FOR FURTHER INFORMATION CONTACT: William Arvin, Office of Exporter Services, at *warvin@bis.doc.gov,* fax 202–482–3355 or telephone 202–482–2440.

SUPPLEMENTARY INFORMATION:

Background

On October 13, 2004, BIS published a proposed rule to amend the EAR by revising the definition of ''knowledge'' that applies throughout most of the regulations, to revise its ''red flag'' guidance and to create a safe harbor with respect to certain violations that have ''knowledge'' as one of the elements of the offense (69 FR 60829, October 13, 2004; Comment period reopened 69 FR 65555, November 15, 2004).

The proposed rule would have revised the definition of knowledge in § 772.1 of the EAR in four ways. It would have incorporated a ''reasonable person'' standard, replaced the phrase ''high probability'' with the phrase ''more likely than not,'' added the phrase ''inter alia'' to the description of the facts and circumstances that could make a person aware of the existence or future occurrence of a fact, and eliminated the phrase ''known to a person'' from the sentence in the knowledge definition that states that knowledge may be inferred from ''conscious disregard of facts known to a person.'' The proposed rule also would have limited the applicability of the definition to certain actors in transactions subject to the Export Administration Regulations (EAR) and excluded certain usages from the definition.

The proposed rule would have increased from 12 to 23 the number of circumstances explicitly set forth as ''red flags'' in Supplement No. 3 to part 732 of the EAR.

The proposed rule would have created a ''safe harbor'' from knowledge based violations. To take advantage of the safe harbor, a party would have to commit no violations of the EAR, in connection with the transaction, identify and resolve any ''red flags'' present in the transaction and report the red flags found and the resolution to BIS. BIS would have been required to acknowledge receipt of all such reports. Thereafter, if BIS responded to the party's report by stating that it concurred that the party had adequately addressed red flags or by advising the party that BIS would not be responding to the report, the party would have been able to take advantage of the safe harbor, assuming the party had accurately disclosed all relevant information to BIS. The proposed rule stated BIS's intention to respond to most reports within 45 days. However, the response might consist of a notice that BIS needed more time to evaluate the party's report. If BIS did not respond to the party's report by the date stated in the acknowledgment provided to the party, the party could have contacted BIS to inquire about the status of the report.

BIS received 18 comments on this proposed rule. Nine of these comments were filed by associations that have multiple members.

With regard to revising the definition of knowledge, the most frequently expressed opinion was that the revisions were, in fact, substantive changes to the definition rather than mere clarifications. Commenters also stated that BIS had not offered any reason as to why any change in the knowledge definition was necessary.

Although the revisions to the ''red flags'' were criticized less than other proposed changes, commenters made suggestions for revisions or elimination of 12 specific ''red flags.'' In addition, some commenters asserted that the proposal increased the number of circumstances that could be red flags without providing adequate guidance as to the circumstances when any particular ''red flag'' would be applicable. The notice did state (as does current Supplement No. 3 to part 732 of the EAR) that not all red flags are applicable in all circumstances.

A number of commenters criticized the safe harbor proposal, stating that it was too complex and lengthy. Several predicted that few, if any, firms would be inclined to use it. Some suggested that submitting a license application for the transaction would be simpler and probably faster than waiting to see if BIS approved of the manner in which the party resolved the ''red flags.''

Withdrawal of Proposal

BIS has considered the comments on the proposed rule. BIS has also reviewed the proposed rule as compared to the corresponding existing provisions of the EAR and has considered several possible modifications of the proposed rule. As a result of this consideration, BIS has concluded that utilizing this proposed rule as a basis for amending the EAR would neither clarify the public's responsibilities under the EAR nor make the regulations more effective. Accordingly, BIS is withdrawing this proposal.

Dated: October 11, 2006.

Christopher A. Padilla,

Assistant Secretary for Export Administration.

[FR Doc. E6–17265 Filed 10–17–06; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1312

[Docket No. DEA–276P]

RIN 1117–AB00

Reexportation of Controlled Substances

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Controlled Substances Export Reform Act of 2005 amended the Controlled Substances Import and Export Act to provide authority for the Drug Enforcement Administration (DEA) to authorize the export of controlled substances from the United States to another country for subsequent export from that country to a second country, if certain conditions and safeguards are satisfied. DEA is hereby proposing to amend its regulations to implement the new legislation.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before December 18, 2006.

ADDRESSES: Please submit comments, identified by ''Docket No. DEA–276,'' by one of the following methods:

1. *Regular mail:* Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL.

