

§ 1304.26 Additional recordkeeping requirements applicable to drug products containing gamma-hydroxybutyric acid.

In addition to the recordkeeping requirements for dispensers and researchers provided in § 1304.22, practitioners dispensing gamma-hydroxybutyric acid that is manufactured or distributed in accordance with an application under section 505 of the Federal Food, Drug, and Cosmetic Act must maintain and make available for inspection and copying by the Attorney General, all of the following information for each prescription:

(a) Name of the prescribing practitioner.

(b) Prescribing practitioner's Federal and State registration numbers, with the expiration dates of these registrations.

(c) Verification that the prescribing practitioner possesses the appropriate registration to prescribe this controlled substance.

(d) Patient's name and address.

(e) Patient's insurance provider, if available.

■ 4. Section 1304.33 is amended by revising paragraph (c) and the introductory text of paragraph (d)(1) to read as follows:

§ 1304.33 Reports to ARCOS.

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(c) *Persons reporting.* For controlled substances in Schedules I, II, narcotic controlled substances in Schedule III, and gamma-hydroxybutyric acid drug product controlled substances in Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repack, label or relabel, and each person who is registered to distribute, including each person who is registered to reverse distribute, shall report acquisition/distribution transactions. In addition to reporting acquisition/distribution transactions, each person who is registered to manufacture controlled substances in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedules I and II, each narcotic controlled substance listed in Schedules III, IV, and V, gamma-hydroxybutyric acid drug product controlled substances in Schedule III, and on each psychotropic controlled substance listed in Schedules III and IV as identified in paragraph (d) of this section.

(d) *Substances covered.* (1) Manufacturing and acquisition/distribution transaction reports shall include data on each controlled substance listed in Schedules I and II, on each narcotic controlled substance listed in Schedule III (but not on any

material, compound, mixture or preparation containing a quantity of a substance having a stimulant effect on the central nervous system, which material, compound, mixture or preparation is listed in Schedule III or on any narcotic controlled substance listed in Schedule V), and on gamma-hydroxybutyric acid drug products listed in Schedule III. Additionally, reports on manufacturing transactions shall include the following psychotropic controlled substances listed in Schedules III and IV:

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PART 1306—PRESCRIPTIONS

■ 5. The authority citation for part 1306 continues to read as follows:

Authority: 21 U.S.C. 821, 829, 871(b) unless otherwise noted.

■ 6. Section 1306.05 is amended by revising paragraph (a) to read as follows:

§ 1306.05 Manner of issuance of prescriptions.

(a) All prescriptions for controlled substances shall be dated as of, and signed on, the day when issued and shall bear the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner. Where a prescription is for gamma-hydroxybutyric acid, the practitioner shall note on the face of the prescription the medical need of the patient for the prescription. A practitioner may sign a prescription in the same manner as he would sign a check or legal document (*e.g.*, J.H. Smith or John H. Smith). Where an oral order is not permitted, prescriptions shall be written with ink or indelible pencil or typewriter and shall be manually signed by the practitioner. The prescriptions may be prepared by the secretary or agent for the signature of a practitioner, but the prescribing practitioner is responsible in case the prescription does not conform in all essential respects to the law and regulations. A corresponding liability rests upon the pharmacist, including a pharmacist employed by a central fill pharmacy, who fills a prescription not prepared in the form prescribed by DEA regulations.

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PART 1310—RECORDS AND REPORTS OF LISTED CHEMICALS AND CERTAIN MACHINES

■ 7. The authority citation for part 1310 is revised to read as follows:

Authority: 21 U.S.C. 802, 827(h), 830, 871(b) 890.

■ 8. Section 1310.03 is amended by revising paragraph (c) to read as follows:

§ 1310.03 Persons required to keep records and file reports.

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(c) Each regulated person who engages in a transaction with a nonregulated person or who engages in an export transaction that involves ephedrine, pseudoephedrine, phenylpropanolamine, or gamma-hydroxybutyric acid, including drug products containing these chemicals, and uses or attempts to use the Postal Service or any private or commercial carrier must file monthly reports of each such transaction as specified in § 1310.05 of this part.

Dated: December 22, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA-137f2]

RIN 1117-AA31

Exemption of Chemical Mixtures; Correction

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule with request for comment; correction.

SUMMARY: This document corrects the Final Rule with request for comment "Exemption of Chemical Mixtures" [Docket No. DEA-137f2, RIN 1117-AA31] which DEA published in the **Federal Register** on Wednesday, December 15, 2004 (69 FR 74957). The Final Rule concerned the exemption of certain chemical mixtures containing listed chemicals from the provisions of the Controlled Substances Act.

DATES: This correction is effective January 14, 2005.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7183

SUPPLEMENTARY INFORMATION:

Background

On Wednesday, December 15, 2004, DEA published a Final Rule with request for comment entitled "Exemption of Chemical Mixtures" in the **Federal Register** (69 FR 74957). The aspect of the Final Rule subject to this correction concerns the amendatory instructions for 21 CFR 1310.04 in which DEA indicated that "Section 1310.04 is to be amended by revising paragraph (h) and adding new paragraphs (i) and (j)". However, it was not DEA's intent to add new paragraphs (i) and (j). DEA only intended to revise paragraph (h). Therefore, to alleviate any confusion which might arise regarding these amendatory instructions, DEA is correcting the amendatory instructions for 21 CFR 1310.04. No substantive changes to 21 CFR 1310.04 are occurring in this correction.

