Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–192P]

RIN 1117–AA56

Exemption From Import/Export Requirements for Personal Medical Use

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

ACTION: Notice of proposed rulemaking.

SUMMARY: The Controlled Substances Import and Export Act (CSI&EA) authorizes the Drug Enforcement Administration (DEA) to accommodate travelers who have a legitimate medical need for controlled substances during their journey. The CSI&EA allows DEA to issue a regulation exempting travelers from application of the CSI&EA requirements regarding importation and exportation of controlled substances. Such a regulation has existed since the CSI&EA came into effect in 1971. However, in recent years, Congress became aware that this regulation was being exploited by some individuals as a means of bringing controlled substances into the United States for illicit use. For this reason, Congress amended the CSI&EA in 1998 to place additional restrictions on the importation of controlled substances for personal use.

In this document, DEA is proposing to amend its regulations to expressly incorporate the restrictions on personal use importation imposed by Congress in 1998 and to expand upon those restrictions to curtail diversion that has continued even after the 1998 congressional amendment. Specifically, DEA is proposing to limit to 50 dosage units the total amount of controlled substances that a United States resident may bring into the United States for legitimate personal medical use when returning from travel abroad.

DATES: Comments must be postmarked by November 10, 2003.

ADDRESSES: Comments should be submitted to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

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

SUPPLEMENTARY INFORMATION:

What Does This Rule Accomplish and by What Authority Is It Being Issued?

Background

The CSI&EA (21 U.S.C. 951 *et seq.*) prohibits the importation of controlled substances into the United States, and the exportation of controlled substances from the United States, except as authorized by the Act. 21 U.S.C. 952, 953, 957, 960. In general, only persons who are registered with DEA to import or export controlled substances may do so. *Id.* In addition, depending on the schedule of the controlled substance being imported or exported, the CSI&EA requires the appropriate permit, notification, or declaration, as specified in the DEA regulations. *Id.;* 21 CFR 1312.11–1312.30. These requirements are necessary and appropriate to ensure that international shipments of controlled substances are limited to that which is necessary to meet the medical, scientific, and other legitimate needs of the country of destination and to prevent diversion of dangerous drugs into illicit channels. In addition, these requirements are necessary to meet United States obligations to control drugs of abuse in accordance with international treaties to which the United States is a party, including the Single Convention on Narcotic Drugs, 1961 (Single Convention), and the Convention on Psychotropic Substances, 1971 (Psychotropic Convention).

The CSI&EA makes a limited allowance, however, for travelers entering and departing the United States who have a legitimate medical need for controlled substances during their journey. As set forth in 21 U.S.C. 956, the Administrator of DEA [1] may, by regulation, exempt an individual traveler from application of the CSI&EA requirements regarding importation and exportation of controlled substances where such traveler possesses a controlled substance (except a substance in Schedule I) for the traveler's personal medical use, provided the controlled substance was obtained lawfully and the traveler makes the appropriate declaration or notification to the United States Customs Service, as specified in the DEA regulation. Such regulation has been in place since the CSI&EA was enacted in 1970. The regulation currently appears in 21 CFR 1301.26.

The allowance for personal use importation and exportation is consistent with United States treaty obligations. Article 4(a) of the Psychotropic Convention states: ''In respect of psychotropic substances other than those in Schedule I, the Parties may permit * * * the carrying by international travellers of small quantities of preparations for personal use; each Party shall be entitled, however, to satisfy itself that these preparations have been lawfully obtained.''

The Official Commentary to the Psychotropic Convention explains the purpose and meaning of article 4(a): ''Paragraph (a) applies only to small quantities needed for personal use, *i.e.*, to such quantities as the traveller may require during his journey or voyage and until he is able to provide himself with the medicine in question in the country of destination.''

It bears emphasis that 21 U.S.C. 956 does not require DEA to permit any minimum amount of controlled substances to be imported or exported for personal medical use. Rather, consistent with article 4(a) of the Psychotropic Convention, Congress gave DEA permissive authority to issue a regulation allowing personal use importation/exportation under such conditions as DEA finds are necessary to prevent diversion of controlled substances into illicit channels and which are consistent with Congressional intent.

