materials needed to fully address all deficiencies identified in the complete response letter. A biologics license application or supplement for which FDA issued a complete response letter, but which was withdrawn before approval and later submitted again, is not a resubmission.

PART 601—LICENSING

■ 23. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.3 [Added]

■ 24. Section 601.3 is added to subpart A to read as follows:

§ 601.3 Complete response letter to the applicant.

(a) *Complete response letter.* The Food and Drug Administration will send the biologics license applicant or supplement applicant a complete response letter if the agency determines that it will not approve the biologics license application or supplement in its present form.

(1) *Description of specific deficiencies.* A complete response letter will describe all of the deficiencies that the agency has identified in a biologics license application or supplement, except as stated in paragraph (a)(2) of this section.

(2) *Inadequate data.* If FDA determines, after a biologics license application or supplement is filed, that the data submitted are inadequate to support approval, the agency might issue a complete response letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed product labeling.

(3) *Recommendation of actions for approval.* When possible, a complete response letter will recommend actions that the applicant might take to place its biologics license application or supplement in condition for approval.

(b) *Applicant actions.* After receiving a complete response letter, the biologics license applicant or supplement applicant must take either of the following actions:

(1) *Resubmission.* Resubmit the application or supplement, addressing all deficiencies identified in the complete response letter.

(2) *Withdrawal.* Withdraw the application or supplement. A decision to withdraw the application or supplement is without prejudice to a subsequent submission.

(c) *Failure to take action.* (1) FDA may consider a biologics license applicant or supplement applicant's failure to either resubmit or withdraw the application or supplement within 1 year after issuance of a complete response letter to be a request by the applicant to withdraw the application or supplement, unless the applicant has requested an extension of time in which to resubmit the application or supplement. FDA will grant any reasonable request for such an extension. FDA may consider an applicant's failure to resubmit the application or supplement within the extended time period or request an additional extension to be a request by the applicant to withdraw the application.

(2) If FDA considers an applicant's failure to take action in accordance with paragraph (c)(1) of this section to be a request to withdraw the application, the agency will notify the applicant in writing. The applicant will have 30 days from the date of the notification to explain why the application or supplement should not be withdrawn and to request an extension of time in which to resubmit the application or supplement. FDA will grant any reasonable request for an extension. If the applicant does not respond to the notification within 30 days, the application or supplement will be deemed to be withdrawn.

Dated: June 26, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–15608 Filed 7–9–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1310

[Docket No. DEA–284F]

RIN 1117–AB11

Elimination of Exemptions for Chemical Mixtures Containing the List I Chemicals Ephedrine and/or Pseudoephedrine

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: The Drug Enforcement Administration (DEA) is finalizing, without change, the Interim Rule with Request for Comment published in the **Federal Register** on July 25, 2007 (72 FR 40738). The Interim Rule removed the Controlled Substances Act (CSA) exemptions for chemical mixtures containing ephedrine and/or pseudoephedrine with concentration limits at or below five percent. Upon the effective date of the Interim Rule, all ephedrine and pseudoephedrine chemical mixtures, regardless of concentration and form, became subject to the regulatory provisions of the CSA. DEA regulated the importation, exportation, manufacture, and distribution of these chemical mixtures by requiring persons who handle these chemical mixtures to register with DEA, maintain certain records common to business practice, and file certain reports, regarding these chemical mixtures. No comments to the Interim Rule were received. This Final Rule finalizes the Interim Rule without change.

