

impose significant costs beyond what the underlying statute imposes. Thus, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Lists of Subjects in 21 CFR Part 812

Health records, Medical devices, Medical research, 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 812 is amended as follows:

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

1. The authority citation for 21 CFR part 812 continues to read as follows:

Authority: Secs. 301, 501, 502, 503, 505, 506, 507, 510, 513–516, 518–520, 701, 702, 704, 721, 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331, 351, 352, 353, 355, 356, 357, 360, 360c–360f, 360h–360j, 371, 372, 374, 379e, 381); secs. 215, 301, 351, 354–360F of the Public Health Service Act (42 U.S.C. 216, 241, 262, 263b–263n).

2. Section 812.2 is amended by revising the introductory text of paragraph (c) to read as follows:

§ 812.2 Applicability.

* * * * *

(c) *Exempted investigations.* This part, with the exception of § 812.119, does not apply to investigations of the following categories of devices: * * *

* * * * *

3. New § 812.119 is added to subpart E to read as follows:

§ 812.119 Disqualification of a clinical investigator.

(a) If FDA has information indicating that an investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has repeatedly or deliberately submitted false information either to the sponsor of the investigation or in any required report, the Center for Devices and Radiological Health will furnish the investigator written notice of the matter under complaint and offer the investigator an opportunity to explain the matter in writing, or, at the option of the investigator, in an informal conference. If an explanation is offered and accepted by the Center for Devices and Radiological Health, the disqualification process will be terminated. If an explanation is offered but not accepted by the Center for Devices and

Radiological Health, the investigator will be given an opportunity for a regulatory hearing under part 16 of this chapter on the question of whether the investigator is entitled to receive investigational devices.

(b) After evaluating all available information, including any explanation presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the requirements of this part, part 50, or part 56 of this chapter, or has deliberately or repeatedly submitted false information either to the sponsor of the investigation or in any required report, the Commissioner will notify the investigator, the sponsor of any investigation in which the investigator has been named as a participant, and the reviewing IRB that the investigator is not entitled to receive investigational devices. The notification will provide a statement of basis for such determination.

(c) Each investigational device exemption (IDE) and each cleared or approved application submitted under this part, subpart E of part 807 of this chapter, or part 814 of this chapter containing data reported by an investigator who has been determined to be ineligible to receive investigational devices will be examined to determine whether the investigator has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval or clearance of any marketing application.

(d) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, the Commissioner will notify the sponsor who shall have an opportunity for a regulatory hearing under part 16 of this chapter. If a danger to the public health exists, however, the Commissioner shall terminate the IDE immediately and notify the sponsor and the reviewing IRB of the determination. In such case, the sponsor shall have an opportunity for a regulatory hearing before FDA under part 16 of this chapter on the question of whether the IDE should be reinstated.

(e) If the Commissioner determines, after the unreliable data submitted by the investigator are eliminated from consideration, that the continued clearance or approval of the marketing application for which the data were submitted cannot be justified, the Commissioner will proceed to withdraw approval or rescind clearance of the

medical device in accordance with the applicable provisions of the act.

(f) An investigator who has been determined to be ineligible to receive investigational devices may be reinstated as eligible when the Commissioner determines that the investigator has presented adequate assurances that the investigator will employ investigational devices solely in compliance with the provisions of this part and of parts 50 and 56 of this chapter.

Dated: March 3, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–6475 Filed 3–13–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 8560; TD 8597; TD 8660]

RIN 1545–AQ69; 1545–AT58; 1545–AT51

Consolidated Returns; Consolidated and Controlled Groups; Correction

AGENCY: Internal Revenue Service, Treasury.

ACTION: Correcting amendments.

SUMMARY: This document contains technical corrections to final regulations [TD 8560; TD 8597; TD 8660] which were published in the Federal Register on Monday, August 15, 1994 (59 FR 41666); Tuesday, July 18, 1995 (60 FR 36671); and Thursday, March 14, 1996 (61 FR 10447); respectively. The final regulations amend the consolidated return investment adjustment provisions, intercompany transaction provisions and the provisions limiting losses and deductions from transactions between members of a nonconsolidated controlled group.