Another critical factor is that transporting controlled substances across international borders entails a

[1] The Attorney General has delegated to the Administrator of DEA functions vested in the Attorney General by the CSA. 28 CFR 0.100.

heightened risk of diversion. Because of this inherent risk of diversion, United States drug control laws and international drug control treaties have, for most of the past century, placed paramount focus on international shipments of drugs of abuse. For example, the CSI&EA has, in general, always prohibited the commercial importation into the United States of controlled substances manufactured abroad, except where domestic production is inadequate to supply the legitimate medical, scientific, research, and industrial needs of the United States. In this manner, drug control authorities in the United States can maintain oversight over the handling of controlled substances from the point of manufacture to the point of dispensing to the ultimate user. Such complete oversight is essential to preventing diversion of controlled substances. This is precisely why Congress made the '' 'closed' system of drug distribution'' the hallmark of the CSA.[2]

The allowance of importation and exportation of controlled substances for personal medical use (first established by Congress in 1970 and codified in 21 U.S.C. 956) was meant to strike a balance between the significant risk of diversion associated with the carrying of controlled substances across international borders and the desire to accommodate the legitimate medical needs of travelers during their actual travel between countries. Stated alternatively, the allowance was meant to accommodate those who have an unavoidable legitimate medical need to import (or export) controlled substances as a result of their travel. The allowance was *not* meant to encourage United States residents to travel abroad to obtain their controlled substances for use in this country. To encourage such obtaining of controlled substances abroad would be to diminish the closed system of drug distribution intended by Congress under the CSA.

Why Congress Amended the Law in 1998

In 1998, Congress became concerned that 21 U.S.C. 956 and the DEA regulation implementing this provision were being misused by individuals—particularly United States residents—whose true intent was to divert controlled substances obtained abroad for illicit use in the United States (rather than to import controlled substances for legitimate personal medical use). Due to this concern, Congress amended 21 U.S.C. 956 to limit to 50 dosage units the amount of a controlled substance that a United States resident may bring into the country through an international land border for personal medical use without a prescription. This amendment was contained in a bill entitled the ''Controlled Substances Trafficking Prohibition Act'' (Pub. L. 105–357), which was enacted November 10, 1998.

The sponsor of the bill in the House of Representatives, Representative Chabot of Ohio, explained the purpose of the amendment as follows:

> This important initiative [the amendment to 21 U.S.C. 956] will close a loophole in Federal law that allows dangerous drugs, particularly drugs used in connection with date rape, to be legally imported into the United States.
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> Federal, State and local law enforcement agencies have raised serious concerns about the trafficking of controlled substances from Mexico. Right now uppers, downers, hallucinogens and date rape drugs similar to Rohypnol may be easily obtained from so-called health care providers or pharmacists in Mexico with no documentation of medical need whatsoever.
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> According to DEA, these drugs are frequently resold illegally in the United States. This situation is especially dangerous because these powerful drugs may be used in connection with date rapes. While Rohypnol, the most well-known date rape drug, has been banned in the U.S., it is still being used to rape young women, and many other dangerous controlled substances have taken its place. Jane Maxwell, director of the Texas Commission on Alcohol and Drug Abuse, says that this loophole continues to allow date rape drugs to cross the border.
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> For example, the drug Rivotril is everywhere, according to Maxwell, and is now being used by juveniles, just as Rohypnol has been used. A 1996 study documented the controlled substance drug trafficking problems along the U.S.-Mexico border. The study found that in just one year at the Laredo border crossing over 60,000 drug products were brought into the U.S. by more than 24,000 people. All of the top 15 drug products, which represented 94 percent of the total quantity of declared drugs, were controlled substances. These dangerous drugs, classified as prescription tranquilizers, stimulants and narcotic analgesics, are potentially addictive and subject to abuse. Specifically, Valium was declared by 70 percent of the people, with the average person bringing in 237 tablets. Rohypnol was brought in by 43 percent of those who declared their prescription medication. Over a full year that means that over 4 million doses of Valium and almost 1.5 million doses of Rohypnol were brought in at one single border crossing.
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> The median age for those who declared Valium and Rohypnol is 24 and 26 years old respectively. The large quantity of dangerous drugs passing through a single border crossing underscores the seriousness of the problem. The quantity and types of pills discovered also back up DEA's view that these drugs are being used for illegal purposes.
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> While this problem is most notable in communities along the U.S.-Mexico border, it impacts communities well outside the Southwest. The study in Laredo found that residents from 39 States crossed the border and returned to the United States with a variety of drug products.
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> Around the country, prescription drug abuse is a growing problem, especially among our youth. The purity and low price of prescription drug pills makes them an attractive alternative to traditional street drugs. At a recent Subcommittee on Crime hearing on date rape drugs, experts testified that GHB, Rohypnol and other date rape drugs are rapidly becoming the drug of choice in various communities and among the different types of users, particularly among teenagers.
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> Mr. Speaker, this legislation will help close the loophole which allows these dangerous drugs into our communities.

