identify appropriate next steps to address this issue, it is essential that FDA identify the number of supplements that will be filed. Therefore, FDA is extending the compliance date under the following condition. If a manufacturer notifies FDA in writing by January 29, 1997, of their intent to submit a supplement, the agency will not consider the manufacturer's supplement to be late if it is received by April 7, 1997.

Because this action only extends the compliance date, FDA finds that there is good cause to dispense with a notice of proposed rulemaking, under 5 U.S.C. 553(b)(3)(B), as impracticable and unnecessary and is publishing this revision as a final rule effective December 30, 1996.

Dated: December 23, 1996.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 96–33098 Filed 12–27–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR PARTS 1301 and 1311

[DEA Number 140R]

RIN NUMBER 1117–AA34

Registration and Reregistration Application Fees

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule; remanded for further notice and comment.

SUMMARY: On October 6, 1992, Congress passed the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993, Pub. L. No. 102–395, 106 Stat. 1828 (1992) (codified at 21 U.S.C. 886a) (Act). In section 886a(3) of this Act, Congress directed that ''fees charged by the DEA under its Diversion Control Program (DCP) shall be set at a level that ensures the recovery of the full costs of operating the various aspects of the (diversion control) program.'' On December 18, 1992, DEA published its proposal to adjust the existing registration fee schedule. 57 FR 60,148. After notice and comment, DEA published a Final Rule on March 22, 1993, setting the new registration fees. 58 FR 15,272.

Following publication of the final rule, a complaint was filed by the American Medical Association (AMA) and others in the United States District Court for the District of Columbia. On July 5, 1994, the district court issued its final order granting the government's motion for summary judgment, and thus disposed of all claims with respect to all parties. *American Medical Association* v. *Reno,* 857 F. Supp. 80 (D.D.C. 1994). The AMA appealed. On June 27, 1995, the United States Court of Appeals for the District of Columbia Circuit issued its decision holding that DEA's rulemaking was inadequate and that the rule must be remanded, without being vacated, to the DEA for further proceedings in which DEA provides both an opportunity for meaningful notice and comment on, and an explanation of, the components of the diversion control program. 57 F.3d 1129 (D.C. Cir. 1995) On August 29, 1995, the United States Court of Appeals for the District of Columbia Circuit remanded this action to the district court with instructions. On November 22, 1995, the District Court remanded the matter to DEA for proceedings consistent with the opinion of the United States Court of Appeals for the District of Columbia Circuit. This document responds to that requirement and provides a description of the components of the fee-funded diversion control program.

DATES: Comments and objections must be submitted on or before March 31, 1997.

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

SUPPLEMENTARY INFORMATION: The Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993 (Pub. L. 102–395) required that DEA recover the costs associated with the DCP through fees charged by DEA under that program. Therefore, DEA published a notice of proposed rulemaking (NPRM) in the Federal Register on December 18, 1992 (57 FR 60148) proposing to amend the fees set forth in Title 21, Code of Federal Regulations (21 CFR), §§ 1301.11 and 1311.11. On March 22, 1993, following notice and comment, DEA published a final rule in the Federal Register amending the fees.

DEA's rulemaking was challenged in court, in part on the grounds that it failed to provide adequate notice or explanation of the costs and scope of the DCP to be funded through the fees. While the United States District Court upheld the rule, on appeal, the United States Court of Appeals, District of Columbia Circuit decided on August 29, 1995, that the rulemaking was to be remanded, without being vacated, to DEA in order to identify the components of the fee-funded DCP and provide a brief explanation of why DEA deemed each component to be part of that program. Such description was to provide the opportunity for meaningful notice and comment regarding the established fee. *AMA, et al.* v. *Janet Reno, Attorney General, et al.,* 57 F.3d 1129 (D.C. Cir. 1995). In response to the decision of the court, the following explanation of the various components of the DCP is provided. Since the court did not vacate the final rule, DEA is not republishing either the original NPRM or final rule. Persons seeking further information regarding those notices should see the December 18, 1992 issue of the Federal Register (57 FR 60148) for the NPRM and the March 22, 1993 issue of the Federal Register (58 FR 15272) for the final rule.

Background of The Budget Item ''Diversion Control Program''

The Comprehensive Drug Abuse Prevention and Control Act of 1970 (Pub. L. 91–513, commonly known as the Controlled Substances Act and the Controlled Substances Import and Export Act (CSA)), established the current Federal authority and programs to control the manufacture, distribution, importation, exportation and dispensing of ''controlled substances'' and to prevent the diversion of such substances from legitimate medical, scientific, research, and industrial channels into the illicit traffic. The CSA established a system of scheduling of substances, registration of legitimate handlers, production quotas, dispensing and distribution controls, record-keeping and reporting, import/export provisions, and penalties for violations of the CSA. It also mandated administrative and enforcement provisions, and cooperative efforts with state and local authorities. Additionally, as discussed in the later section regarding international activities, the United States has obligations under the United Nations Single Convention on Narcotic Drugs, 1961 (1961 Convention), and the Convention on Psychotropic Substances, 1971 (1971 Convention) (referred to collectively as the international treaties), to which it is a party, with respect to international control and cooperation to prevent the diversion of controlled substances. The CSA programs relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances are the domestic mechanism for implementing these treaty provisions. Over the past 25 years, the CSA has

been amended to include various enhancements and refinements needed to achieve the goals of the CSA and fulfill the U.S.'s obligations under international treaties in an ever changing milieu of diversion, abuse and illicit trafficking of drugs. These modifications include, among others, the Narcotic Addict Treatment Act of 1974 (Pub. L. 93–281), The Psychotropic Substance Act of 1978 (Pub. L. 95–633), the Diversion Control Amendments of 1984 (Pub. L. 98–473), the Anti-Drug Abuse Act of 1986 (Pub. L. 99–570), and the Anabolic Steroids Control Act of 1990 (Pub. L. 101–647).

In executing the CSA mandates and international treaty obligations related to the registration and control of the manufacture, distribution, dispensing, importation and exportation of controlled substances, Congress and the DEA (and its predecessor agency the Bureau of Narcotics and Dangerous Drugs, BNDD) established an identified work force and programs generally known as the DCP. Within DEA, the programmatic authority and responsibility for this effort is exercised by the Office of Diversion Control (OD) using the Congressionally authorized resources identified in the budget category DCP which are committed to those responsibilities and programs.