DATES: The correcting amendments affecting §§ 1.267(f)–1, 1.1502–13(f)(2)(ii), (g)(5), (l)(1), 1.1502–20, 1.1502–32(b), and 1.1502–80(b) are effective July 18, 1995. The correcting amendments affecting §§ 1.1502–11, 1.1502–19, 1.1502–32(f), 1.1502–43, 1.1502–76 and 1.1502–80(d)(1) are effective January 1, 1995. The correcting amendments affecting § 1.1502–13(f)(6) are effective March 14, 1996. For dates of applicability see §§ 1.267(f)–1(l), § 1.1502–11(b)(5), 1.1502–13(l)(1), 1.1502–13(f)(6)(v), 1.1502–19(h), 1.1502–32(h), 1.1502–76(b)(5), 1.1502–80(d), and other relevant provisions.

FOR FURTHER INFORMATION CONTACT: William Barry of the Office of Assistant

Chief Counsel (Corporate), (202) 622-7770 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these correcting amendments are under sections 267 and 1502 of the Internal Revenue Code.

Need for Correction

As published, the final regulations contain errors and omissions which may prove to be misleading and are in need of clarification.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Accordingly, 26 CFR Part 1 is corrected by making the following correcting amendments:

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 1.267(f)-1 is amended as follows:

1. In paragraph (c)(1)(iii), the first sentence is revised.

2. Paragraph (l)(2) is revised.

The revisions read as follows:

§ 1.267(f)-1 Controlled groups.

(c) * * * (1) * * *
(iii) * * * To the extent S's loss or deduction from an intercompany sale of property is taken into account under this section as a result of B's transfer of the property to a nonmember that is a person related to any member, immediately after the transfer, under sections 267(b) or 707(b), or as a result of S or B becoming a nonmember that is related to any member under section 267(b), the loss or deduction is taken into account but allowed only to the extent of any income or gain taken into account as a result of the transfer. * * *

(l) * * *

(2) *Avoidance transactions.* This paragraph (l)(2) applies if a transaction is engaged in or structured on or after April 8, 1994, with a principal purpose to avoid the rules of this section (and instead to apply prior law). If this paragraph (l)(2) applies, appropriate adjustments must be made in years beginning on or after July 12, 1995, to prevent the avoidance, duplication, omission, or elimination of any item (or tax liability), or any other inconsistency with the rules of this section.

* * * * *

Par. 3. Section 1.1502-11 is amended by revising paragraph (b)(2)(iii), *Example 3.* (e) to read as follows:

§ 1.1502-11 Consolidated taxable income.

* * * * *

(b) * * *

(2) * * *

(iii) * * *

Example 3. * * *

(e) Under paragraph (b)(2)(ii) of this section, S's \$30 of loss limited under this paragraph (b) is treated as a separate net operating loss.

* * * * *

Par. 4. Section 1.1502-13 is amended as follows:

1. In paragraph (f)(2)(ii), a sentence is added before the last sentence of the paragraph.

2. In paragraph (f)(6) introductory text, the last sentence is revised.

3. In paragraph (g)(5), *Example 5.* (c), the tenth sentence is revised.

4. In paragraph (l)(1) the third, fourth, and fifth sentences are revised.

The addition and revisions read as follows:

§ 1.1502-13 Intercompany transactions.

* * * * *

(f) * * *

(2) * * *

(ii) * * * B's dividend received deduction under section 243(a)(3) is determined without regard to any intercompany distributions under this paragraph (f)(2) to the extent they are not included in gross income. * * *

* * * * *

(6) * * * For this purpose, P stock is any stock of the common parent held (directly or indirectly) by another member or any stock of a member (the issuer) that was the common parent if the stock was held (directly or indirectly) by another member while the issuer was the common parent.

