Tax Years of RICs and the Foreign Corporations in Which They Invest

One commentator requested guidance in instances where the RIC and a foreign corporation in which it invests have different or "mismatching" taxable years. This commentator noted that a RIC may experience uncertainties with respect to determining its taxable income and minimum distribution amount in situations where, following the end of its taxable year, the RIC learns that a foreign corporation in which it has invested is a PFIC or that the foreign corporation no longer satisfies the income or asset tests of section 1297(a) for the current taxable year. To address administrative concerns arising in this situation, this commentator recommended that RICs be permitted to recognize a change in a foreign corporation's PFIC status in the RIC's taxable year within which the taxable year of the foreign corporation ends.

Issues arising from different taxable years are not specific to PFICs for which a taxpayer has made a section 1296 election. Accordingly, this issue is beyond the scope of this regulations project. However, comments are requested for approaches that address issues arising when a taxpayer and a PFIC have different taxable years. Such issues may be addressed in a future regulations project.

C. Situations Where a RIC Owns Stock in a Foreign Corporation That No Longer Satisfies the PFIC Definition in the Current Year

One commentator suggested that the regulations should address certain issues that arise with respect to a shareholder that has made a section 1296 election for its PFIC stock and the foreign corporation does not satisfy the income or asset test in section 1297(a) for the year. First, the commentator suggested that the regulations clarify that the character of gains from the disposition of the stock of the foreign corporation during the time that the corporation did not qualify as a PFIC should be capital gain. The commentator also requested that the regulations provide that the character of losses with respect to stock for which a section 1296 election was made but that is recognized in a taxable year during which the foreign corporation is not a PFIC be treated as ordinary income to the extent of any unreversed inclusions at the time of disposition.