Historically, for the purposes of budget formulation and appropriation, only resources, along with their individual ''modular'' or overhead costs, devoted to diversion control efforts, were administratively identified as the DCP within the annual budget request to Congress. Other resources which support a broad range of DEA activities, including ''Diversion Control'', were carried for administrative purposes in the budget formulation and appropriation process under other budget categories, such as legal support. For example, DEA's Office of Chief Counsel, which is carried as part of the DEA Budget Category ''Management and Administration,'' exists primarily to provide legal support to the entire agency. Although that office has a full section devoted to ''Diversion Control'' support, such as legal interpretation, DEA registration revocation actions, and quota hearings, no resources of the Office of Chief Counsel are included in the ''DCP'' category of DEA's annual budget submission, since the overall Chief Counsel function is not primarily devoted to Diversion Control and is carried elsewhere in the DEA budget.

Since 1970, the CSA has provided that the Attorney General ''is authorized to promulgate rules and regulations and to charge reasonable fees'' relating to the registration and control of the manufacture, distribution, dispensing, import, and export of controlled substances. See 21 U.S.C. 821 and 958. Prior to 1993, the fees collected solely for registration to handle controlled substances were deposited into the general fund of the United States Treasury; they did not accrue to DEA.

In October 1992, during the annual Congressional appropriation process, Congress established the ''Diversion Control Fee Account.'' This was an amendment to the Department of Justice and Related Agencies Appropriations Act, and did not purport to realign or curtail any DEA programs, activities, or priorities; the amendment established legislatively the future funding mechanism for Congressionally approved resources related to ''the operation of the diversion control program.'' In setting the parameters for this funding mechanism, Congress identified the functions and resources within DEA which have historically been assigned to the administratively determined budget category ''DCP'', as submitted by DEA, the Department of Justice, Office of Management and Budget, and the President of the United States. Any future Congressionally approved adjustment of resources devoted to these components, or Congressionally approved realignment of appropriated resources from other DEA budget categories which are related to the registration and control of the manufacture, distribution, and dispensing of controlled substances and herein identified, will be encompassed in the Diversion Control Fee Account.

Diversion Control Program and Responsibilities

The components of the DCP have their basis in the CSA and international treaties to which the U.S. is a party. The resources approved by Congress are directed toward these responsibilities. The components of the DCP as they relate to the specific provisions of the CSA and the treaties are set forth below:

Regulatory Development and Maintenance

(21 U.S.C. 821—Rules and regulations.)

The CSA sets the requirements with respect to the control of the manufacture, distribution, and dispensing of controlled substances. Development and refinement of the regulations set out in 21 CFR Parts 1301–1308, 1311–1312, and 1316 are an essential part of the DCP, for they establish the specific procedures and guidelines that are necessary to implement the requirements of the CSA.

The control of drug diversion and abuse is not static. Shifts in health care practices, patterns of diversion and drug abuse, drug treatment, industry practices, and technology present an ever-changing milieu of diversion and abuse. Regulatory changes are necessary to adjust to these shifts. The Attorney General (AG) is authorized to promulgate rules and regulations relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances. See 21 U.S.C. 821. The AG has delegated that authority to DEA. See 28 CFR 0.100(b) and 0.104.

DEA, through the DCP, is responsible for regulatory development or change. In order to carry out these functions DEA employs a specialist staff that identifies the need for regulatory change or development, performs the research and data collection in support of changes, promulgates the regulatory changes, and provides guidance to DEA personnel, other regulatory and law enforcement personnel, and industry regarding the regulatory requirements.

Activities in support of these functions include meetings and national conferences with representatives of the regulated industry, representatives of the law enforcement community, and other interested parties to discuss the current regulatory program and identify areas that may need to be addressed. There are five different industry workgroups: Practitioner, Distributor, Manufacturer, Pharmacy, and Mid-Level Practitioner. Meetings with each workgroup are scheduled on a regular basis. In addition, separate national conferences are held approximately every 24 months for the pharmaceutical manufacturers and distributors and for drug control personnel. In addition to the administrative work required to prepare for such meetings and conferences, including the solicitation of agenda topics from the attendees, DCP personnel conduct research and prepare position papers and briefing materials regarding the various agenda topics.

If regulatory change is needed, DCP personnel conduct the research, reviews of scientific and technical literature and other Federal and state laws and regulations; collect data; and consult with industry, law enforcement/regulatory sources, or other interested parties. Following drafting and publication of the notice of proposed rulemaking, personnel review all comments and determine whether substantive issues have been raised that require adjustment to the proposed regulations. In drafting the final rule, issues raised in the comments are

addressed and, where appropriate, adjustments to the proposed regulations are made to accommodate any substantive issues. Following establishment of new regulations, DCP staff prepare and distribute interpretations, guidelines and informational material regarding the new requirements for DEA personnel, industry, and other law enforcement/regulatory personnel. As needed, direct consultations to clarify the requirements of new regulations are also held with industry and law enforcement/regulatory groups.

In addition to the activities relating to regulatory changes, DCP personnel respond to requests from industry and law enforcement/regulatory personnel for information and interpretation of existing regulatory requirements and policy; respond to congressional inquiries regarding issues related to controlled substances; draft legislation relating to controlled substances; and prepare testimony and briefings for congressional hearings on the diversion of controlled substances.

Classification of Substances

(21 U.S.C. 811, 812, and 813—Authority to Control; Authority and criteria for classification of Substances; Schedules of Controlled Substances; Treatment of analogues; 1961 Convention, Articles 2 and 3—Substances under control; Changes in the scope of control; 1971 Convention, Articles 2 and 3—Scope of control; Control of preparations)

The authority to control substances of abuse is central to the effective application of the CSA and DEA's programs relating to the registration and control of the manufacture, distribution and dispensing of controlled substances. The CSA provides the criteria for the classification of substances into five schedules of control. The DCP collects, monitors, and analyzes data for recommendations to add, transfer between, or delete from such schedules any drug or other substance. These activities include the development of methodologies to predict and confirm the abuse potential of substances and combinations of substances; the application of scientific knowledge concerning the actual and relative potential of abuse of substances; the collection and appraisal of international scientific literature and information from DEA, and other Federal, state, local and foreign sources regarding the abuse, abuse and trafficking of substances; and the maintenance of liaison and information exchange with the Department of Health and Human Services (HHS) and other domestic and international agencies, such as the World Health Organization and the International Narcotics Control Board, having similar scientific, regulatory, law enforcement, and drug control interests.