* * * * *

(g) * * *

(5) * * *

Example 5. * * *

(c) * * * Under § 1.446-3(f), the deemed \$100 up front payment by M1 to M2 is taken into account over the term of the new contract in a manner reflecting the economic substance of the contract (for example, allocating the payment in accordance with the forward rates of a series of cash-settled forward contracts that reflect the specified index and the \$1,000 notional principal amount). * * *

* * * * *

(l) * * * (1) * * * For example, S's and B's items from S's sale of property to B which occurs in a consolidated return year beginning before July 12, 1995, are taken into account under prior

law, even though B may dispose of the property in a consolidated return year beginning on or after July 12, 1995. Similarly, an intercompany distribution to which a shareholder becomes entitled in a consolidated return year beginning before July 12, 1995, but which is distributed in a consolidated return year beginning on or after that date is taken into account under prior law (generally when distributed), because this section generally takes dividends into account when the shareholder becomes entitled to them but this section does not apply at that time. If application of prior law to S's deferred gain or loss from a deferred intercompany transaction (as defined under prior law) occurring in a consolidated return year beginning prior to July 12, 1995, would be affected by an intercompany transaction (as defined under this section) occurring in a consolidated return year beginning on or after July 12, 1995, S's deferred gain or loss continues to be taken into account as provided under prior law, and the items from the subsequent intercompany transaction are taken into account under this section. * * *

* * * * *

Par. 5. Section 1.1502-19 is amended as follows:

1. In paragraph (c)(1)(iii)(A), the last sentence is revised.

2. Paragraph (g) is amended by:

a. Revising the first sentence of the introductory text.

b. Revising the fourth and fifth sentences in *Example 1.* (d).

c. Revising the first sentence in *Example 4.* (b).

d. Revising the first sentence in *Example 6.* (b).

The revisions read as follows:

§ 1.1502-19 Excess loss accounts.

* * * * *

(c) * * *

(1) * * *

(iii) * * *

(A) * * * An asset of S is not considered to be disposed of or abandoned to the extent the disposition is in complete liquidation of S or is in exchange for consideration (other than relief from indebtedness);

* * * * *

(g) *Examples.* For purposes of the examples in this section, unless otherwise stated, P owns all 100 shares of the only class of S's stock and S owns all 100 shares of the only class of T's stock, the stock is owned for the entire year, T owns no stock of lower-tier members, the tax year of all persons is the calendar year, all persons use the accrual method of accounting, the facts set forth the only corporate activity, all

transactions are between unrelated persons, and tax liabilities are disregarded. * * *

Example 1. * * *

(d) * * * Under section 301(d), P's basis in the T stock is \$60. Under § 1.1502-13, and paragraph (b)(2) of this section, S's \$160 gain from the distribution is deferred and taken into account in Year 5 as a result of P's sale of the T stock. * * *

* * * * *

Example 4. * * *

(b) *Analysis.* Under paragraph (c)(2) of this section, S is treated as disposing of each of its shares of T's stock immediately before T becomes a nonmember. * * *

* * * * *

Example 6. * * *

(b) *Analysis.* Under paragraph (c)(1)(iii)(A) of this section, P's excess loss account on each of its shares of S's stock ordinarily is taken into account at the time substantially all of S's assets are treated as disposed of, abandoned, or destroyed for Federal income tax purposes. * * *

* * * * *

Par. 6. Section 1.1502-20 is amended as follows:

1. In paragraph (b)(6), *Example 5.* (iii) is revised.

2. In paragraph (e)(3), *Example 1.* (i), the third sentence is revised.

3. In paragraph (e)(3), *Example 1.* (ii) is revised.

The revisions read as follows:

§ 1.1502-20 Disposition or deconsolidation of subsidiary stock.

* * * * *

(b) * * *

(6) * * *

Example 5. * * *

(iii) T's issuance of additional shares to the public results in S's intercompany loss being taken into account under the acceleration rule of § 1.1502-13(d) because there is no difference between P's \$100 basis in the T stock and the \$100 basis the T stock would have had if P and S had been divisions of a single corporation. S's loss taken into account is disallowed under paragraph (a)(1) of this section.

* * * * *

(e) * * *

(3) * * *

Example 1. * * * (i) * * * With the view described in paragraph (e)(1) of this section, P transfers land with a value of \$100 and a basis of \$100 to T in exchange for preferred stock with a \$200 redemption price and liquidation preference. * * *

(ii) Under section 305, the redemption premium is treated as a distribution of property to which section 301 and § 1.1502-13(f)(2) apply. Under §§ 1.1502-13 and 1.1502-32, P's aggregate basis in the preferred and common stock is unaffected by the deemed distributions.