2. *Express mail:* DEA Headquarters, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301.

3. *E-mail comments directly to agency: dea.diversion.policy@usdoj.gov.*

4. *Federal eRulemaking portal: http://www.regulations.gov.* Follow the online instructions for submitting comments.

Anyone planning to comment should be aware that all comments received before the close of the comment period will be made available in their entirety for public inspection, including any personal information submitted. For those submitting comments electronically, DEA will accept attachments only in the following

formats: Microsoft Word, WordPerfect, Adobe PDF, or Excel.

FOR FURTHER INFORMATION CONTACT: Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Background

The Controlled Substances Export Reform Act of 2005 (Pub. L. 109–57) was enacted on August 2, 2005. The Act amended the Controlled Substances Import and Export Act to provide authority for the Attorney General (and DEA, by delegation) [1] to authorize the export of controlled substances from the United States to another country for subsequent export from that country to a second country, if certain conditions and safeguards are satisfied.

Previously under the Controlled Substances Import and Export Act (prior to the 2005 legislation), there were no circumstances in which it was permissible to export a controlled substance in Schedules I and II, or a narcotic controlled substance in Schedules III and IV, for the purpose of reexport to another country. Such controlled substances could lawfully be exported only to the immediate country where they would be consumed.

With the passage of the Controlled Substances Export Reform Act of 2005, Congress added a new provision, designated Section 1003(f) of the Controlled Substances Import and Export Act (21 U.S.C. 953(f)), which states:

> Notwithstanding [21 U.S.C. 953] subsections (a)(4) and (c)(3), the Attorney General may authorize any controlled substance that is in schedule I or II, or is a narcotic drug in schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met:
>
> (1) Both the country to which the controlled substance is exported from the United States (referred to in this subsection as the 'first country') and the country to which the controlled substance is exported from the first country (referred to in this subsection as the 'second country') are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971.
>
> (2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Attorney General deems adequate.
>
> (3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country.
>
> (4) With respect to the second country, substantial evidence is furnished to the Attorney General by the person who will export the controlled substance from the United States that—
>
> (A) The controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and
>
> (B) The controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country.
>
> (5) The controlled substance will not be exported from the second country.
>
> (6) Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred.
>
> (7) A permit to export the controlled substance from the United States has been issued by the Attorney General.

Note: The above text of the Act is published for the convenience of the reader, given that the Act sets forth what are essentially regulatory requirements that must be directly incorporated into this proposed rule. The official text is published at 21 U.S.C. 953(f).

DEA Proposed Implementation of the Controlled Substances Export Reform Act of 2005

The rule being proposed here would amend DEA regulations to implement this new legislation. Most of the amendments to the regulations being proposed here either reiterate the new statutory provisions added by the 2005 Act or specify the procedural details for complying with the new statutory provisions. In three respects, however, the proposed rule contains substantive requirements not contained in the statute. The first additional proposed requirement is that the reexporter notify DEA when the shipment leaves the United States. The second additional proposed requirement is that the reexport from the first country to the second country take place within 90 days after the shipment leaves the United States. The third additional proposed requirement is that bulk materials undergo further manufacturing in the first country prior to being shipped to the second country. This is the same requirement contained in existing DEA regulations for reexports of nonnarcotic controlled substances in Schedules III and IV and Schedule V controlled substances (21 CFR 1312.27(b)(5)).

It is proposed that these three additional requirements would entail minimal regulatory burden yet allow the agency to carry out the 2005 Act more effectively. Under the 2005 Act (subsection (6)), Congress mandated that the reexporter notify DEA within 30 days after the controlled substance is shipped from the first country to the second country. It can be inferred that one purpose of this provision is to provide a means for DEA to maintain an awareness of the status of shipments leaving the United States for reexport and thereby enhance the agency's ability to monitor and prevent diversion of such shipments. The three additional proposed requirements listed above further this same goal by eliminating the possibility that DEA would be unable to ascertain the status of an approved reexport for an indefinite period of time. Without the requirements being proposed here, a scenario could arise in which DEA has issued a permit authorizing a reexport, yet be without sufficient documentation to determine whether the shipment (i) has remained for many months in the first country without being reexported, (ii) has been improperly reexported to a different second country than that indicated on the reexport application, or (iii) was properly reexported to the second country but the reexporter failed to notify DEA within 30 days as required by the statute. The proposed additional notification requirement and the 90-day time limit for reexports is intended to minimize the likelihood of such uncertainties regarding the status of reexport shipments and thereby minimize the likelihood of diversion.

