## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

### 21 CFR Part 1301

**[Docket No. DEA–192F]**

**RIN 1117–AA56**

## Exemption From Import/Export Requirements for Personal Medical Use

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

**ACTION:** Final rule.

**SUMMARY:** The Drug Enforcement Administration (DEA) is amending its regulations to expressly incorporate the restrictions on personal use importation imposed by Congress in 1998 and to expand upon those restrictions to curtail the diversion that has continued even after the 1998 congressional amendment. Specifically, DEA is limiting 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 at any location and by any means. This regulation will help prevent importation of controlled substances for unlawful use while still accommodating travelers who have a legitimate medical need for controlled substances during their journey.

**EFFECTIVE DATE:** October 14, 2004.

**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:** DEA published a Notice of Proposed Rulemaking (NPRM) in the **Federal Register** on September 11, 2003 (68 FR 53529), proposing to amend its regulations to incorporate restrictions on personal use importation of controlled substances imposed by Congress in 1998 and expand upon those restrictions as Congress contemplated to curtail continued diversion. In 1998, Congress amended a provision of the Controlled Substances Import and Export Act (CSI&EA) (21 U.S.C. 956) to limit to 50 dosage units the amount of a controlled substance that a United States resident [1] may bring into the country through an international land border for personal medical use without a prescription. Congress took this action because it had become aware that many individuals were exploiting the regulation that implements 21 U.S.C. 956(a) as a means of bringing controlled substances into the United States for illicit use. Because the law, even after the amendment made by Congress in 1998, continues to be used by many for diversion of controlled substances, and because Congress envisioned that DEA would fine tune the law over time, DEA is expanding upon the 1998 restrictions to limit to a combined total of 50 dosage units all controlled substances that a United States resident may bring into the United States for legitimate personal medical use when returning from travel abroad. The rule being finalized here applies 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). This rule does not allow United States residents to travel to a foreign country for the sole purpose of obtaining controlled substances to bring to the United States. Further, as DEA stated in a Notice published in the **Federal Register** June 29, 2004: ''The personal medical use exemption does not apply to the shipment of controlled substances into the United States from a foreign country, regardless of whether the individual receiving the shipment possesses a valid prescription issued by a United States practitioner for the controlled substances, and regardless of the fact that those controlled substances are intended for the personal medical use of an individual.'' (69 FR 38922).

### Background

The CSI&EA 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 [2] 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 Bureau of Customs and Border Protection (CBP).[3] These requirements are specified in 21 CFR 1301.26 and have been part of the regulations since the CSI&EA was enacted in 1970.

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.''

[1] For purposes of this rule, a United States resident is a person whose residence (*i.e.*, place of general abode—meaning one's principal, actual dwelling place in fact, without regard to intent) is in the United States.

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

[3] Effective March 1, 2003, the United States Customs Service underwent organizational changes under the Homeland Security Act of 2002. As a result of this reorganization, travelers entering or departing the United States with controlled substances will be required to make the appropriate declaration or notification referenced in 21 CFR 1301.26 to the appropriate official from the Bureau of Customs and Border Protection (CBP).

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 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.[4]

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 an appropriate 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 carry lawfully obtained controlled substances acquired for legitimate personal medical use during the course of travel). 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.
>
> 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.
>
> According to DEA, these drugs are frequently resold illegally in the United States. * * *

144 Cong. Rec. H6903–01, H6904 (August 3, 1998).

**Discussion of Comments**

DEA received two comments in response to the Notice of Proposed Rulemaking published in the **Federal Register** on September 11, 2003 (68 FR 53529). One commenter disagreed with the proposed rulemaking and the other commenter supported the proposed rulemaking with additional requirements. Both commenters were individual citizens.

One commenter stated that DEA ''was interpreting the [1998] amendment incorrectly and changing the meaning of 50 dosage units'' by limiting 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.

The 1998 amendment to the CSI&EA limited the amount of a controlled substance a United States resident could bring into the country through an international land border for personal medical use without a prescription to a maximum (not a minimum) of 50 dosage units of the controlled substance. During the hearings preceding enactment of the amendment, Senator Leahy stated that the 1998 amendment to the CSI&EA was ''only a stopgap measure.'' (144 Cong. Rec. S. 12680–04, 12681 (October 20, 1998)). Senator Leahy explained: ''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.'' He directed ''the Department of Justice [DEA by delegation of authority] to study the problems and to pass regulations that are more finely tuned to address those problems'' (*id.*). By this final rule DEA is carrying out its obligations in the manner that Senator Leahy suggested—by reevaluating the situation following passage of the 1998 amendment and issuing more fine-tuned regulations to better achieve Congress' goal of minimizing the exploitation of the law for purposes of diversion.