In addition to collecting information regarding the control of substances, DEA provides scientific and other information for international, national, and state scheduling of substances; responds to scheduling petitions and reviews and determines the status of controlled, excepted, excluded, or exempted drugs and analogues; and provides training, guidance, expert testimony, assistance and/or information on drug control and classification to law enforcement agencies, the scientific community, industry, the public, and other interested parties.

DEA has initiated over a dozen drug reviews of both controlled and non-controlled substances in the recent past. Examples of controlled substances reviewed are fenfluramine, methylphenidate, flunitrazepam, quazepam, dronabinol, and marijuana (to Schedule II for medical or industrial use). The review of noncontrolled substances being considered for control include ketamine, butorphanol, gamma hydroxy butyrate, and carisoprodol to determine if control of the manufacture, distribution, and dispensing of the substances is appropriate. Each review requires a comprehensive study of the national and international scientific literature regarding the properties and use of the drugs, the current national and international controls over the drugs, data regarding annual production and consumption, and information from domestic and international law enforcement, regulatory, and medical sources regarding the diversion, trafficking, and abuse of the drugs. As appropriate, action may be taken, through formal rulemaking on the record with opportunity for hearing, to schedule, reschedule, or decontrol the drugs.

Identification of Controlled Substances

(21 U.S.C. 825—Labeling and packaging; 1961 CONVENTION, ARTICLE 30—Trade and distribution; 1971 CONVENTION, ARTICLE 10—Warnings on packages)

In conjunction with the classification of substances as controlled under the law, the CSA and international treaties require that such substances contain certain identifying symbols, warnings, and seals. DCP personnel monitor compliance with the requirements of 21 U.S.C. 821 as promulgated by 21 CFR 1302 pertaining to labeling and packaging requirements by reviewing 200 to 300 labels per year which are collected by DEA or are submitted to DEA by manufacturers. Additionally, DCP personnel provide interpretation of the requirements to registrants and Federal and state authorities, and review and enforce the requirements on an ongoing operational basis.

Registration

(21 U.S.C. 822, 823, 824, 957, 958—Persons required to register; Registration Requirements; Denial, revocation, or suspension of registration; 1961 Convention, Article 30—Trade and distribution; 1971 Convention, Article 8—Licenses)

Another component of the DCP is the registration of those persons authorized to manufacture, distribute, dispense, import, or export controlled substances. The CSA requires that every person who manufactures, distributes, dispenses, imports, or exports a controlled substance shall obtain a registration, and establishes the requirements for such registration. The CSA also includes provisions relating to the denial, revocation, or suspension of registrations. The international treaties require that the signatories allow trade and distribution of controlled substances only under license.

DEA manages and operates the registration and reregistration process for over 900,000 handlers of controlled substances. DCP personnel process an average of 300,000 renewal applications and 48,000 new applications per year. The process includes reviewing the forms, processing and accounting for the fees, entering the appropriate data into the registration system, obtaining corrections from applicants when appropriate, and referring the applications to the appropriate office for review of the applicant's qualifications and bona fides for registration. Applications for the bulk manufacture or importation of Schedule I and II controlled substances require the preparation of notices of application for publication in the Federal Register. New applications to conduct research with Schedule I controlled substances and for narcotic treatment programs must be evaluated and considered in conjunction with the Food and Drug Administration. Further, all new applications for registration must be examined and evaluated with the appropriate state authorities to ensure that the applicant has been granted the appropriate state authorization.

DCP personnel process over 150,000 requests per year from registrants for modification of registration (name, address, drug schedule changes, etc.), voluntary retirement of registration, or

for order forms; respond to over 10,000 telephonic inquiries per month from applicants and registrants regarding registration; respond to Freedom of Information Act and Congressional requests regarding registrant information; and prepare affidavits and certification statements regarding the registration status of DEA registrants and applicants for use in DEA hearings and other proceedings.

DCP personnel also prepare and distribute registrant information to other DEA elements, Federal, state and local regulatory personnel, and registrants for the purpose of confirming registrant status; and initiate studies and new systems to support and enhance the registration program.

Records and Reports

(21 U.S.C. 827, 828 AND 829—Records and Reports of Registrants; Order Forms; Prescriptions; 1961 CONVENTION, ARTICLES 19, 20, AND 30—Estimates of drug requirements, Statistical returns furnished to the Board; Trade and distribution; 1971 CONVENTION, ARTICLES 11, 16 AND 9—Records and Reports to be furnished by the parties; Prescriptions)

The CSA and international conventions provide for the maintenance of a system of records and accountability for controlled substances by authorized handlers. Registrants are required by the CSA to maintain records and inventories of controlled substances manufactured, received, distributed, dispensed, imported, exported, or otherwise disposed of; make such records available for inspection and copying; and make certain reports to the Attorney General (DEA).

Establishment and enforcement of the record-keeping and reporting provisions of the CSA and examination of the records to identify potential diversion constitute a substantial part of the DCP activities. With respect to records, program personnel conduct comprehensive cyclic investigations of registrants' records and inventories to ensure the integrity of the diversion control system. Investigations of registrants for failure to comply with the record-keeping and reporting provisions of the CSA are conducted and the appropriate administrative, civil, or criminal action is pursued. Additional discussion of these investigations can be found in the section relating to Enforcement Activities.

DCP personnel conduct a variety of duties utilizing various reports required to be submitted by registrants. As part of the closed system to control the manufacture, distribution and dispensing of controlled substances, registrants must make reports to DEA regarding the bulk or dosage form manufacture of all Schedule I and II controlled substances, all narcotic controlled substances in Schedules III–V, and certain psychotropic controlled substances in Schedules III and IV; and the repackaging and relabeling of and the distribution of all Schedule I and II controlled substances and all narcotic controlled substances in Schedule III. In addition, registrants must provide copies of order forms documenting the distribution of Schedule I and II controlled substances, excessive purchase and suspicious order reports, theft or loss reports, and reports of the disposal of controlled substances.