Requiring that reexports be completed within a finite time frame is also consistent with the historical approach in the DEA regulations that export permits be of a finite duration. See 21 CFR 1312.25 (setting forth expiration dates for export permits and providing maximum duration of six months).

Finally, it is anticipated that it will not be unduly burdensome for reexporters to notify DEA within 30 days after the shipment has left the United States or to complete the reexport within 90 days thereafter. DEA notes that the statute requires the reexporter (as a condition of obtaining an export permit from DEA) to specify both the first and the second countries, and to provide substantial evidence that, with respect to the second country, the controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country.

[1] 28 CFR 0.100(b).

Further, the statute requires the exporter to provide substantial evidence that the controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the second country. Therefore, DEA anticipates that reexporters will, themselves, seek to complete the reexport well within 90 days of arriving within the first country. DEA welcomes comments on these and any other relevant considerations.

Treaty Considerations

The first two subsections of the 2005 Act pertain to the Single Convention on Narcotic Drugs, 1961 (Single Convention), and the Convention on Psychotropic Substances, 1971 (Psychotropic Convention). Under these provisions, a reexport may take place only if both the first and second country are parties to both treaties and only if the Attorney General (DEA) determines that both the first country and the second country maintain an adequate system of controls in conformity with the treaties.

Thus, Congress expressly intended that reexports take place in accordance with the treaties. The control measures imposed under the 2005 Act, along with the regulations being proposed here, are intended to work in tandem with the international control regimes under the treaties. The ultimate goal of the 2005 Act and this proposed rule is to permit exportation of controlled substances in Schedules I and II and narcotic controlled substances in Schedules III and IV from the United States to a first country for subsequent exportation to one or more second countries while preventing international diversion resulting from reexports. Whenever considering safeguards against diversion of international shipments, one must bear in mind the backdrop of the treaties. Toward this end, the following treaty principles are noted.

Under the Single Convention, each country that is a party to the treaty is required to furnish the International Narcotics Control Board (INCB) with annual estimates of, among other things, the quantities of narcotic drugs on hand, the anticipated amounts that will be consumed by the party for legitimate purposes, and the anticipated production quantities. The Single Convention also requires parties to furnish the INCB with statistical returns for the prior year, indicating the amounts of drugs produced, utilized, consumed, imported, exported, seized, disposed of, and in stock. The Psychotropic Convention requires the parties to provide the INCB with statistical reports and assessments containing similar information with respect to psychotropic substances. Through the collection of this information, the INCB provides exporting countries with information on the legitimate requirements of the importing countries and can take steps to reduce the likelihood of international diversion. For example, the INCB may notify parties if the quantity of drugs exported to a particular country exceeded the estimates for that country. Parties that receive such notification from the INCB are prohibited from authorizing further exports of the drug concerned to that country.

The United States has always viewed as critical its obligation to work with the INCB closely to monitor imports and exports, and to take additional appropriate measures to safeguard against diversion. Therefore, based on the principles of the Single Convention and Psychotropic Convention pertaining to international drug control, and based on the requirements of the Controlled Substances Export Reform Act regarding the reporting of reexportations, DEA is proposing the additional requirements discussed above to ensure that DEA has the information necessary to determine whether controlled substances shipments intended for reexportation are occurring as initially reported to DEA or being diverted to illicit purposes.

Issuance of Permits

Under the 2005 Act, before a controlled substance can be exported for subsequent reexport, the exporter must obtain from DEA a permit that authorizes the export for this purpose. Consistent with the 2005 Act, DEA may only issue such permit if each of the conditions specified in the Act is met. Each of these conditions is restated in the proposed rule. Although most of these conditions are self-explanatory, some additional explanation is warranted.

First, as the proposed rule indicates, DEA will be issuing a new application form, DEA Form 161–r, for a permit to export controlled substances for subsequent reexport in accordance with the 2005 Act. The proposed rule also indicates what will constitute ''substantial evidence'' for purposes of subsection (4) of the 2005 Act. Specifically, if on the completed DEA 161–r, the applicant has identified an appropriately licensed or permitted consignee in the second country and certified that the second country is a party to the Conventions and maintains a system of controls of imports consistent with the requirements of the treaties, and so affirmed in the affidavit section of the application, DEA will consider this substantial evidence that a permit or license to import the controlled substance will be issued by the second country.

