

and standard temperature, and the type of surface for which it is valid;

(4) The effect on landing distances of operation on other than smooth hard surfaces, when dry, determined under SC 23.45(g); and

(5) The effect on landing distances of runway slope and 50 percent of the headwind component and 150 percent of the tailwind component.

(b) Not applicable.

(c) Not applicable.

(d) In addition to paragraph (a) of this section the following information must be furnished—

(1) The accelerate-stop distance determined under SC 23.55;

(2) The takeoff distance determined under SC 23.59(a);

(3) At the option of the applicant, the takeoff run determined under SC 23.59(b);

(4) The effect on accelerate-stop distance, takeoff distance and, if determined, takeoff run, of operation on other than smooth hard surfaces, when dry, determined under SC 23.45(g);

(5) The effect on accelerate-stop distance, takeoff distance, and if determined, takeoff run, of runway slope and 50 percent of the headwind component and 150 percent of the tailwind component;

(6) The net takeoff flight path determined under SC 23.61(b);

(7) The enroute gradient of climb/descent with one engine inoperative, determined under § 23.69(b);

(8) The effect, on the net takeoff flight path and on the enroute gradient of climb/descent with one engine inoperative, of 50 percent of the headwind component and 150 percent of the tailwind component;

(9) Overweight landing performance information (determined by extrapolation and computed for the range of weights between the maximum landing and maximum takeoff weights) as follows—

(i) The maximum weight for each airport altitude and ambient temperature at which the airplane complies with the climb requirements of SC 23.63(d)(2); and

(ii) The landing distance determined under § 23.75 for each airport altitude and standard temperature.

(10) The relationship between IAS and CAS determined in accordance with § 23.1323 (b) and (c).

(11) The altimeter system calibration required by § 23.1325(e).

Issued in Kansas City, Missouri on March 23, 2007.

**Kim Smith,**

*Manager, Small Airplane Directorate, Aircraft Certification Service.*

[FR Doc. E7-5951 Filed 3-29-07; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 310

[Docket No. 2007N-0099]

#### New Drugs Exempted From Prescription-Dispensing Requirements; Technical Amendment

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** Amendments to the Federal Food, Drug, and Cosmetic Act (the act) necessitate several changes to the citations used in Food and Drug Administration (FDA) regulations regarding the prescription-exemption procedure and the list of new drugs that are exempted from the prescription-dispensing requirements. These changes are editorial, pertaining only to citations, and do not constitute a change in FDA regulation.

**DATES:** This rule is effective March 30, 2007.

**FOR FURTHER INFORMATION CONTACT:** Gerald M. Rachanow, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 5496, Silver Spring, MD 20993, 301-796-2090.

**SUPPLEMENTARY INFORMATION:** Section 126 of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105-115) amended section 503(b)(1) of the act (21 U.S.C. 353(b)(1)). Specifically, the previous paragraph (b)(1)(A) of the act was stricken from the act and paragraphs (b)(1)(B) and (b)(1)(C) were redesignated as paragraphs (b)(1)(A) and (b)(1)(B), respectively. This amendment to the act necessitates that FDA revise the corresponding citations in its regulations. FDA is making this change in 21 CFR part 310 (§§ 310.200 and 310.201). These changes are editorial, pertaining only to citations, and do not constitute a change in FDA regulation.

Publication of this document constitutes final action on this change under the Administrative Procedure Act

(5 U.S.C. 553). Notice and public procedures are unnecessary because FDA is merely implementing a change in citation to a section of the act as a result of amendment of the act.

#### List of Subjects in 21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 310 is amended as follows:

#### PART 310—NEW DRUGS

■ 1. The authority citation for 21 CFR part 310 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b-360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b-263n.

#### § 310.200 [Amended]

■ 2. In § 310.200(a), (b), and (e) remove “503(b)(1)(C)” wherever it appears and add in its place “503(b)(1)(B)”.

#### § 310.201 [Amended]

■ 3. In § 310.201(a) remove “503(b)(1)(C)” and add in its place “503(b)(1)(B)”.

Dated: March 22, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-5895 Filed 3-29-07; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TD 9320]

**RIN 1545-BF67**

#### United States Dollar Approximate Separate Transactions Method

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulation.

**SUMMARY:** This document contains final regulations which provide the translation rates that must be used when translating into dollars certain items and amounts transferred by a qualified business unit (QBU) to its home office or parent corporation for purposes of computing dollar approximate separate transactions method (DASTM) gain or loss. This regulation is necessary to provide guidance under section 985

regarding the proper translation rates that must be used under the DASTM method. Taxpayers affected by these regulations are taxpayers with QBUs required to use the DASTM method of accounting described in § 1.985-3.