The order forms, excessive purchase, suspicious order, and theft or loss of reports are reviewed by DCP personnel, both on an individual basis and with reference to other reports that have been filed to determine whether further investigation is required. Theft or loss data are also electronically compiled and tracked to allow for identification of suspicious or unusual local, regional, or national trends in the theft or loss of controlled substances.

Manufacturing reports are reviewed by DCP personnel to determine if registrants are complying with quota requirements and to determine various trends and availability of substances. The information is then extracted and collated for domestic manufacturing reports required by the U.N. conventions.

DCP personnel receive and process over 9,500 reports per year regarding controlled substances distributions, commonly referred to as ''ARCOS'' reports, from approximately 1,400 registrants. The reports contain data regarding approximately 14,000,000 controlled substances transactions per year. Each report must be processed, corrected, and entered into the ARCOS system. From this, as mandated by the CSA, DEA operates a diversion targeting system for DEA and state and local officials. In addition, special reports regarding regional distribution and distributions to specific registrants are generated as needed.

Production Quotas

(21 U.S.C. 826—Production Quotas for Controlled Substances; 1961 CONVENTION, ARTICLE 21—Limitations on Manufacture and Importation; 1971 CONVENTION, ARTICLE 5—Limitation of use to medical and scientific purposes)

The CSA and international treaties require that DEA determine the total quantity of certain controlled substances that is necessary for medical, scientific, research, and industrial use in the U.S. and that the manufacture of such substances be limited accordingly through a system of production quotas.

In fulfilling this mandate, the DCP collects and analyzes information regarding the legitimate use, trafficking and abuse of Schedule I and II controlled substances in the U.S. from such sources as manufacturing and distribution reports, treatment and prescription utilization data, case data, drug abuse indicators, and HHS estimates of medical use. Based on the information collected, more than 1200 manufacturing and procurement quotas are established annually for Schedule I and II controlled substances. Aggregate production quotas are then determined for each basic class of controlled substance in Schedule I and II. Notices regarding the aggregate production quotas are provided to the Federal Register for publication. The DCP monitors the manufacture, utilization, trafficking and abuse of controlled substances against the quotas, processes requests for adjustments to specific quotas, and, where appropriate, drafts notices adjusting specific quotas for publication in the Federal Register. To facilitate the quota process, DCP staff also conduct training seminars for the industry. The DCP conducts domestic and international reviews of controlled substances utilization trends and coordinates with the UN control and scientific bodies regarding such trends, and prepares reports concerning the domestic manufacture of controlled substances.

Import and Export of Controlled Substances

(21 U.S.C. 952, 953, 954 AND 958—Importation of controlled substances; Exportation of controlled substances; Transshipment and in-transit shipment of controlled substances; 1961 CONVENTION, ARTICLE 31—Special provisions relating to international trade; 1971 CONVENTION, ARTICLE 12—Provisions relating to international trade)

The CSA and the international treaties require that controlled substance imports and exports be subject to registration requirements; be allowed only when necessary to provide for the medical, scientific, or other legitimate needs of the United States; and be subject to a system of permits or declarations for each individual importation or exportation. Further, the U.N. International Narcotics Control Board (INCB), which administers the international conventions, establishes annual ''estimates'' of the amount of

Schedule I and II narcotic drugs that each country may import.

In addressing these requirements, the DCP operates a system of declarations and permits for imports and exports. Under this system, DCP personnel receive and examine requests for permission to import or export controlled substances to determine if they are in compliance with the CSA, the international treaties, and the laws of the country that is involved in the transaction. DCP personnel maintain records of all controlled substance imports and exports, and of international treaty and specific foreign country provisions relating to the import and export of controlled substances. DCP personnel also monitor all Schedule I and II narcotic imports and exports to insure that they are consistent with the legitimate needs of the United States and the INCB estimates. If an import or export appears inconsistent with legitimate need or will exceed the estimates, DCP personnel will examine the circumstances of the request to import or export. DEA will subsequently either pursue a course of action to comply with the international obligations or initiate proceedings to deny the request to import or export.

As required by the international conventions, DCP personnel prepare reports of controlled substances imports and exports for submission to the UN control bodies; provide support and assistance to foreign governments in the establishment and maintenance of import/export control programs; and coordinate with foreign authorities and the INCB in monitoring the international commerce of controlled substances.

International Activities

The registration and control of the manufacture, distribution, and dispensing of controlled substances is not restricted by domestic borders. The CSA's system of controls was not developed, and is not administered, parochially; it is part of a global system comprised of international laws and obligations designed to establish a consistent, worldwide structure of control of the manufacture, distribution, and dispensing of controlled substances to prevent the compromise of any country's systems of controls by preventing the diversion of pharmaceutical controlled substances from one country for abuse in another. The international treaties mandate that each party to the conventions shall establish a domestic program of controls relating to the registration and control of the manufacture, distribution (including import/export), and dispensing of controlled substances. The treaty provisions include requirements for licensure, scheduling, quotas, records and reports, import/export investigation, control and cooperation, prescriptions, penalties, and mutual assistance. The international community, through the International Narcotics Control Board and the Commission on Narcotic Drugs, continuously monitors the workings of the treaties and recommends and adopts resolutions to maintain the safeguards against trafficking, with which the United States is obliged to comply. The United States participates in the debates and discussions to insure that its interests are considered.

The United States' obligations under the conventions are recognized in the specific language of the CSA and the implementing regulations (see 21 USC 801, 801(a), 811(d)(1), 823(a) and 958(a), and 21 CFR 1307.02). Further, upon the United States becoming a signatory to the Psychotropic Convention, Congress acknowledged that before the Senate could ratify the convention, the CSA would have to be amended to bring it into compliance with the requirements of the convention, acknowledging that the conventions are an integral part of the United States' programs regarding the registration and control of the manufacture, distribution, dispensing, import, and export of controlled substances. By implementing the CSA and ratifying the international treaties, Congress recognized that a strong domestic program relating to the registration and control of the manufacture, distribution, dispensing, import, and export of controlled substances is inter-dependent on the establishment and maintenance of strong international controls.

