Department of Justice, Patrick Henry Building, Suite 1600, 601 D Street NW., Washington, DC 20530.

Dated: June 23, 2004.

Brenda E. Dyer,

Deputy Clearance Officer, Department of Justice.

[FR Doc. 04–14657 Filed 6–28–04; 8:45 am]

BILLING CODE 4410–FY–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–245N]

Importing Controlled Substances From Canada and Other Foreign Countries

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice.

SUMMARY: On April 27, 2001, the Drug Enforcement Administration (DEA) published a notice in the **Federal Register** (66 FR 21181) to provide guidance to prescribers, pharmacists, law enforcement authorities, regulatory authorities, and the public concerning the application of current laws and regulations as they relate to the use of the Internet for dispensing, purchasing, or importing controlled substances. Since publication of that notice, DEA has noted increasing numbers of both Internet Web sites and ''brick and mortar businesses'' claiming to be able to assist individual consumers in purchasing prescription medications, including controlled substances, from Canada and other foreign countries. This document reiterates current Federal law and DEA regulations pertaining to the importation of controlled substances from foreign countries. Persons who have controlled substances sent from other countries into the United States violate Federal law unless those persons are registered with DEA as importers of controlled substances and have received from DEA an import permit.

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:

Introduction

Recently, the Drug Enforcement Administration (DEA) has noted increasing public interest in, and use of, both Internet Web sites and ''brick and mortar businesses'' claiming to be able to assist individual citizens in having their prescriptions filled at pharmacies in foreign countries and mailed to them in the United States. For purposes of this document, DEA uses the term ''brick and mortar businesses'' to refer to physical storefront locations of a business having direct contact with customers. It has been DEA's experience that the vast majority of such prescriptions are for drugs for treatment of such conditions as high blood pressure or cholesterol, arthritis pain, diabetes, infections, etc., which are not controlled substances; of all prescriptions issued each year, approximately 89% are for non-controlled substances and 11% are for controlled substances. DEA is concerned solely with the 11% of controlled substances prescriptions. (Controlled substances are those prescription medications which, among other factors, have the potential for abuse, which may lead to physical or psychological dependency.) The remaining 89% of prescriptions that do not involve controlled substances are not the subject of this notice or any requirement under the Controlled Substances Act or the Controlled Substances Import and Export Act.

Background

DEA administers the Controlled Substances Act and the Controlled Substances Import and Export Act (herein jointly called the CSA) which together form the basis for laws governing the manufacture, distribution, dispensing, importation and exportation of controlled substances. These laws may be found in Title 21, United States Code (U.S.C.), Sections 801–971. Regulations implementing these laws are found in Title 21, Code of Federal Regulations (CFR), Parts 1300 to 1316. Together, the CSA and its implementing regulations provide the framework for DEA to ensure adequate supplies of controlled substances for the legitimate medical, scientific, research, and industrial needs of the United States, while preventing the diversion of those controlled substances.

To do this, the CSA creates a ''closed system of drug distribution'' which requires DEA to register manufacturers, distributors, dispensers, importers, and exporters of controlled substances within the legitimate distribution chain, and makes transactions outside the legitimate distribution chain illegal.

The CSA provides that any person who causes controlled substances to be brought into the United States by any means—including causing items to be sent from other countries to the United States by mail or private shipping company—has imported controlled substances into the United States and is subject to criminal penalties (21 U.S.C. 951, 952, 960). Except as authorized by law, no person may import a controlled substance into the United States unless such person is registered with DEA and has obtained the appropriate permit or authorization from DEA to engage in such importation (21 U.S.C. 957). Illegal importation of controlled substances into the United States is a felony that may result in imprisonment and fines (21 U.S.C. 960).

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Explanation Regarding Controlled Substances

Medications which can be purchased without a prescription are over the counter medications. Drugs which may only be obtained pursuant to a practitioner's order are prescription medications. Many drugs and medications which have potential for abuse are controlled substances. Most drugs requiring a prescription from a physician or other practitioner are not controlled substances. The CSA and its implementing regulations assign controlled substances to one of five ''schedules.'' These substances are placed in a schedule based on, among other factors, their potential for abuse, which may lead to physical or psychological dependency. Schedule I substances have no accepted medical use for treatment in the United States and are not available by prescription. Schedule II controlled substances have a high potential for abuse and a currently accepted medical use in treatment in the United States or a currently accepted medical use with severe restrictions. The substances in each successive schedule have a lower potential for abuse and dependency relative to the higher schedules.

Schedule II, III, IV and V controlled substances may be dispensed by, or pursuant to, the lawful order of a practitioner acting in the usual course of professional practice for a legitimate medical purpose. Practitioners include, but are not limited to, doctors, dentists, veterinarians, and, where authorized by an appropriate state authority, physician assistants and advance practice nurses. Controlled substances include narcotics (pain relievers), stimulants, depressants, hallucinogens, and anabolic steroids. A listing of controlled substances can be found in 21 CFR Part 1308. Examples of controlled substances may also be found at the Diversion Control Program Web site: http://www.deadiversion.usdoj.gov. A few examples are shown below.