Reexportation to More Than One Second Country

DEA believes it is consistent with the text, structure, and purpose of the 2005 Act to allow a shipment of controlled substances to be exported from the United States to a ''first country'' for reexport to more than one ''second country,'' (but not further export from any second country to a third country) provided the exporter notifies DEA of such intent in the application for export permit, and provided further that the statute is fully complied with in all other respects. The proposed rule expressly provides for reexport to more than one second country, and the new Form 161–r will be structured accordingly. For example, DEA must be able to determine, based on information contained in the permit application (DEA Form 161–r), that each named second country is a party to the Single Convention and Psychotropic Convention and that each such country has instituted and maintains, in conformity with such treaties, a system of controls that DEA deems adequate.

Refused Shipments

Under current DEA regulations, 21 CFR 1312.27(b)(5), it is permissible under the conditions specified therein to reexport non-narcotic controlled substances in Schedules III and IV, and controlled substances in Schedule V. Subsection 1312.27(b)(5)(iv) of this existing regulation addresses the situation where a shipment has been exported from the United States but is refused by the consignee in the country of destination (the second country), or is otherwise unacceptable or undeliverable. The rule being proposed here would apply the same type of procedures set forth in subsection 1312.27(b)(5)(iv) to reexports under the 2005 Act, whereby the exporter may seek permission from DEA, in appropriate circumstances, to return the shipment to the registered exporter in the United States.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial

number of small entities. This rulemaking permits Schedule I and II controlled substances, and narcotic controlled substances in Schedules III and IV, to be exported from the United States to the first country for subsequent reexport to second countries for consumption. Previously such reexportation was not permitted within DEA law and regulations.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 1(b). DEA has determined that this is a significant regulatory action. Therefore, this action has been reviewed by the Office of Management and Budget.

Executive Order 12988

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

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 $118,000,000 or more 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 of 1995

The Department of Justice, Drug Enforcement Administration, is revising the information collection entitled ''Application for Permit to Export Controlled Substances'', by adding a new DEA Form 161–r to be used by persons applying for a permit to reexport controlled substances in Schedules I and II, and narcotic controlled substances in Schedules III and IV. DEA has submitted the new DEA Form 161–r and the information collection request to the Office of Management and Budget for review and clearance in accordance with review procedures of the Paperwork Reduction Act of 1995. The proposed information collection is published to obtain comments from the public and affected agencies.

All comments and suggestions, or questions regarding additional information, to include obtaining a copy of the proposed information collection instrument with instructions, should be directed to Mark W. Caverly, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, *Telephone:* (202) 307–7297. Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Comments should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Revision of an existing collection.

(2) *Title of the Form/Collection:* Application for Permit to Export Controlled Substances.

(3) *Agency form number, if any, and the applicable component of the Department of Justice sponsoring the collection:*

Form Number: DEA Form 161, Application for Permit to Export Controlled Substances; DEA Form 161–r, Application for Permit to Export Controlled Substances for Subsequent Reexport.

Office of Diversion Control, Drug Enforcement Administration, U.S. Department of Justice.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: None.

Abstract: Title 21 CFR 1312.21 and 1312.22 require persons who export controlled substances in Schedules I and II and who reexport controlled substances in Schedules I and II and narcotic controlled substances in Schedules III and IV to obtain a permit from DEA. Information is used to issue export permits, exercise control over exportation of controlled substances, and compile data for submission to the United Nations to comply with treaty requirements.

(5) An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond: It is estimated that 90 respondents will respond, with submissions as follows:

	Number of responses	Average time per response	Total (hours)
DEA Form 161 (exportation only)	2,200	30 minutes (0.5 hours)	1,100
DEA Form 161–r (reexportation)	400	45 minutes (0.75 hours)	300
Certification of exportation from United States to first country	400	15 minutes (0.25 hours)	100
Certification of reexportation from first country to second country*	1,200	15 minutes (0.25 hours)	300
Total	4,200		1,800

*Assumes three separate reexports to second countries.

(6) An estimate of the total public burden (in hours) associated with the collection: The total public burden (in hours) for this collection is estimated to be 1,800 hours.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. 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 1312

Administrative practice and procedure, Drug traffic control, Exports, Imports, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1312 is proposed to be amended as follows:

PART 1312—IMPORTATION AND EXPORTATION OF CONTROLLED SUBSTANCES [AMENDED]

1. The authority citation for part 1312 continues to read as follows:

Authority: 21 U.S.C. 952, 953, 954, 957, 958.