* * * * *

Par. 7. Section 1.1502-32 is amended as follows:

1. In paragraph (b)(3)(ii)(A), the second sentence is revised.

2. In paragraph (b)(3)(v), the last sentence is revised.

3. In paragraph (b)(5)(ii), *Example 5.* (c), the second sentence is revised.

4. In paragraph (b)(5), *Example 6.* (b) is revised.

5. In paragraph (f), a sentence is added after the second sentence.

The addition and revisions read as follows:

§ 1.1502-32 Investment adjustments.

* * * * *

(b) * * *

(3) * * *

(ii) * * * (A) * * * For example, S's dividend income to which § 1.1502-13(f)(2)(ii) applies, and its interest excluded from gross income under section 103, are treated as tax-exempt income. * * *

* * * * *

(v) * * * See § 1.1502-13(f)(2)(iv) for taking into account distributions to which section 301 applies (but not other distributions treated as dividends) under the entitlement rule.

* * * * *

(5) * * *

(ii) * * *

Example 5. * * *

(c) * * * Under § 1.1502-13(f)(2)(iv), S is treated as making a \$70 distribution to P at the time P becomes entitled to the distribution. * * *

Example 6. * * *

(b) *Analysis.* Under section 358, P's basis in the S stock is increased by its basis in the T stock. Under § 1.1502-13(f)(3) the money received is treated as being taken into account immediately after the transaction. Thus, the \$10 is treated as a dividend distribution under section 301 and under paragraph (b)(3)(v) of this section, the \$10 is a distribution to which paragraph (b)(2)(iv) of this section applies. Accordingly, P's basis in the S stock is \$160 immediately after the merger, which is then decreased by the \$10 distribution taken into account immediately after the transaction, resulting in a basis of \$150.

* * * * *

(f) * * * For example, if T merges into S, S is treated, as the context may require, as a successor to T and as becoming a member of the group. * * *

* * * * *

Par. 8. Section 1.1502-43 is amended by revising paragraph (a)(3)(iii) to read as follows:

§ 1.1502-43 Consolidated accumulated earnings tax.

(a) * * *

(3) * * *

(iii) Earnings and profits resulting from the disposition of a member's stock are determined without regard to the stock basis adjustments under §§ 1.1502-32 and 1.1502-33(c)(1).

* * * * *

Par. 9. Section 1.1502-76 is amended by revising paragraph (b)(4), *Example 1.* (a) and the first sentence of *Example 1.* (c) to read as follows:

§ 1.1502-76 Taxable year of members of group.

* * * * *

(b) * * *

(4) * * *

Example 1. Items allocated between consolidated and separate returns. (a) *Facts.* P and S are the only members of the P group. P sells all of S's stock to individual A on June 30, and therefore S becomes a nonmember on July 1 of Year 2.

* * * * *

(c) *Acquisition of another subsidiary before end of tax year.* The facts are the same as in paragraph (a) of this *Example 1*, except that on July 31 P acquires all the stock of T (which filed a separate return for its year ending on November 30 of Year 1) and T therefore becomes a member on August 1 of Year 2. * * *

* * * * *

Par. 10. Section 1.1502-80 is amended as follows:

1. Paragraph (b) is revised.

2. In paragraph (d)(1), a sentence is added to the end of the paragraph.

The addition and revision reads as follows:

§ 1.1502-80 Applicability of other provisions of law.

* * * * *

(b) *Non-applicability of section 304.*

Section 304 does not apply to any acquisition of stock of a corporation in an intercompany transaction or to any intercompany item from such transaction occurring on or after July 24, 1991.

* * * * *

(d) * * * (1) * * * For purposes of this paragraph (d), any reference to a transferor or transferee includes, as the context may require, a reference to a successor or predecessor.

* * * * *

Cynthia E. Grigsby,
Chief, Regulations Unit, Assistant Chief
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BILLING CODE 4830-01-P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4044

Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.