EFFECTIVE DATE: August 11, 2008.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug & Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307–7183, fax (202) 353–1263, or e-mail *ode@dea.usdoj.gov.*

SUPPLEMENTARY INFORMATION:

Background

On July 25, 2007 (72 FR 40738), the Drug Enforcement Administration (DEA) published an Interim Rule with Request for Comment removing the Controlled Substances Act (CSA) exemptions for chemical mixtures containing ephedrine and/or pseudoephedrine with concentration limits at or below five percent. Those chemical mixtures included dietary supplements containing the List I chemicals ephedrine or pseudoephedrine, which are regulated as chemical mixtures under the CSA. DEA had previously exempted these products from CSA regulatory control if the total concentration of the ephedrine and/or pseudoephedrine was at or below five percent, in an effort to reduce the regulatory burden on the dietary and nutritional supplement industry (68 FR 23195, May 1, 2003). However, on February 11, 2004, the Food and Drug Administration (FDA) issued a Final Rule (69 FR 6787) declaring dietary supplements containing ephedrine alkaloids adulterated under the Federal Food, Drug, and Cosmetic Act (the FFD&C Act) because these dietary supplements present an unreasonable risk of illness or injury. Effective April 12, 2004, the FDA rule prohibited the sale of dietary supplements containing ephedrine alkaloids such as ephedra (also known as Ma Huang, sida

cordifolia and pinellia). The effect of the FDA rule was to ban the lawful marketing of these products.

DEA notes that the FDA ban addresses only the marketing of dietary supplements containing ephedrine alkaloids. The raw materials used to manufacture these dietary supplements are not restricted by the FDA ban. Accordingly, to control those materials, DEA needed to address the importation, exportation, manufacture, or distribution of chemical mixtures with concentration limits of ephedrine and/or pseudoephedrine at or below five percent. As there yet may be legitimate uses for chemical mixtures with concentration limits at or below five percent, the importation, exportation, manufacture, and distribution of these chemical mixtures (for purposes other than use in dietary supplements containing ephedrine alkaloids) are not prohibited by either FDA's ban regarding the marketing of such dietary supplements or by DEA law and regulations. Accordingly, as discussed in the Interim Rule (72 FR 40738, July 25, 2007), DEA removed the exempt status of chemical mixtures containing ephedrine and/or pseudoephedrine with concentration limits at or below five percent.

DEA recognizes that ephedra materials containing ephedrine and/or pseudoephedrine are used legitimately by practitioners of Traditional Chinese Medicine. This rulemaking does not restrict the utilization of such material for such legitimate purposes. This rulemaking will simply require importers and suppliers of such material to comply with DEA recordkeeping, registration, quota and import/export requirements.

Elimination of Exemption for Plant Material

The Interim Rule also removed the exemption for DEA chemical mixture regulations for certain plant materials. Specifically, the ephedrine alkaloids, including, among others, ephedrine, pseudoephedrine, norephedrine, N-methylephedrine, norpseudoephedrine, N-methylpseudoephedrine, are chemical stimulants that occur naturally in some botanicals, but can be synthetically derived. The ingredient sources of the ephedrine alkaloids include raw botanicals (i.e., plants) and extracts from botanicals. Ma Huang, Ephedra, Chinese Ephedra, and epitonin are several names used for botanical ingredients, primarily from Ephedra sinica Stapf, Ephedra equisetina Bunge, Ephedra intermedia var. tibetica Stapf and Ephedra distachya Linne (the Ephedras), that are sources of ephedrine alkaloids (including ephedrine and pseudoephedrine.) Other plant sources that contain such ephedrine alkaloids include Sida cordifolia L. and Pinellia ternata (Thunb.) Makino. Common names that have been used for the various plants that contain ephedrine alkaloids include sea grape, yellow horse, joint fir, popotillo, and country mallow. As DEA discussed in its Interim Rule, although the proportions of the various ephedrine alkaloids in botanical species vary from one species to another, in most species used commercially, ephedrine is typically the predominant alkaloid in the raw material. In addition to chemical mixtures from synthetic sources, the Interim Rule removed the exemption for those plant sources that contain the ephedrine alkaloids, ephedrine and/or pseudoephedrine.

The names desert herb, Squaw tea, Brigham tea, and Mormon tea refer to North American species of ephedra that do not contain ephedrine alkaloids but have been misused to identify ephedrine alkaloid containing ingredients. The Interim Rule did not pertain to species of ephedra that do not contain ephedrine and/or pseudoephedrine.