144 Cong. Rec. H 6903–01, H6904 (August 3, 1998).

Will the Proposed Rule Eliminate Any of the Current Requirements for Personal Use Importation?

The proposed rule will expand upon, but not eliminate, the requirements currently in effect as a result of Congress's 1998 amendment to 21 U.S.C. 956. The current requirements are as follows:

Under 21 CFR 1301.26, any individual may enter or depart the U.S. with a controlled substance listed in Schedule II, III, IV, or V, which he/she has lawfully obtained for his/her personal medical use, or for administration to an animal accompanying him/her, provided that the following conditions are met:

(a) The controlled substance is in the original container in which it was dispensed to the individual; and

(b) The individual makes a declaration to an appropriate official of the U.S. Customs Service stating:

(1) That the controlled substance is possessed for his/her personal use, or for an animal accompanying him/her; and

(2) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or, if such name does not appear on the label, the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number, if any; and

(c) The importation of the controlled substance for personal medical use is authorized or permitted under other Federal laws and state law.

[2] *See* House Report No. 91–1444, 1970 U.S.C.C.A.N. 4566–4572. ''The [CSA] provides for control by the Justice Department of problems related to drug abuse through registration of manufacturers, wholesalers, retailers, and all others in the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.'' *Id.*

21 CFR 1301.26.

The 1998 amendments to the CSI&EA made by Congress added restrictions that are *in addition to* the foregoing requirements in the DEA regulations. These amendments are contained in 21 U.S.C. 956(a)(2). This subsection provides that, where a United States resident is returning to this country through a land border (*i.e.*, returning by land from Mexico or Canada), and such person seeks to bring into the country a controlled substance obtained abroad for personal medical use (not obtained pursuant to a prescription issued by a DEA registrant), such person may bring in no more than 50 dosage units of the controlled substance.

The rule proposed here would specify that the 50-dosage-unit limit mandated by Congress under 956(a)(2) applies to *the combined total of all controlled substances that the returning traveler seeks to import for personal medical use* (rather than up to 50 dosage units of each of a variety of controlled substances). [A dosage unit is considered by DEA to be the basic unit used to quantify the amount to be taken in normal usage (*i.e.*, tablet, capsule, milliliter, or teaspoon).] This limitation applies whether or not the controlled substances were obtained using a prescription issued by a DEA-registered practitioner.

The rule, as proposed here, would also be applied to all United States residents who return to the United States at any location and by any means (not just travelers returning to the United States through a land border with Canada or Mexico). The United States Customs Service has advised DEA that it would be beneficial to have the rule written in a manner that is applied uniformly at all United States border checkpoints.

Does the 50-Dosage-Unit Limit Mean That a Returning Traveler May Bring Into the United States Up to 50 Dosage Units of Controlled Substances ''No Questions Asked''?