In meeting the U.S. treaty obligations, the DCP participates in international policy activities, including the development and formulation of United Nations (UN) resolutions, position papers, other background documents, and briefing materials relating to controlled substances for use by U.S. delegations to several UN bodies. DCP personnel also participate in a number of international conferences and meetings related to drug control. For example, in Fiscal Year (FY) 1995 there were two such conferences which were organized, sponsored, and funded jointly by DEA and the European Union (EU): the first was held in Austria to improve the design and administration of, and cooperation regarding, controlled substance and chemical controls in the Commonwealth of Independent States (CIS) [the former Soviet Republics] which was attended by representatives from the CIS, EC and the INCB. The second conference was held in Istanbul regarding illicit drug traffic, the diversion of psychotropic substances, and chemical controls in the Middle East, which was attended by national authorities in the region, the EC, Interpol, and the INCB. The DEA share of the costs for these multi-topic conferences (approximately 50% of total conference cost) was split between the free account and appropriated funds in approximation to the subject matter covered. In FY 1995, DCP personnel also participated in the annual Commission on Narcotic Drugs meeting in Austria, a meeting with EC officials in Spain to discuss programs to control the manufacture and distribution of steroids, and an INCB drug training seminar for African drug control authorities regarding the establishment of effective national controls of the manufacture and distribution of controlled substances. The fee account expenditures for these activities totaled less than $150,000 in FY 1995.

In addition to those activities directly related to the administration of the controls under the international conventions, DCP personnel conduct conferences and operational initiatives with representatives from the appropriate foreign governments regarding specific controlled substances to provide and collect information regarding the use and abuse of the substances and, where necessary, to promote the strengthening of controls of the manufacture, distribution, dispensing, import, and export of the substances to prevent their diversion from international sources into the United States. Recent examples include meetings with officials of several European governments to discuss programs relating to pain management, the distribution and use of methylphenidate, narcotic treatment programs, and the medical use of marihuana, and meetings with officials in Colombia and Mexico regarding the manufacture and distribution of products containing flunitrazepam which are being illegally distributed and abused in the U.S.

The DCP compiles and analyzes information on the U.S. production and distribution of, and estimated needs for narcotic and psychotropic substances, as well as trafficking data, and prepares periodic reports for submission to the UN.

The above demonstrates the variety of international activities that fall within the purview of the Diversion Control Fee Account by virtue of the United States' obligations under the international conventions relating to the

registration and control of the manufacture, distribution, and dispensing of controlled substances. However, these activities, as funded through the fee account, are limited to those carried out by personnel assigned to domestic offices of DEA; expenses of diversion personnel assigned to overseas positions are funded by appropriated funds, not through the Diversion Control Fee Account, even though they may conduct activities in support of the DCP.

Enforcement Activities

(21 U.S.C. 841, 842, 843, 853, 875, 876, 878, 879, 880, 881, 883, 886, 960, 961, and Related Penalty and Enforcement Proceedings Sections—Penalties for violations of the CSA, and related enforcement proceedings; 1961 CONVENTION, ARTICLES 36 AND 37—Penal provisions; Seizure and Confiscation; 1971 CONVENTION, ARTICLE 22—Penal provisions)

The DCP has responsibility for monitoring, in large part through investigations, all activities related to legitimately manufactured substances for which registration is required or excepted and where those controls are circumvented or disregarded. As such, it initiates and conducts investigations of individuals and institutions which are suspected of violating the CSA or which undermine public confidence in the safety and authenticity of controlled substances found within pharmaceutical and health care channels. The targets and types of investigations conducted by the DCP pursuant to 21 U.S.C. 821 are identified below.

(1) Registrants and their agents or employees suspected of diverting controlled substances from legitimate channels;

(2) Persons who engage in the smuggling, theft, robbery and/or trafficking of pharmaceutical controlled substances, including, where appropriate, identifying and immobilizing their sources of supply, whether domestic or foreign, through enforcement of the controls relating to the manufacture, distribution, import, export, and dispensing of controlled substances;

(3) Persons, both registered and non-registered, who conduct controlled substances activities for which they do not have the required DOA or state authorization;

(4) Persons who obtain pharmaceutical controlled substances from registrants through fraud, deceit, or circumvention of the controls on manufacturing, distribution, or dispensing, i.e. fraudulent use of another person's DEA registration number to obtain controlled substances, doctor shoppers, prescription forgers, etc.;

(5) The trafficking by non-registrants in controlled substances which are fraudulently promoted as legitimate therapies (such as ''herbal remedies'' sold ''under the counter'' which actually contain a controlled substance);

(6) Persons who use their DEA registrations to assist in the diversion or misuse of controlled substances for other than medical purposes, such as health care fraud, self-abuse, trading controlled substances for non-medical purposes, etc.

A majority of the efforts of the field elements of the DCP is devoted to the investigation of manufacturing, distributing, dispensing, importing, and exporting activities under the requirements of the law and regulations and to collecting evidence and preparing material in support of administrative, civil, and criminal proceedings against violators. The investigations conducted by DCP personnel fall into three categories.

Pre-Registrant Investigations

The CSA requires that all individuals and institutions proposing to manufacture, distribute, or dispense controlled substances must obtain a registration from the Attorney General who is further authorized to inspect the establishment of a registrant or applicant for registration. DEA Diversion Investigators and registration personnel must insure that all applicants for registration and reregistration are authorized to conduct the activities for which they are applying within their jurisdiction. DEA Diversion Investigators are required to inspect the physical premises, interview appropriate applicant personnel, conduct employee background checks, and review record-keeping and security procedures for manufacturers, distributors, importers, exporters, and narcotic treatment programs to determine if the proposed registration is consistent with the public interest.