The second commenter supported the proposed rulemaking, but did not consider it restrictive enough. The commenter proposed a dual approach—not permitting any controlled substance to enter the United States without a ''U.S. prescription'' and also limiting the amount of controlled substances imported. The commenter would base the amount of controlled substance allowed on its schedule (50 dosage units for Schedule II; 100 dosage units for Schedule III; 150 dosage units for Schedule IV, and 200 dosage units for Schedule V).

DEA believes that limiting the personal medical use allowance to those who obtained controlled substances pursuant to prescriptions issued by

[4] *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.*

United States practitioners is too restrictive and inconsistent with the purpose of the law, which is to accommodate travelers' legitimate medical needs for controlled substances, or those of an animal accompanying them, during the course of their travel. There are instances when United States travelers may legitimately need to see a foreign doctor and be given a controlled substance by the foreign doctor and thus would not have a prescription issued by a practitioner in the United States. Under such circumstances, according to the commenter's proposal, the returning United States residents would have these controlled substances confiscated upon entry into the United States, even if the travelers still have a legitimate need for the medications until they can see their own doctors.

The commenter also suggested allowing a greater quantity of controlled substances in a lower schedule to be imported than in a higher one because they have a lower potential for abuse. The importation of any controlled substance for personal medical use is based on medical need and not on the schedule of the controlled substance. Only necessary controlled substances are allowed to be imported. This suggested requirement would also become confusing and time-consuming for the Bureau of Customs and Border Protection to enforce given the large number of controlled substances that exist and the number of travelers entering and leaving the United States.

**Final Rule Expands Current Requirements for Personal Use Importation**

This final rule expands upon, but does not eliminate, the requirements currently in effect as a result of Congress' 1998 amendment to 21 U.S.C. 956.

Under the current regulation, 21 CFR 1301.26, any individual may enter or depart the United States 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 Bureau of Customs and Border Protection 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; * * *

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.

This final rule specifies 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 United States traveler seeks to import for personal medical use* (rather than up to 50 dosage units of each of a variety of controlled substances).[5]

DEA believes that this approach strikes an appropriate balance between the need to prevent diversion of controlled substances for illicit purposes and the legitimate medical needs of United States residents to lawfully carry controlled substances for a legitimate medical purpose during the course of their travel. To reiterate, the purpose of the international treaties, Federal law, and this regulation is to permit travelers to carry, on their person, small quantities of controlled substances, lawfully obtained in a foreign country for legitimate medical use, until the traveler is able to obtain the medicine in question in the country of destination. As noted above, Congress intended when it revised the law in 1998 that DEA would implement additional restrictions as warranted to prevent any continued misuse of the law for illicit purposes. Restricting to 50 dosage units the total number of all controlled substances that may be imported by United States residents who legitimately obtained the controlled substances abroad fits within this Congressional mandate.

To promote uniform enforcement, this final rule applies 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).

[5] For purposes of this rule, a dosage unit is the basic unit used to quantify the amount to be taken in normal usage (*i.e.*, tablet, capsule, or teaspoonful (5 ml)).

**Total Limit of 50 Dosage Units for a Returning Traveler's Legitimate Personal Medical Use**

Many persons appear to be under the mistaken impression that Congress' 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). Nor did Congress preclude DEA from imposing more restrictive requirements by regulation. 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 Section 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 Bureau of Customs and Border Protection 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.

DEA wishes to clarify, however, that the amendment to the regulation being finalized here does not apply to controlled substances lawfully obtained by a United States resident within the United States for a legitimate medical purpose which the United States resident then carries with them during the course of their foreign travel—provided such traveler otherwise meets all requirements of 21 CFR 1301.26. In such a circumstance, because these controlled substances were lawfully obtained by a United States resident within the United States, it is appropriate not to impose the 50 dosage unit restriction when the traveler returns to the United States with the controlled substances in their original container. This is consistent with Congress' chief concern in enacting the 1998 amendment—to prevent persons from obtaining controlled substances abroad for illicit purposes in the United States. To ensure that this is clear, DEA is revising paragraph (c) of 21 CFR 1301.26 from that which was proposed to note that the requirements of this paragraph apply solely to controlled substances obtained abroad.