**DATES:** *Effective Date:* This regulation is effective March 30, 2007.

*Applicability Date:* This regulation is applicable to any transfer, dividend, or distribution that is a return of capital that is made after March 8, 2005, and that gives rise to an adjustment under § 1.985-3(d)(3).

**FOR FURTHER INFORMATION CONTACT:** Sheila Ramaswamy, at (202) 622-3870.

**SUPPLEMENTARY INFORMATION:**

**Background**

On July 13, 2006, a notice of proposed rulemaking (REG-118897-06), United States Dollar Approximate Separate Transactions Method, was published in the **Federal Register** (71 FR 39604). The notice of proposed rulemaking proposed to amend § 1.985-3(d)(3). No requests for a public hearing were received, and no public hearing was held. The IRS received no comments in response to the notice of proposed rulemaking. The proposed regulation is adopted without change by this Treasury decision.

**Explanation of Provisions**

For taxable years beginning after August 24, 1994, a U.S. taxpayer's QBU that would otherwise be required to use a hyperinflationary currency as its functional currency generally must use the dollar as its functional currency and must compute income or loss under the DASTM method of accounting described in § 1.985-3. See § 1.985-1(b)(2)(ii). Under the DASTM method of accounting, a QBU's income or loss for a taxable year is computed in U.S. dollars and adjusted to account for its DASTM gain or loss. See § 1.985-3(b). A QBU's DASTM gain or loss for a taxable year is determined under § 1.985-3(d) by first computing the QBU's change in net worth from the prior year. In computing the QBU's change in net worth, items whose dollar value fluctuates with changes in exchange rates are translated using the year-end exchange rate while items whose dollar value does not change with exchange rate fluctuations are translated using the exchange rate for the translation period in which the cost of the item was incurred. Specified adjustments are made to the QBU's change in net worth. Under § 1.985-3(d)(3), one of the adjustments requires adding back to the change in net worth transactions that decrease the QBU's net worth without affecting the QBU's income or loss

including dividend distributions, certain transfers, and returns of capital from the QBU to its home office or parent corporation. This final regulation provides the translation rate to be used in translating these items into dollars for purposes of computing DASTM gain or loss.

Under § 1.985-3(d)(3), the applicable translation rate to be used generally depends upon whether the dollar value of the item transferred changes with fluctuations in exchange rates. Accordingly, the regulation provides that if the item giving rise to the adjustment is an asset which would be translated under § 1.985-3(d)(5) at the exchange rate for the last translation period of the taxable year if it were on the QBU's year-end balance sheet, the item will be translated at the exchange rate on the date the item is transferred. However, if the item giving rise to the adjustment is an asset which would be translated under § 1.985-3(d)(5) at the exchange rate for the translation period in which the cost of the item was incurred if it were on the QBU's year-end balance sheet, the item will be translated at the same historical rate.

**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 been determined that sections 553 (b) and (d) of the Administrative Procedure Act (5 U.S.C. chapter 5) do not apply to this regulation, and because this regulation does not impose a collection of information on small entities, the provisions of 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 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.

**Adoption of 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.** Section 1.985-3 is amended by revising paragraph (d)(3) to read as follows:

**§ 1.985-3 United States dollar approximate separate transactions method.**

\* \* \* \* \*

(d) \* \* \*

(3) *Positive adjustments*—(i) *In general.* The items described in this paragraph (d)(3) are dividend distributions for the taxable year and any items that decrease net worth for the taxable year but that generally do not affect income or loss or earnings and profits (or a deficit in earnings and profits). Such items include a transfer to the home office of a QBU branch and a return of capital.

(ii) *Translation.* Except as provided by ruling or administrative pronouncement, items described in paragraph (d)(3)(i) of this section shall be translated into dollars as follows:

(A) If the item giving rise to the adjustment would be translated under paragraph (d)(5) of this section at the exchange rate for the last translation period of the taxable year if it were shown on the QBU's year-end balance sheet, such item shall be translated at the exchange rate on the date the item is transferred.

(B) If the item giving rise to the adjustment would be translated under paragraph (d)(5) of this section at the exchange rate for the translation period in which the cost of the item was incurred if it were shown on the QBU's year-end balance sheet, such item shall be translated at the same historical rate.

(iii) *Effective date.* Paragraph (d)(3)(ii) of this section is applicable for any transfer, dividend, or distribution that is a return of capital that is made after March 8, 2005, and that gives rise to an adjustment under this paragraph (d)(3).

\* \* \* \* \*

**Kevin M. Brown,**

*Deputy Commissioner for Services and Enforcement.*

Approved: March 20, 2007.

**Eric Solomon,**

*Assistant Secretary for Tax Policy.*

[FR Doc. E7-5857 Filed 3-29-07; 8:45 am]

**BILLING CODE 4830-01-P**