Cyclic Investigations

In exercising the controls of the CSA, DCP personnel conduct periodic investigations of all controlled substance manufacturers, distributors, importers, exporters, and narcotic treatment programs for the purpose of (1) ensuring that the registrants are complying with the requirements of the CSA by maintaining effective controls and procedures to prevent the diversion of controlled substances, and (2) detecting criminal or civil violations by such registrants or practices which undermine or neglect such controls. See 21 CFR 1316.01–1316.13. In the course of conducting such investigations, DCP personnel perform a wide variety of activities. These include taking a physical inventory of controlled substances; interviewing the appropriate registrant personnel; reviewing records relating to the receipt, distribution, and disposal of controlled substances; verifying transactions against the records of other registrants; reviewing manufacturing/distribution records and reports to ascertain their accuracy and validity; inspecting and testing the adequacy of physical and procedural safeguards to detect and deter diversion; identifying and pursuing questionable or illegal distributions; and collecting samples of controlled substances.

Complaint Investigations

Complaint investigations are those investigations that may result in an administrative, civil, or criminal complaint being filed against the subject for violations of the CSA or regulations. Complaint investigations are initiated upon information or evidence received from public sources, other law enforcement or regulatory personnel, or review of registrant records or reports, etc., that violations of the CSA have, or may have, occurred. DCP personnel undertake investigative activities to determine the type and extent of the violations, the identity of the violators, and the source and methods of diversion. The types of investigative activities performed include: audits of controlled substance records, examination and collection of related business records, prescription surveys, interviews and debriefings, undercover purchases of evidence, reviews of manufacturer/distribution records and reports, service of administrative inspection warrants and search warrants, and intelligence gathering and analysis.

The conduct of complaint investigations often involves cooperation and coordination with other Federal, state, and local law enforcement and regulatory officials and occasionally international officials. In some instances, investigations may also involve cooperation and coordination with members of the legitimate drug industry. Investigators, in conjunction with other agencies, evaluate and pursue evidence of health care fraud, falsification of records, and other crimes that can establish key elements of proof that controlled substance violations have occurred.

Upon completion of the investigation, a number of actions may be undertaken depending on the severity of the

violations. The case may be referred to the United States Attorney's Office or State's Attorney for civil or criminal prosecution. Violators may be referred for an enforcement hearing pursuant to 21 U.S.C. 883 and 21 CFR 1316.31, at which the registrant is provided with details regarding alleged violations and afforded the opportunity to present his/her views and proposed actions to come into compliance with the law. The investigation may result in an administrative hearing, pursuant to a show cause order, to determine whether registration of the person should be revoked or denied.

Cooperative Efforts

(21 U.S.C. 801, 801a, 872, and 873—Congressional findings; Education and research programs of Attorney General; Cooperative Arrangements; 1961 Convention, Preamble; 1971 Convention, Article 21—Action against the illicit traffic)

DEA is not alone in the efforts to combat the diversion of controlled substances. There are related authorities regarding the control of the manufacture, distribution, dispensing, import, and export of controlled substances in other Federal, state, and local regulatory and law enforcement agencies. In addition, the national and local organizations representing the pharmaceutical and health care industry actively participate in diversion control efforts. Internationally, there are foreign government agencies and international organizations, such as the United Nations International Narcotics Control Board and the Drug Control Program which administer the requirements of the international conventions; the World Health Organization, which is involved with international drug scheduling matters; and Interpol which helps coordinate international law enforcement activities directed against the international traffic in licitly produced controlled substances, committed to the establishment and maintenance of consistent international control of the manufacture, distribution, and dispensing of controlled substances. The CSA and the international treaties, recognizing the need for a coordinated effort against diversion, demand cooperative efforts between the interested parties.

As noted, the DCP engages in extensive cooperative efforts with other officials involved in diversion control activities. DCP personnel meet regularly with state and local law enforcement and regulatory personnel to share information, identify areas of concern, and coordinate joint initiatives and investigations. DCP personnel also provide special training regarding controlled substances diversion to local regulatory and law enforcement personnel and hold a national conference regarding the control and diversion of controlled substances approximately every 24 months, to which regulatory and law enforcement administrators from each state and territory are invited. DCP personnel also engage in a variety of activities with UN bodies, international organizations, and foreign governments in meeting the U.S. responsibilities under the international conventions.

In addition to its activities with other law enforcement and regulatory agencies, the DCP maintains an active program of liaison with the pharmaceutical industry. DCP activities in this area include scheduling biannual workgroup meetings with five different industry groups (manufacturers, distributors, pharmacies, practitioners, and mid-level practitioners) and a national industry conference held approximately every 24 months, which is attended by representatives from the national associations representing the controlled substances industry and by individual registrants. DCP personnel also prepare and conduct training sessions at universities for medical and pharmacy students, make presentations to industry conferences and meetings, participate in the development of pharmacy certification examinations; and draft for publication articles regarding the controlled substances laws and programs.

To assist registrants in understanding and complying with the controlled substances laws, DCP personnel create informational manuals (Pharmacist's Manual, Practitioner's Manual, Mid-Level Practitioner's Manual, and the Security Outline to the Controlled Substances Act) which are distributed to registrants. Where new laws or regulations require, specific guides and informational circulars are prepared and made available to the affected parties. DCP personnel also meet directly with individual registrants to provide information and assistance regarding the controlled substances laws.

New Initiatives

Since publication of the proposed rule in 1993, DEA has established two new initiatives, the National Forensic Laboratory Information System (NFLIS) and the Tactical Diversion Squads (TDS), which were not previously identified in the rulemaking. Each of these initiatives will enhance the DCP's ability to administer and enforce the program relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances, and investigate and act against persons who would violate those controls, as discussed above. Congress has been notified of these new initiatives and has approved funding for them.

The collection of accurate and validated data concerning the abuse of controlled substances and the scientific review of actual or potential drugs of abuse is a necessary function for scheduling controlled substances, setting quotas for manufacturing levels, and to provide more effective leadership in establishing drug policy under the CSA. The NFLIS will provide in a single system information from analyzed drug evidence associated with criminal activity collected from non-Federal forensic laboratories across the country. That information must currently be obtained by separate contacts with individual laboratories across the country. The system will also enhance the investigative ability of DCP personnel by allowing efficient and quick identification of local, regional, and national division and abuse trends and distribution patterns of diverted and abused controlled substances.