Combat Methamphetamine Epidemic Act of 2005

On March 9, 2006, the President signed the Combat Methamphetamine Epidemic Act of 2005 (CMEA), which is Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005. The CMEA mandates that DEA limit the domestic production and importation of materials containing ephedrine and pseudoephedrine (including ephedra) to quantities necessary for medical, scientific and other legitimate purposes (21 U.S.C. 826 and 952(a)(1) as amended). As DEA discussed extensively in the Interim Rule, DEA is concerned about the illicit use of ephedra type material in the clandestine production of methamphetamine. While the legitimate market for dietary supplements containing such material has been cut by FDA's recent action, DEA observed an increasing number of requests for importation of below-five percent ephedrine and/or pseudoephedrine material. While there may be legitimate uses for these chemical mixtures, in light of FDA's action, DEA had become increasingly concerned about the intended purpose of such material, especially given that such material has been seized in clandestine drug laboratories.

Action Taken by the Interim Rule

The Interim Rule published by DEA July 25, 2007 (72 FR 40738) removed the exemption for chemical mixtures having a total concentration of ephedrine and/or pseudoephedrine of five percent (or less). By removing these exemptions, all chemical mixtures containing ephedrine and/or pseudoephedrine became regulated chemical mixtures subject to control under the CSA, including registration, recordkeeping, reporting, and security controls. The rule also removed the exemption for the category of products consisting of harvested plant material meeting the definition of chemical mixture, even when the plant material is unaltered from its natural state, (i.e., ephedra) that contains ephedrine, N-methylephedrine, N-methylpseudoephedrine, norpseudoephedrine, phenylpropanolamine, and/or pseudoephedrine.

The Interim Rule did not prohibit the importation, exportation, manufacture, or distribution of chemical mixtures containing ephedrine or pseudoephedrine in concentrations less than or equal to five percent. Rather, DEA regulated the importation, exportation, manufacture, and distribution of these chemical mixtures by requiring persons who handle these chemical mixtures to register with DEA, maintain certain records common to business practice, and file certain reports, regarding these chemical mixtures. Chemical mixtures containing the List I chemicals ephedrine and pseudoephedrine are still available for use.

Comments Received

DEA did not receive any comments to its Interim Rule with Request for Comment (72 FR 40738, July 25, 2007) eliminating the exemption for chemical mixtures with concentration limits of the List I chemicals ephedrine and/or pseudoephedrine of less than or equal to five percent. Therefore, DEA is hereby finalizing that Interim Rule without change.

Provisions Specifically Applying to Regulated Chemical Mixtures Containing These List I Chemicals

Effective August 24, 2007, any chemical mixture that contains ephedrine or pseudoephedrine is treated as a List I chemical. Transactions that meet or exceed the cumulative monthly threshold for the listed chemical, set forth at 21 CFR 1310.04, became regulated transactions. Persons interested in handling a regulated

mixture must comply with the following:

Registration. Any person who manufactures, distributes, imports or exports a regulated mixture, or proposes to engage in such activities, with respect to a regulated mixture containing a List I chemical, shall obtain a registration pursuant to the CSA (21 U.S.C. 822). Regulations describing registration for List I chemical handlers are set forth in 21 CFR part 1309.

Separate registration is required for manufacture, distribution, importing, and exporting. A separate registration is required for each principal place of business at one general physical location where List I chemicals are manufactured, distributed, imported, or exported by a person (21 CFR 1309.23). Effective August 24, 2007, any person manufacturing, distributing, importing, or exporting any amount of a regulated mixture became subject to the registration requirement under the CSA. Recognizing that it is not possible for DEA to immediately issue registrations to all applicants, DEA established in 21 CFR 1310.09 a temporary exemption from the registration requirement for persons desiring to engage in activities with regulated mixtures, provided that DEA received a properly completed application for registration on or before August 24, 2007. The temporary exemption for such persons will remain in effect until DEA takes final action on their application for registration.