**Foreign Travelers**

By its express terms, Congress' 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. Rather, this Final Rule 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. These requirements, which have been part of the CSI&EA implementing regulations since 1971, have not changed and are unaffected by this rulemaking.

Thus, regardless of the quantity possessed, *any* individual, including a foreign traveler, possessing a Schedule II, III, IV or V controlled substance lawfully obtained for the individual's personal medical use, or for administration to an animal accompanying the individual, may enter the United States with the controlled substance, provided that the individual declares their possession of the controlled substance to an appropriate official of the Bureau of Customs and Border Protection, including the reason for possession (*i.e.*, intended for the individual's personal medical use or the administration to an animal accompanying the individual). The individual must also state 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. Finally, the controlled substance must be in the original container in which it was dispensed to the individual (21 CFR 1301.26(a) and (b)).

**The Combined 50 Dosage Unit Limit and Congress' 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.

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.

**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 were ''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 carry, on their person, 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, while DEA has eliminated the original paragraph (c) of 21 CFR 1301.26 which stated: ''The importation of the controlled substance for personal medical use is authorized or permitted under other Federal laws and state law.'' as being redundant, 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. As 21 CFR 1307.02 states: ''Nothing in this chapter shall be construed as authorizing or permitting any person to do any act which such person is not authorized or permitted to do under other Federal laws or obligations under international treaties, conventions or protocols, or under the law of the State in which he/she desires to do such act * * *''.

**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. 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 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 Deputy 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 amended as follows:

**PART 1301—[AMENDED]**

■ 1. The authority citation for 21 CFR Part 1301 is revised 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 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 Bureau of Customs and Border Protection 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 that were obtained abroad for personal medical use. (For purposes of this section, a United States resident is a person whose residence (*i.e.*, place of general abode—meaning one's principal, actual dwelling place in fact, without regard to intent) is in the United States.) This 50 dosage unit limitation does not apply to controlled substances lawfully obtained in the United States pursuant to a prescription issued by a DEA registrant.

Dated: September 1, 2004.

**Michele M. Leonhart,**

*Deputy Administrator.*

[FR Doc. 04–20628 Filed 9–13–04; 8:45 am]

BILLING CODE 4410–09–P

**DEPARTMENT OF THE INTERIOR**

**Office of Surface Mining Reclamation and Enforcement**

**30 CFR Part 914**

**[Docket No. IN–155–FOR]**

## Indiana Regulatory Program and Abandoned Mine Land Reclamation Plan

**AGENCY:** Office of Surface Mining Reclamation and Enforcement, Interior.

**ACTION:** Final rule; approval of amendment.

**SUMMARY:** We, the Office of Surface Mining Reclamation and Enforcement (OSM), are approving an amendment to the Indiana regulatory program (Indiana program) and abandoned mine land reclamation plan (Indiana plan) under the Surface Mining Control and Reclamation Act of 1977 (SMCRA or the Act). Indiana proposed revisions to and additions of statutes about performance bond release, the Indiana bond pool, and government-financed construction. Indiana intends to revise its program to be consistent with SMCRA and to improve operational efficiency.

**DATES:** Effective September 14, 2004.

**FOR FURTHER INFORMATION CONTACT:** Andrew R. Gilmore, Chief, Alton Field Division. Telephone: (317) 226–6700. Internet address: *IFOMAIL@osmre.gov.*

**SUPPLEMENTARY INFORMATION:**



### I. Background on the Indiana Program and Indiana Plan

Section 503(a) of the Act permits a State to assume primacy for the regulation of surface coal mining and reclamation operations on non-Federal and non-Indian lands within its borders by demonstrating that its State program includes, among other things, ''a State law which provides for the regulation of surface coal mining and reclamation operations in accordance with the requirements of this Act * * *; and rules and regulations consistent with regulations issued by the Secretary pursuant to this Act.'' See 30 U.S.C. 1253(a)(1) and (7). On the basis of these criteria, the Secretary of the Interior conditionally approved the Indiana program effective July 29, 1982. You can find background information on the Indiana program, including the Secretary's findings, the disposition of