The TDS program is a modernization of a program that was operated in the late 1970's and early 1980's in as many as 24 states in a form designed to address present diversion trends. DEA has received approval to fund the formation of two enforcement teams consisting of Federal, state, and local law enforcement personnel fully dedicated to the investigation and prosecution of persons involved in the diversion of controlled substances from legitimate manufacturing, distributing, and dispensing sources. The program will allow the unification of separate, and sometimes disparate, Federal, state, and local information, authorities, and enforcement programs; provide State and local law enforcement authorities with assistance in developing more effective enforcement programs against diversion; and help coordinate the various jurisdictional responsibilities of agencies that otherwise may hinder investigations and prosecutions of those involved in the diversion of controlled substances. Funding has also been provided to establish another 2 to 3 TDS's in 1997.

Budget and Appropriations

In order to accomplish the mandates of the CSA and the international treaties, Congress in past years authorized and appropriated funds within the ''Diversion Control Decision Unit'' of the DEA Salaries and Expenses Appropriation. The President's annual budget request to Congress contained

proposed appropriations for the Department of Justice, including the DEA. DEA's budget requests are required to meet OMB policy guidelines for budget preparation. [OMB Circular No. A–11]

Once Congress and the President approve the appropriation level, funds are made available from the appropriate source in the U.S. Treasury. Prior to fiscal year 1993, registration fees collected under the CSA were deposited into the general fund of the U.S. Treasury. Prior to fiscal year 1993, registration fees collected under the CSA were deposited into the general fund of the U.S. Treasury and scored to DEA's Salaries and Expenses Appropriation. [31 U.S.C. 3302; 21 U.S.C. 821; OMB Circular No. A–25 (1959)].

On October 6, 1992, the President signed the Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act of 1993, Pub. L. No. 102–395, 102d Cong. 2d Sess., 106 Stat. 1828, 1835 (1992) (''Appropriations Act'') (DEA Salaries and Expenses Appropriation). Section 111(b) of the Appropriations Act established in the U.S. Treasury, for fiscal year 1993 and thereafter, a separate account, to be known as the Diversion Control Fee Account. The Appropriations Act directed that ''[n]otwithstanding [a]ny [o]ther [p]rovision of [l]aw * * *] fees charged by the Drug Enforcement Administration under its Diversion Control Program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program''. Congress specified that the amount ''required to be refunded'' to DEA from the Diversion Control Fee Account for fiscal year 1994 and thereafter ''shall be refunded in accordance with estimates made in the budget request of the Attorney General for those fiscal years''.

For fiscal year 1993, in order to provide the opportunity to establish and implement a new fee structure to meet the legislative requirement, Congress appropriated funds, as it had in past years, for the DCP from the general fund of the U.S. Treasury, less $12 million. The $12 million was to be funded through increased CSA registration fees established as a result of the creation of the Diversion Control Fee Account in 1993. Congress further directed in the Appropriations Act that ''[a]ny proposed changes in the amounts designated in said budget requests shall only be made after notification to the Committees on Appropriations of the House of Representatives and the Senate fifteen days in advance''.

The fiscal year 1997 resources for the DCP, as authorized by Congress, include 598 full-time employees charged with the responsibility for overseeing the activities of one of the largest pharmaceutical industries in the world to ensure controlled substances are manufactured, imported, exported, distributed, and dispensed for legitimate medical and scientific reasons.

These resources includes a staff of Diversion Investigators, Special Agents, Administrative Law Judges, program analysts, pharmacologists, chemists, information systems specialists, registration assistants, examiners, and management and support staff assigned to field offices across the country and assigned to DEA Headquarters. Overhead and program expenses include salaries and employee benefits (retirement, health and life insurance); travel; rent and utilities; equipment and supplies, including vehicles, computers, communications, furniture, etc.

In the overall Budget process, the estimated cost per full time employee is based on a module which includes salary and overhead items. Modular costs are part of the specific Congressionally approved positions, as they are with the positions within the rest of the DEA Budget. For example, when Congress authorized 588 positions for the DCP in 1994, included therein are the modular costs of maintaining those positions (such as rent, equipment, per diem and travel, background investigation costs, etc.)

There are separate DEA activities which support the DCP, but are covered elsewhere in the DEA Salaries and Expenses Budget and are therefore not supported by CSA Registration Fees. Examples of this include: Support provided by the Attorneys in DEA's Office of Chief Counsel Diversion/ Regulatory Section; laboratory Services support; DEA Automated Data Processing systems support (except ARCOS and CSA); Office of Training staff, DEA Management and Administrative support; Office of Congressional and Public Affairs; Intelligence Support and Diversion Investigators assigned overseas.

Resources not initially identified in the 1993 Federal Register establishing the fee (57 FR 60,148 and 58 FR 15,272) which have been subsequently approved and funded through CSA registration fees as part of the above discussed DCP components include: (1) Congressional approval in FY 1994 for 11 Special Agents to enforce the Anabolic Steroid Control Act; (2) Transfer of 7 positions and associated costs previously provided for in the DEA Salaries and Expenses Budget for operation of the ARCOS and CSA data systems—these systems exist at DEA solely to support the DCP; (3) Authorization to establish a National Forensic Laboratory Information System (as discussed above); (4) Authorization to expand assistance and cooperation with state and local law enforcement with the establishment of Tactical Diversion Squads (as discussed above).

While DEA's budget is formulated, reviewed, and approved on an annual basis, the majority of DEA registrations, from which the fees to fund DCP activities are derived, are issued for a three year term. Further, the registrant population is not evenly distributed across the three year registration cycle; current figures indicate approximately 320,103 renewals will be received for October 1996 to September 1997, 305,200 renewals for October 1997 to September 1998, and 290,698 for October 1998 to September 1999. Thus, attempting to calculate the fee on an annual basis would preclude a uniform application of the costs of the DCP for each year across either the entire registrant population or the registrants that would renew in each of the individual years. Either a return to a one year registration term for all registrants or a multi-year fee schedule would be necessary.

