

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 DEA¹ 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.