2. § 1312.22 is proposed to be amended by revising paragraph (a) and adding paragraphs (c) through (e) to read as follows:

§ 1312.22 Application for export permit.

(a) An application for a permit to export controlled substances shall be made on DEA Form 161, and an application for a permit to reexport controlled substances shall be made on DEA Form 161–r. Forms may be obtained from, and shall be filed with, the Drug Enforcement Administration, Import/Export Unit, Washington, DC 20537. Each application shall show the exporter's name, address, and registration number; a detailed description of each controlled substance desired to be exported including the drug name, dosage form, National Drug Code (NDC) number, the Administration Controlled Substance Code Number as set forth in Part 1308 of this chapter, the number and size of packages or containers, the name and quantity of the controlled substance contained in any finished dosage units, and the quantity of any controlled substance (expressed in anhydrous acid, base, or alkaloid) given in kilograms or parts thereof. The application shall include the name, address, and business of the consignee, foreign port of entry, the port of exportation, the approximate date of exportation, the name of the exporting carrier or vessel (if known, or if unknown it should be stated whether shipment will be made by express, freight, or otherwise, exports of controlled substances by mail being prohibited), the date and number, if any, of the supporting foreign import license or permit accompanying the application, and the authority by whom such foreign license or permit was issued. The application shall also contain an affidavit that the packages are labeled in conformance with obligations of the United States under international treaties, conventions, or protocols in effect on May 1, 1971. The affidavit shall further state that to the best of affiant's knowledge and belief, the controlled substances therein are to be applied exclusively to medical or scientific uses within the country to which exported, will not be reexported therefrom and that there is an actual need for the controlled substance for medical or scientific uses within such country, unless the application is submitted for reexport in accordance with paragraphs (c) and (d) of this section. In the case of exportation of crude cocaine, the affidavit may state that to the best of affiant's knowledge and belief, the controlled substances will be processed within the country to which exported, either for medical or scientific use within that country or for reexportation in accordance with the laws of that country to another for medical or scientific use within that country. The application shall be signed and dated by the exporter and shall contain the address from which the substances will be shipped for exportation.

* * * * *

(c) Notwithstanding paragraphs (a) and (b) of this section, the Administration may authorize any controlled substance listed in Schedule I or II, or any narcotic drug listed in Schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country, if each of the following conditions is met, in accordance with § 1003(f) of the Controlled Substances Import and Export Act (21 U.S.C. 953(f)):

(1) Both the country to which the controlled substance is exported from the United States (referred to in this section as the ''first country'') and the country to which the controlled substance is exported from the first country (referred to in this section as the ''second country'') are parties to the Single Convention on Narcotic Drugs, 1961, and the Convention on Psychotropic Substances, 1971;

(2) The first country and the second country have each instituted and maintain, in conformity with such Conventions, a system of controls of imports of controlled substances which the Administration deems adequate;

(3) With respect to the first country, the controlled substance is consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance has been issued by the country;

(4) With respect to the second country, substantial evidence is furnished to the Administration by the applicant for the export permit that—

(i) The controlled substance is to be consigned to a holder of such permits or licenses as may be required under the laws of such country, and a permit or license to import the controlled substance is to be issued by the country; and

(ii) The controlled substance is to be applied exclusively to medical, scientific, or other legitimate uses within the country;

(5) The controlled substance will not be exported from the second country;

(6) The person who exported the controlled substance from the United States has complied with paragraph (d) of this section and a permit to export the controlled substance from the United States has been issued by the Administration; and

(7) Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States must deliver to the Administration documentation certifying that such export from the first country has occurred. If the permit issued by the Administration authorized the reexport of a controlled substance from the first country to more than one second country, notification of each individual reexport shall be provided. This documentation shall be submitted on company letterhead, signed by the responsible company official, and shall include the following information:

(i) Name of second country;

(ii) Actual quantity shipped;

(iii) Actual date shipped; and

(iv) DEA export permit number for the original export.

(d) Where a person is seeking to export a controlled substance for

reexport in accordance with paragraph (c) of this section, the following requirements shall apply in addition to (and not in lieu of) the requirements of paragraphs (a) and (b) of this section:

(1) Bulk substances will not be reexported in the same form as exported from the United States, i.e., the material must undergo further manufacturing process. This further manufactured material may only be reexported to a country of ultimate consumption.