The temporary exemption applies solely to the registration requirement; all other chemical control requirements, including recordkeeping and reporting, were effective on August 24, 2007. Additionally, the temporary exemption does not suspend applicable federal criminal laws relating to the regulated mixture, nor does it supersede state or local laws or regulations. All handlers of a regulated mixture must comply with applicable state and local requirements in addition to the CSA regulatory controls.

Records and Reports. The CSA (21 U.S.C. 830) requires certain records to be kept and reports to be made involving listed chemicals. Regulations describing recordkeeping and reporting requirements are set forth in 21 CFR part 1310. A record must be made and maintained for two years after the date of a regulated transaction involving a List I chemical. Only a distribution, receipt, sale, importation, exportation, brokerage, or trade of a regulated mixture above the established threshold is a regulated transaction (21 CFR 1300.02(b)(28)).

Each regulated bulk manufacturer of a regulated mixture shall submit manufacturing, inventory, and use data on an annual basis (21 CFR 1310.05(d)). Bulk manufacturers producing the mixture solely for internal consumption, *e.g.* formulating a nonregulated mixture, are not required to submit this information. Existing standard industry reports containing the required information are acceptable, provided the information is readily retrievable from the report.

Further, 21 CFR 1310.05(a) requires that each regulated person shall report to DEA: (1) Any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the CSA; (2) any proposed regulated transaction with a person whose description or other identifying characteristics the Administration has previously furnished to the regulated person; (3) any unusual or excessive loss or disappearance of a listed chemical under the control of the regulated person, and any in-transit loss in which the regulated person is the supplier; and (4) any domestic regulated transaction in a tableting or encapsulating machine. 21 CFR 1310.03(c) requires that regulated persons who engage in a transaction with a nonregulated person or who engage in an export transaction that involves ephedrine or pseudoephedrine, 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.

Imports/Exports. All imports/exports and brokered transactions of regulated mixtures containing ephedrine and/or pseudoephedrine shall comply with the CSA (21 U.S.C. 952, 957 and 971). Regulations for importation and exportation of List I chemicals are described in 21 CFR part 1313. Separate registration is necessary for each activity (21 CFR 1309.22).

Security. Regulated persons must provide effective controls and procedures to guard against theft and diversion of regulated mixtures through physical means or human or electronic monitoring. Regulated persons must store the regulated mixtures in containers sealed so that tampering will be evident; if the mixture cannot be stored in a sealed container, access to the chemicals must be controlled (21 CFR 1309.71).

Administrative Inspection. Places, including factories, warehouses, or other establishments and conveyances, where regulated persons may lawfully hold, manufacture, or distribute, dispense, administer, or otherwise dispose of a regulated mixture or where records relating to those activities are maintained, are controlled premises as defined in 21 CFR 1316.02(c). The CSA (21 U.S.C. 880) allows for administrative inspections of these controlled premises as provided in 21 CFR part 1316 subpart A.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612) and by approving it certifies that this rule will not have a significant economic impact on a substantial number of small entities. This rule finalizes, without change, an Interim Rule with Request for Comment eliminating the exemption for chemical mixtures containing ephedrine and/or pseudoephedrine with concentration limits at or below five percent. DEA did not receive any comments to that Interim Rule.

Executive Order 12866

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866. It has been determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget (OMB). This rule finalizes, without change, an Interim Rule eliminating the exemption for chemical mixtures containing ephedrine or pseudoephedrine with concentration limits at or below five percent. DEA did not receive any comments to its Interim Rule.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal

governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Paperwork Reduction Act

With publication of the Interim Rule (72 FR 40738, July 25, 2007), DEA eliminated the current exemption for chemical mixtures with concentration limits of the List I chemicals ephedrine and/or pseudoephedrine of less than or equal to five percent. This means that all chemical mixtures containing the List I chemicals ephedrine and/or pseudoephedrine are regulated chemical mixtures, regardless of concentration limits.

Due to this change in the regulations, all persons who import, export, manufacture, or distribute chemical mixtures containing these two List I chemicals were required to register with DEA. They were also required to file reports regarding certain transactions, should certain criteria be met.