Schedule	Example of Controlled Substances
Schedule I	Heroin, marijuana, methylenedioxymethamphetamine (MDMA; Ecstasy).
Schedule II	Amphetamine, codeine, fentanyl (Duragesic®), hydromorphone (Dilaudid®), meperidine (Demerol®), methadone (Dolophine®), methylphenidate (Ritalin®, Metadate ER®, Concerta®), morphine, oxycodone (Percodan®, Tylox®, OxyContin®).
Schedule III	Anabolic steroids (Anadrol®, Depo-Testosterone®, Dianabol®), phendimetrazine (Prelu-2®), acetaminophen with codeine, hydrocodone/acetaminophen (Lorcet®, Vicodin®).
Schedule IV	Alprazolam (Xanax®), diazepam (Valium®), lorazepam (Ativan®), phentermine (Fastin®, Ionamin®, Adipex-P®).
Schedule V	Some cough preparations that contain a limited amount of codeine.

Basic Requirements for Prescribing and Dispensing Controlled Substances

Only practitioners who are authorized to prescribe controlled substances by the state in which they are licensed, are registered with DEA, and are acting in the usual course of their professional practice for a legitimate medical purpose may prescribe controlled substances. Pharmacies filling prescriptions for controlled substances must be licensed to dispense controlled substances by the state(s) in which they operate and also be registered with DEA. A prescription not issued for a legitimate medical purpose and not in the usual course of professional practice (or not for legitimate and authorized research) is not valid.

Importing Controlled Substances into the United States

Federal law and DEA regulations prohibit any person or entity from importing any controlled substance into the United States unless that person or entity is registered with DEA and specifically authorized by DEA to import the controlled substances (21 U.S.C. 952 and 957). Controlled substances may only be imported into the United States for medical and scientific purposes or other legitimate purposes (21 U.S.C. 952). Controlled substances may only be imported pursuant to a permit or declaration, as applicable, obtained from DEA (21 U.S.C. 952, 21 CFR 1312.11). As with all other registered handlers of controlled substances, importers of controlled substances must provide effective controls and procedures to guard against the theft and diversion of controlled substances (21 CFR 1301.71). Such security includes, depending on the schedule of the controlled substance, a vault, safe, cage or other secure storage facility (21 CFR 1301.72). The regulations specify the construction of each storage facility to adequately secure these controlled substances. Such storage facility, regardless of its type, must be alarmed, and the alarm system, upon attempted unauthorized entry, must transmit a signal directly to a central protection company or a local or state police agency which has a legal duty to respond, or a 24-hour control station operated by the importer (21 CFR 1301.72). As with other registered handlers of controlled substances, importers must design and operate a system to disclose suspicious orders (21 CFR 1301.74(b)), and must file reports regarding the theft or significant loss of controlled substances with DEA (21 CFR 1301.74(c)). As with other registered handlers of controlled substances, importers must maintain records regarding controlled substances imported, received, sold, delivered or destroyed (21 CFR 1304.21, 1304.22(d)). Finally, importers must take a periodic inventory, at least biennially, of all controlled substances on hand (21 CFR 1304.03, 1304.11(e)(4)).

Illegal importation of controlled substances is a felony that may result in imprisonment and fines (21 U.S.C. 960).

Purchasing Controlled Substances From Foreign Countries

DEA has become aware of both ''brick and mortar businesses'' and Internet sites within the United States which claim that they are able to have United States consumers' prescriptions filled in Canada or other foreign countries, or are able to facilitate a United States consumer's acquisition of prescription medications from pharmacies in Canada or other foreign countries. These stores and Internet sites accomplish this in a number of ways. Some stores or Internet sites send prescriptions issued by United States practitioners to Canadian companies which then have Canadian practitioners write equivalent prescriptions for Canadian medications. Some companies simply mail the United States prescriptions to Canadian pharmacies which fill the prescriptions based on the United States prescriptions only.

Some Internet sites do not require a prescription, but instead require the consumer to complete a questionnaire to receive a desired medication. These sites claim the questionnaire is evaluated by a physician and a prescription is written, if appropriate, based on the information provided in the questionnaire. Some foreign Internet sites claim they can legally sell controlled substances to consumers within the United States. Many of these sites require United States patients to waive their right to take legal action if a medication error occurs. Still other Internet sites sell listings of foreign Internet pharmacies which these sites claim will sell prescription medications without prescriptions.

It is illegal for a United States consumer or business to have controlled substances shipped to the United States from a foreign country unless the person receiving the controlled substances is registered with DEA as an importer or researcher and is in compliance with 21 U.S.C. 952 and 957 and 21 CFR Part 1312. Importers must comply with recordkeeping and reporting requirements regarding the controlled substances they import.