(2) Finished dosage units, if reexported, must be in a commercial package, properly sealed and labeled for legitimate medical use in the country of destination (the second country);

(3) Any proposed reexportation must be made known to the Administration at the time the initial DEA Form 161–r is submitted. In addition, the following information must also be provided where indicated on the form:

(i) Whether the drug or preparation will be reexported in bulk or finished dosage units;

(ii) The product name, dosage strength, commercial package size, and quantity;

(iii) The name of consignee, complete address, and expected shipment date, as well as the name and address of the ultimate consignee in the country to where the substances will be reexported.

(4) The application (DEA Form 161–r) must also contain an affidavit that the consignee in the country of ultimate destination (the second country) is authorized under the laws and regulations of the country of ultimate destination to receive the controlled substances. The affidavit must also contain the following statement, in addition to the statements required under paragraph (a) of this section:

(i) That the packages are labeled in conformance with the obligations of the United States under the Single Convention on Narcotic Drugs, 1961, the Convention on Psychotropic Substances, 1971, and any amendments to such treaties;

(ii) That the controlled substances are to be applied exclusively to medical or scientific uses within the country to which reexported (the second country);

(iii) That the controlled substances will not be further reexported from the second country, and

(iv) That there is an actual need for the controlled substances for medical or scientific uses within the second country.

(5) If the applicant proposes that the shipment of controlled substances will be separated into parts after it arrives in the first country and then reexported to more than one second country, the applicant shall so indicate on the DEA Form 161-r, providing all the information required in this section for each second country.

(6) Within 30 days after the controlled substance is exported from the United States, the person who exported the controlled substance shall deliver to the Administration documentation on the DEA Form 161-r initially completed for the transaction certifying that such export occurred. This documentation shall be signed by the responsible company official and shall include the following information:

(i) Actual quantity shipped;

(ii) Actual date shipped; and

(iii) DEA export permit number.

(7) The controlled substance will be reexported from the first country to the second country (or second countries) no later than 90 days after the controlled substance was exported from the United States.

(8) Shipments that have been exported from the United States and are refused by the consignee in the country of destination (the second country), or are otherwise unacceptable or undeliverable, may be returned to the registered exporter in the United States upon authorization of the Administration. In these circumstances, the exporter in the United States shall file a written request for the return of the controlled substances to the United States with a brief summary of the facts that warrant the return, along with a completed DEA Form 357, Application for Import Permit, with the Drug Enforcement Administration, Import/Export Unit, Washington, DC 20537. The Administration will evaluate the request after considering all the facts as well as the exporter's registration status with the Administration. If the exporter provides sufficient documentation, the Administration will issue an import permit for the return of these drugs, and the exporter can then obtain an export permit from the country of original importation. The substance may be returned to the United States only after affirmative authorization is issued in writing by the Administration.

(e) In considering whether to grant an application for a permit under paragraphs (c) and (d) of this section, the Administration shall consider whether the applicant has previously obtained such a permit and, if so, whether the applicant complied fully with the requirements of this section.

3. Section 1312.23 is proposed to be amended by revising paragraphs (a) and (f) to read as follows:

§ 1312.23 Issuance of export permit.

(a) The Administration may authorize exportation of any controlled substance listed in Schedule I or II or any narcotic controlled substance listed in Schedule III or IV if he finds that such exportation is permitted by subsections 1003(a), (b), (c), (d), or (f) of the Act (21 U.S.C. § 953(a), (b), (c), (d), or (f).

* * * * *

(f) No export permit shall be issued for the exportation, or reexportation, of any controlled substance to any country when the Administration has information to show that the estimates or assessments submitted with respect to that country for the current period, under the Single Convention on Narcotic Drugs, 1961, or the Convention on Psychotropic Substances, 1971, have been, or, considering the quantity proposed to be imported, will be exceeded. If it shall appear through subsequent advice received from the International Narcotics Control Board of the United Nations that the estimates or assessments of the country of destination have been adjusted to permit further importation of the controlled substance, an export permit may then be issued if otherwise permissible.

Dated: October 10, 2006.

Joseph T. Rannazzisi,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–141901–05]

RIN 1545–BE92

Exchanges of Property for an Annuity

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations that provide guidance on the taxation of the exchange of property for an annuity contract. These regulations are necessary to outline the proper taxation of these exchanges and will affect participants in transactions involving these exchanges. This document also provides notice of public hearing.

DATES: Written or electronic comments must be received by January 16, 2007.