■ Accordingly, the publication on Wednesday, December 15, 2004 of the Final Rule with request for comment [Docket No. DEA-137f2, RIN 1117-AA31], which was the subject of FR Doc. 04-27449, is corrected as follows:

PART 1310—[CORRECTED]

■ 1. On page 74970, amendatory instruction 2 is corrected to read as follows: "2. Section 1310.04 is amended by revising paragraph (h) to read as follows:"

Dated: December 27, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 05-57 Filed 1-3-05; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 20 and 301

[TD 9172]

RIN 1545-BB12

Gross Estate; Election to Value on Alternate Valuation Date

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that amend § 20.2032-1(b) to reflect the change made to section 2032 of the Internal Revenue Code by the Deficit Reduction Act of 1984 and the technical change to that section made by the Tax Reform Act of 1986. In addition, the final regulations remove temporary

regulation § 301.9100-6T(b) of the Procedure and Administration Regulations so that estates that fail to make the alternate valuation election on the last estate tax return filed before the due date of the return, or on the first estate tax return filed after the due date of the return may request an extension of time to make the election under the provisions of §§ 301.9100-1 and 301.9100-3. The final regulations affect estates that are required to file Form 706, United States Estate (and Generation-Skipping Transfer) Tax Return.

DATES: *Effective Date:* These regulations are effective January 4, 2005.

Applicability Date: For dates of applicability, see § 20.2032-1(h).

FOR FURTHER INFORMATION CONTACT: Theresa M. Melchiorre at (202) 622-7830 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On December 24, 2003, proposed regulations (REG-139845-02) were published in the **Federal Register** (68 FR 74534). The proposed regulations contained proposed amendments to the Estate Tax Regulations (26 CFR part 20) and the Procedure and Administration Regulations (26 CFR part 301) relating to the election under section 2032 to value a decedent's gross estate on the alternate valuation date. The proposed regulations reflected changes that were made to section 2032 by the Deficit Reduction Act of 1984, Public Law 98-369 (98 Stat. 494). Written comments were received on the proposed regulations, and a public hearing was held on June 3, 2004. The proposed regulations, with certain changes in response to the written and oral comments, are adopted as final regulations.

Summary of Comments and Explanation of Provisions

Determination of Eligibility To Make the Alternate Valuation Election

The proposed regulations provided that the alternate valuation election may be made only if the election results in a decrease both in the value of the gross estate and in the sum of the estate tax and generation-skipping transfer tax liability (reduced by credits allowable against these taxes). One commentator noted that it may not be possible to determine whether the election will reduce the sum of estate tax and generation-skipping transfer tax if the generation-skipping transfer tax will not be imposed until a later time, as in the case of a later taxable termination or taxable distribution. In response to this

comment, the final regulations provide that the determination of whether there has been a decrease in the sum of the estate tax and generation-skipping transfer tax liability (reduced by credits allowable against these taxes) is made with reference to the estate tax and generation-skipping transfer tax payable by reason of the decedent's death.

Availability of Relief Under §§ 301.9100-1 and 301.9100-3

In view of the 1-year limitation imposed under section 2032(d)(2), the proposed regulations provided that no request for an extension of time to make the alternate valuation election under the provisions of §§ 301.9100-1 and 301.9100-3 will be granted if the request is submitted to the IRS more than 1 year after the due date of the return of tax imposed by section 2001 (including extensions of time actually granted). One commentator argued that the 1-year limitation in section 2032(d)(2) applies only to late-filed returns, and therefore should not limit the availability of relief under §§ 301.9100-1 and 301.9100-3 to make a late alternate valuation election if the taxpayer timely filed its return, but failed to make the election on the return. After considering the language and intent of section 2032 and §§ 301.9100-1 and 301.9100-3, the IRS and Treasury Department have determined that taxpayers may request relief under §§ 301.9100-1 and 301.9100-3, even after the expiration of the 1-year period, and that such relief may be granted (subject to the requirements of §§ 301.9100-1 and 301.9100-3) provided that the return of tax is filed no later than 1 year after the due date of the return (including extensions of time actually granted). This rule also will apply to requests under §§ 301.9100-1 and 301.9100-3 for an extension of time to make a protective election under section 2032.

The IRS and Treasury Department also have determined that taxpayers should be permitted to apply for relief under §§ 301.9100-1 and 301.9100-3 to make a late election under section 2056A to be treated as a Qualified Domestic Trust (QDOT). Like the alternate valuation election of section 2032, no election under section 2056A to be treated as a QDOT may be made on a return that is filed more than 1 year after the due date of the return (including extensions of time actually granted). Section 2056A(d). Thus, taxpayers will be permitted to apply for an extension of time under the provisions of §§ 301.9100-1 and 301.9100-3 to make an election under section 2056A(d), provided that the