Many persons appear to be under the mistaken impression that Congress's 1998 amendment to 21 U.S.C. 956 was intended to allow United States residents to travel to Mexico or Canada, purchase controlled substances, then return to the United States with up to 50 dosage units ''no questions asked.'' It is DEA's intention, through this publication, to end any such misconceptions. In 1998 Congress placed a *limit* of 50 dosage units on the amount of a controlled substance that may be imported by United States residents entering from Mexico or Canada; Congress did not eliminate any of the existing requirements established by DEA in its regulation governing personal use importation (21 CFR 1301.26). It remains true that *all persons who wish to import controlled substances for personal medical use may do so only for legitimate personal medical use and must satisfy all of the requirements in 21 CFR 1301.26.* The requirements found in § 1301.26 are necessary to ensure that the drugs possessed by the traveler will actually be used by the traveler for legitimate personal medical use; Congress had no intention of eliminating these appropriate safeguards against diversion.

In all instances, if there is evidence that the traveler is attempting to bring into the United States controlled substances (in any amount) for other than legitimate personal medical use, the importation does not comport with either the statute (21 U.S.C. 956) or the DEA regulation (21 CFR 1301.26) and must be disallowed. The Customs official should, of course, take into account all facts and circumstances of a particular case in determining whether the traveler is attempting to bring in controlled substances for legitimate personal medical use or attempting to do so in order to divert the drugs for illicit use. Though neither dispositive nor exhaustive, the following factors may, depending on the circumstances, be indicative of diversion: (i) The same traveler has made repeated attempts over a short period of time to import controlled substances for claimed personal medical use; (ii) the traveler is carrying a variety of different controlled substances that are either contraindicated or in a combination that is commonly used by drug abusers.

Does the 50-Dosage-Unit Limit Apply to Foreign Travelers?

By its express terms, Congress's 1998 amendment, which imposed the 50-dosage-unit limit, applies only to United States residents; it does *not* apply to foreign travelers entering the United States. Likewise, the DEA regulation proposed here will apply only to United States residents.

Having made this distinction, it must be emphasized that all travelers—United States residents or non-United States residents—may only import (or export) controlled substances for *legitimate personal medical use* and must comply fully with all of the current provisions of 21 CFR 1301.26.

How Does the Combined 50-Dosage-Unit Limit Contained in the Proposed Rule Comport With Congress's 1998 Amendment to the CSI&EA?

On its face, the 1998 amendment to the CSI&EA (contained in 21 U.S.C. 956(a)(2)) does not mandate that United States residents be allowed to bring into the United States 50 dosage units of each of a variety of controlled substances purchased abroad. Rather, 50 dosage units is the *maximum* amount of a controlled substance that DEA may permit, through regulation, to be imported for personal medical use without a prescription. As explained above, Congress in 1998 was responding to the exploitation of the personal use allowance by persons seeking to divert controlled substances. Congress recognized that DEA would continue to monitor the situation and, if necessary, modify its regulation to impose tighter controls. As Senator Leahy stated during consideration of the bill:

> Such abuses have increased dramatically in recent years, and there is a need to address this problem now. [The 1998 amendment] does this by limiting the personal use exemption in certain circumstances to 50 dosage units. But this is only a stopgap measure. What constitutes ''personal use'' is a complicated issue that will turn on a number of circumstances, including the nature of the controlled substance and the medical needs of the individual. It is the sort of issue that should be addressed not through single-standard legislation but through measured regulations passed by an agency with the expertise in this matter. For this reason, * * * I [will] direct the Department of Justice to study the problems at our borders and to pass regulations that are more finely tuned to address those problems.

144 Cong. Rec. S 12680–04, 12681 (October 20, 1998).

Indeed, recently obtained information indicates that the misuse of the personal use importation allowance persists even after the 1998 amendment by Congress. Thus, revising the DEA regulations such that the 50-dosage-unit limit enacted by Congress applies to the combined total of all controlled substances in the traveler's possession is a necessary and appropriate step to further curtail the misuse of the personal use importation exception. DEA will continue to monitor the situation to determine whether future revisions to the regulation are needed to maintain adequate safeguards against diversion.