The acquisition of a controlled substance from a foreign country by any person other than a DEA-registered importer or researcher is a violation of the Controlled Substances Act. Therefore, United States pharmacies which fill prescriptions for controlled substances by obtaining those controlled substances from Canada, or any other

foreign country, are in violation of the Controlled Substances Act, regardless of whether the consumer possesses a legitimate prescription issued by a United States practitioner in the usual course of their professional practice. Likewise, consumers are also in violation of the Controlled Substances Act if they have prescriptions for controlled substances filled in foreign countries and shipped to the United States.

Personal Medical Use Exemption

The CSA contains a ''personal medical use'' exemption (21 U.S.C. 956; 21 CFR 1301.26) which makes a limited allowance for travelers entering and departing the United States who have a legitimate medical need for controlled substances during their journey. Under this exemption, United States residents who travel to foreign countries and non-United States residents who travel to the United States may carry controlled substances on their person for their legitimate personal medical use. DEA published a Notice of Proposed Rulemaking in the **Federal Register** on September 11, 2003 addressing the personal medical use exemption (68 FR 53529).

The ''personal medical use'' exemption only applies to individual travelers who themselves are entering or departing the United States who require controlled substances. 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. As stated previously, purchasing controlled substances from a foreign country or from a foreign Internet site and having them shipped to a business or individual within the United States is not permitted by the ''personal medical use'' exemption. Such purchases and shipments are considered ''imports'' under the Controlled Substances Act even if the substances are for personal use. Unless the business or individual within the United States receiving the shipment is registered as an importer with DEA and is in compliance with the requirements of Federal law and DEA regulations, such shipments are illegal and subject to seizure.

Conclusion

The Controlled Substances Act prohibits persons from importing controlled substances into the United States unless those persons are registered with DEA to do so. Persons importing controlled substances into the United States without being properly registered to do so are in violation of the CSA and are subject to prosecution for violation of Federal drug laws.

Dated: May 24, 2004.

William J. Walker,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 04–14716 Filed 6–28–04; 8:45 am]

BILLING CODE 4410–09–P

NUCLEAR REGULATORY COMMISSION

Meeting; Sunshine Act

DATE: Weeks of June 28, July 5, 12, 19, 26, August 2, 2004.

PLACE: Commissioners' Conference Room, 11555 Rockville Pike, Rockville, Maryland.

STATUS: Public and closed.

MATTERS TO BE CONSIDERED:

Week of June 28, 2004

There are no meetings scheduled for the week of June 28, 2004.

Week of July 5, 2004—Tentative

Wednesday, July 7, 2004:
1:55 p.m.—Affirmation Session (public meeting) (if needed).

Week of July 12, 2004—Tentative

Tuesday, July 13, 2004:
2:15 p.m.—Discussion of Security Issues (closed—Ex. 1).

Week of July 19, 2004—Tentative

Wednesday, July 21, 2004:
9:30 a.m.—Meeting with Advisory Committee on Nuclear Waste (ACNW) (public meeting) (contact: John Karkins (301) 415–7360). This meeting will be Web cast live at the Web address—*http://www.nrc.gov.*

Week of July 26, 2004—Tentative

There are no meetings scheduled for the week of July 26, 2004.

Week of August 2, 2004—Tentative

There are no meetings scheduled for the week of August 2, 2004.

* The schedule for Commission meetings is subject to change on short notice. To verify the status of meetings call (recording)—(301) 415–1292. Contact person for more information: Dave Gamberoni, (301) 415–1651.

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The NRC Commission Meeting Schedule can be found on the Internet at: *http://www.nrc.gov/what-we-do/policy-making/schedule.html.*

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The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings, or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.*, braille, large print), please notify the NRC's Disability Program Coordinator, August Spector, at (301) 415–7080, TDD: (301) 415–2100, or by e-mail at *aks@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

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This notice is distributed by mail to several hundred subscribers; if you no longer wish to receive it or would like to be added to the distribution please contact the Office of the Secretary, Washington, DC 20555 (301) 415–1969. In addition, distribution of this meeting notice over the Internet system is available. If you are interested in receiving this Commission meeting schedule electronically, please send an electronic message to *dkw@nrc.gov.*

Dated: June 24, 2004.

Dave Gamberoni,

Office of the Secretary.

[FR Doc. 04–14771 Filed 6–25–04; 9:29 am]

BILLING CODE 7590–01–M

OFFICE OF PERSONNEL MANAGEMENT

Proposed Collection; Comment Request for a Revised Information Collection Mail Reinterview Form (OFI 10), OMB No. 3206–0106

AGENCY: Office of Personnel Management.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104–13), this notice announces that the Office of Personnel Management intends to submit to the Office of Management and Budget a request for clearance of a revised information collection. OPM sends the OFI 10 questionnaire to a random sampling of record and personal sources contacted during background investigations when investigators have performed fieldwork. The OFI 10 is used as a quality control instrument designed to ensure the accuracy and integrity of the investigative product, as it inquires of the sources about the investigative procedure employed by the investigator,