As the impact of this regulation was minimal, DEA made minor revisions to the OMB information collections entitled ''Application for Registration Under Domestic Chemical Diversion Control Act of 1993 and Renewal Application for Registration under Domestic Chemical Diversion Control Act of 1993'' (OMB control number 1117–0031, DEA Form 510), ''Report of Mail Order Transactions'' (OMB control number 1117–0033), and ''Import/Export Declaration for List I and List II Chemicals'' (OMB control number 1117–0023). DEA did not receive any comments regarding the number of persons who may be affected by this regulation. With publication of the Interim Rule, DEA received approval from the OMB to revise these information collections as discussed above.

Congressional Review Act

This Rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This Rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects In 21 CFR Part 1310

Drug traffic control, Exports, Imports, List I and List II chemicals, Reporting and recordkeeping requirements.

Adoption as Final Rule

The Interim Rule amending part 1310 of Title 21 of the Code of Federal Regulations, which published in the **Federal Register** on July 25, 2007, at 72 FR 40738, is hereby adopted as a Final Rule without change.

Dated: June 27, 2008.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E8–15704 Filed 7–9–08; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9413]

RIN 1545–BD19

Escrow Accounts, Trusts, and Other Funds Used During Deferred Exchanges of Like-Kind Property

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations under section 468B of the Internal Revenue Code (Code). The regulations provide rules regarding the taxation of income earned on escrow accounts, trusts, and other funds used during deferred like-kind exchanges of property, and final regulations under section 7872 regarding below-market loans to facilitators of these exchanges. The regulations affect taxpayers that engage in deferred like-kind exchanges and escrow holders, trustees, qualified intermediaries, and others that hold funds during deferred like-kind exchanges.

DATES: *Effective Date:* These regulations are effective *July 10, 2008.*

Applicability Dates: For dates of applicability, see §§ 1.468B–6(f), 1.7872–5(d), and 1.7872–16(g).

FOR FURTHER INFORMATION CONTACT: Concerning the final regulations under section 468B, Jeffrey T. Rodrick, (202) 622–4930; concerning the final regulations under section 7872, David B. Silber, (202) 622–3930 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) regarding the taxation of qualified escrow accounts, qualified trusts, and other escrow accounts, trusts, or funds used during section 1031 deferred exchanges of like-kind property, and of below-market loans to facilitators of these exchanges, under sections 468B(g) and 7872.

On February 7, 2006, a partial withdrawal of notice of proposed rulemaking, a notice of proposed rulemaking, and notice of public hearing were published in the **Federal Register** (REG–209619–93 and REG–113365–04, 71 FR 6231). A public hearing was held on June 6, 2006. A revised Initial Regulatory Flexibility Analysis (IRFA) for REG–113365–04 was published in the **Federal Register** on March 20, 2007 (72 FR 13055). Written and electronic comments responding to the notice of proposed rulemaking and the revised IRFA were received. After consideration of all the comments, the proposed regulations are adopted as amended by this Treasury decision. The comments and amendments are discussed below.

Explanation of Provisions and Summary of Comments

1. Definitions

The proposed regulations define *exchange funds* as relinquished property, cash, or cash equivalent that secures an obligation of the transferee to transfer replacement property, or proceeds from a transfer of relinquished property. A commentator suggested that the definition of exchange funds as relinquished property, cash, or cash equivalent that secures an obligation of the transferee to transfer replacement property should be deleted as confusing and unnecessary, because it is irrelevant whether amounts held in a qualified account or fund secure or are intended to secure the obligations of the transferee. The final regulations do not adopt this comment. This definition of exchange funds is necessary because it encompasses transactions contemplated in § 1.1031(k)–1(g)(3) in which, for example, a transferee of the relinquished property pays a deposit before the property is transferred, or a transferee of the relinquished property agrees to transfer replacement property and deposits funds to secure the obligations of the transferee (see § 1.468B–6(e), *Example 1*). The definition is an alternative to the definition of exchange funds as proceeds from a transfer of relinquished property, and does not create a