What Is the Meaning of ''Lawfully Obtained'' In the Context of Personal Use Importation?

Both the statute (21 U.S.C. 956) and the DEA regulation (21 CFR 1301.26) allow personal use importation only

where the controlled substances was ''lawfully obtained'' by the traveler abroad. In harmony with international drug control treaties, many countries, including Canada and Mexico, have laws that govern the prescribing and dispensing of controlled substances. For example, as is the case in the United States, Canadian law allows pharmacies to dispense controlled substances only pursuant to a prescription issued by a practitioner licensed to prescribe controlled substances in the province in which the controlled substance is dispensed.

The traveler seeking to import into the United States controlled substances obtained abroad for personal medical use may only do so if the controlled substances were dispensed in full compliance with the laws of the country in which they were obtained. It is the duty of the individual seeking to import a controlled substance for personal medical use pursuant to 21 U.S.C. 956(a) and DEA's regulation to know and comply with the laws of the jurisdiction in which the controlled substance was dispensed. Additionally, compliance with the CSI&EA and DEA's regulation does not excuse noncompliance with other Federal laws and state laws that may regulate the importation of controlled substances.

Regulatory Certifications

Regulatory Flexibility Act

The Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This proposed regulation affects only individual travelers and personal use quantities of controlled substances. Small businesses are subject to other DEA regulations for the importation and exportation of controlled substances, including registration, recordkeeping, reporting and security requirements. Businesses would not be using the personal use importation exemption to bring controlled substances into the United States. In fact, this rule could help small businesses as United States residents will purchase controlled substances from United States pharmacies rather than traveling outside the United States to make such purchases.

Executive Order 12866

The Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866, section 1(b). This action has been determined to be a significant regulatory action. Therefore, this regulation has been reviewed by the Office of Management and Budget.

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 regulation will not result in the expenditure by State, local, and tribal governments in the aggregate, or by the private sector, of $100 million or more in any one year, and would not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

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 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation or on the ability of U.S.-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

For the reasons set out above, 21 CFR Part 1301 is proposed to be amended as follows:

PART 1301—[AMENDED]

1. The authority citation for 21 CFR Part 1301 is proposed to be amended to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 951, 952, 953, 956, 957.

2. Section 1301.26 is proposed to be revised to read as follows:

§ 1301.26 Exemptions from import or export requirements for personal medical use.

Any individual who has in his/her possession a controlled substance listed in schedules II, III, IV, or V, which he/she has lawfully obtained for his/her personal medical use, or for administration to an animal accompanying him/her, may enter or depart the United States with such substance notwithstanding sections 1002–1005 of the Act (21 U.S.C. 952–955), provided the following conditions are met:

(a) The controlled substance is in the original container in which it was dispensed to the individual; and

(b) The individual makes a declaration to an appropriate official of the U.S. Customs Service stating:

(1) That the controlled substance is possessed for his/her personal use, or for an animal accompanying him/her; and

(2) The trade or chemical name and the symbol designating the schedule of the controlled substance if it appears on the container label, or, if such name does not appear on the label, the name and address of the pharmacy or practitioner who dispensed the substance and the prescription number.

(c) In addition to (and not in lieu of) the foregoing requirements of this section, a United States resident may import into the United States no more than 50 dosage units combined of all such controlled substances in the individual's possession.

Dated: September 4, 2003.

Karen P. Tandy,

Administrator.

[FR Doc. 03–23169 Filed 9–10–03; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 179

Munitions Response Site Prioritization Protocol

AGENCY: Department of Defense.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects the proposed rule published in the **Federal Register** on Friday, August 22, 2003 to correct typos and a Web address.

FOR FURTHER INFORMATION CONTACT: If there are specific questions, please contact Ms. Patricia Ferrebee, Office of the Deputy Under Secretary of Defense (Installations & Environment) (ODUSD(I&E)), 703–695–6107. This