Rather than establish an annual registration, which would impose an enormous burden on both the registrants and DEA, a fee schedule which averages income over three years was adopted. Use of the three year fee schedule allows for (1) uniform application of fees necessary to cover the costs of the DCP across the entire registrant population, (2) accommodation of such factors as inflation and an uneven number of registration renewals in each of the individual years, and (3) minimizing the administrative burden associated with frequent adjustment to the fee schedule. Use of a multi-year cycle does, however, require that estimated fee collection and funding authorization figures be used in calculating the fees.

During the transition to the Diversion Fee Account (DFA) system in FY 93, funding was provided from the general fund in the United States Treasury to cover the period leading up to the implementation date of the DFA. Because the rule implementing the Diversion Fee Account system became effective two months early, a $7 million surplus resulted. Additional surplus funds have accrued as a result of DEA estimates of the costs of the program, as reflected in the Congressional Budget Authorization, that were greater than the actual expenses, in part due to

hiring constraints within DEA that resulted in a diversion investigator vacancy rate of between 50 and 70 positions from 1993 to present; and DEA estimates of fee income that were less than the actual income. As a result, the DFA surplus was 45 million dollars as of September, 1996.

While some surplus in the DFA is necessary to cover the variations in the fees collected each year and the need for some carry-over funds from one fiscal year to the next, the current surplus exceeds the amounts necessary to insure the fiscal continuity of the DCP. However, the surplus will delay the need for any fee increases for a number of years; based on out-year projections for collections and appropriations, the surplus will begin to be drawn down in FY 98 and will be exhausted by FY 2001.

Conclusion

In sum, DEA is mandated to maintain a multi-faceted endeavor encompassing scientific, cooperative, regulatory, criminal, and international programs to prevent the diversion of controlled substances to illicit uses. The DCP has been authorized and has served for the past 25 years as an effective vehicle for carrying out these mandates. Creation of the Diversion Control Fee Account in 1993 altered the funding mechanism of the program, but not its duties, objectives, or priorities.

The Acting Deputy Administrator of the Drug Enforcement Administration hereby certifies that this rule will not have a significant economic impact upon entities whose interests must be considered under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.). The majority of DEA registrants are practitioners, pharmacies, and hospital/clinics, for whom the annual impact of the fee increase is $50.00 per registrant. Further, the total annual impact of the fee increase for the entire registrant population is less than $50 million. However, consistent with the principles of the Regulatory Flexibility Act, DEA gave consideration to alternative approaches to the fee schedule.

Since 1971, the CSA has permitted the Attorney General to collect fees relating to the registration and control of the manufacture, distribution, import, export and dispensing of controlled substances (21 U.S.C. 821 and 958). DEA and its predecessor agency have collected such fees pursuant to a schedule based upon the five basic activities cited in the law. That fee schedule was proposed for public comment as part of the regulations to implement the CSA which were finalized in 1971. The ration of fees was: A distributor's fee is 50% of the manufacturer's fee and a dispenser's fee is 16–20% of the distributor's fee. The fee ratios have remained consistent for the past 25 years and have not been the subject of any substantive comment or objection by the regulated industry.

The Federal Register notice proposing the new fee structure (57 FR 60148, December 18, 1992) specifically noted that this fee schedule was to be continued since the administrative structure to collect it was well established and operating efficiently. There were no practical or substantive alternative proposals submitted on the record regarding the fee structure. Individual interest groups questioned the possibility of alternative structures after the rule was finalized.

In reaching the decision to propose the existing fee ratio as the basis for establishing the new fees, several alternatives were discussed by DEA, including:

(1) Establish a fee based on volume of drugs handled by individual registrants. This was rejected as impractical on several grounds: (a) DEA has no way of determining the volume handled; (b) the volume changes due to a variety of market, health care, and competition issues, thus requiring frequent modification of individual fees; and (c) DEA would be unable to budget due to income fluctuations.

(2) Establish a fee based upon DEA work hours expended per class of registrant. This was rejected as impractical because: (a) Work hours vary from year to year based upon particular drug problems, identification of violative firms, political or mandated priorities, travel restrictions, and many other factors; (b) due to the degree of control established over the past years, less work hours are currently expended at the wholesale level than at the retail level; however indications of diversion at the wholesale level will always receive priority attention. Therefore, this measure would fluctuate year to year, causing an administrative burden on both the registrants and DEA due to frequent fee modifications.

(3) Establish a different fee for various types of practitioner activities (i.e., hospital, medical doctor, dentist, veterinarian, narcotic treatment program, teaching institution). Again , this was rejected as impractical because: (a) Many of the same issues in items 1 and 2 above apply equally; (b) a new administrative system to handle 8–10 registration categories, rather than five, would have to be created, with attendant costs of computer programming, staffing, form design, printing, inventory, etc.; and (c) an entirely new system of criteria would have to be developed to distinguish between categories (i.e., a general practice dentist may prescribe less than a general practice M.D., but an oral surgeon may prescribe more; a small rural hospital/clinic my utilize less controlled substances than an M.D. specialist in cancer treatment).

(4) Charge for Order Forms (DEA 222) used to order Schedule II drugs. This was impractical because: (a) A substantial number of registrants are not registered for Schedule II so an additional fee system would have to be used for registrants in Schedules III–V; and (b) order form volume is not reflective of activity, i.e., practitioners who prescribe rather than dispense do not use many order forms.

Therefore, although various options were considered, none offered a feasible alternative, each would require the establishment of complex, labor-intensive, expensive new programs (the cost of which would be borne by the registrants) with complicated fee schedules that would be difficult to understand and administer. The existing fee structure, which is operating efficiently and is well understood by the registrant population, remained the most suitable choice.

This document has been drafted and reviewed in accordance with Executive Order 12866. The Acting Deputy Administrator of the Drug Enforcement Administration has determined that this is not a significant action under the provisions of Executive Order 12866, section 3(f); accordingly this rule has not been reviewed by the Office of Management and Budget. This action involves the implementation of non-discretionary mandate under the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993 (Pub. L. 102–395), the annual impact of which is less than $100 million.

This action has been analyzed in accordance with the principles and criteria contained in E.O. 12612, and it has been determined that the rule has no implications which would warrant the preparation of a Federalism Assessment.

Dated: December 20, 1996.

James S. Milford,

Acting Deputy Administrator, Drug Enforcement Administration.

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