DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[DEA–140F]

RIN 1117–AA34

Registration and Reregistration Application Fees

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Confirmation of final rule, remanded for further notice and comment, and response to comments.

SUMMARY: DEA is publishing a final rule regarding the registration and reregistration fees charged to controlled substances registrants. DEA is required to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances. To address this mandate, on March 22, 1993 DEA published a final rule in the **Federal Register**, establishing registration fees for controlled substances registrants (58 FR 15272). Following publication of the final rule, the American Medical Association (AMA) and others filed a complaint in the United States District Court for the District of Columbia objecting to the new fees. The district court issued its final order granting the government's motion for summary judgment and disposing of all claims. The AMA appealed. The United States Court of Appeals for the District of Columbia Circuit found DEA's rulemaking to be inadequate. The appeals court remanded, without vacating, the rule to DEA, requiring the agency to provide an opportunity for meaningful notice and comment on the fee-funded components of the Diversion Control Program. DEA responded to the remand requirement through a document published in the **Federal Register** on December 30, 1996 (61 FR 68624). This Final Rule supplements the December 30, 1996 **Federal Register** document and with that document, constitutes the final rule on the Drug Diversion Control Fee Account.

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SUPPLEMENTARY INFORMATION:

I. Introduction

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), on October 6, 1992. Congress directed in Section 111(b) of the act, codified at 21 U.S.C. 886a(3), that ''[f]ees 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.'' The Drug Enforcement Administration (DEA) published its proposal to adjust the existing registration fee schedule in accordance with this mandate on December 18, 1992. 57 FR 60148. After notice and comment, DEA published a final rule adjusting registration fees on March 22, 1993. 58 FR 15272.

Following publication of the final rule, the American Medical Association (AMA) and others filed a complaint in the United States District Court for the District of Columbia objecting to the new fees. The district court issued its final order granting the government's motion for summary judgment and disposing of all claims on July 5, 1994. *AMA* v. *Reno,* 857 F. Supp. 80 (D.D.C. 1994). The AMA appealed. The United States Court of Appeals for the District of Columbia Circuit found DEA's rulemaking to be inadequate on July 27, 1995. The appeals court remanded, without vacating, the rule to DEA, requiring the agency to provide an opportunity for meaningful notice and comment on the fee-funded components of the Diversion Control Program (DCP). Specifically, the court held that DEA ''was required to identify the components of the fee-funded diversion control program and provide a brief explanation of why it deemed each component to be a part of that program.'' *AMA* v. *Reno,* 57 F.3d 1129, 1135 (D.C. Cir. 1995). The appeals court remanded this action to the district court with instructions on August 29, 1995. The district court remanded the matter to DEA for proceedings consistent with the appeals court opinion on November 22, 1995.

DEA responded to the remand requirement through a notice in the **Federal Register** on December 30, 1996, describing the fee-funded components and activities of the DCP with an explanation of how each satisfies the statutory requirements for fee-funding. 61 FR 68624–32. This document supplements the December 30, 1996 **Federal Register** notice and with that notice, constitutes the final rule on the Drug Diversion Control Fee Account (DDCFA).

II. Statutory Basis of Diversion Control Fee Account

The Controlled Substances Act (CSA) has authorized the Attorney General since 1970 ''to promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances' and ''to charge reasonable fees relating to the registration of importers and exporters of controlled substances.'' 21 U.S.C. 821 and 958(f). The Attorney General delegated that authority to the Administrator of the Drug Enforcement Administration (DEA), who in turn redelegated it to DEA's Deputy Administrator. *See* 28 CFR 0.100(b) and 0.104. Congress, through the 1993 Appropriations Act, established the Diversion Control Fee Account (DDCFA), changing the source of Diversion Control Program (DCP) funding from being part of DEA's congressional appropriation to full funding by registration and reregistration fees. The 1993 Appropriations Act made no changes in the DCP's duties or authorities, directing that ''[f]ees 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'' and that funds from the DDCFA will be provided to DEA from the U.S. Treasury in accordance with ''the budget request of the Attorney General.'' 21 U.S.C. 886a(3) and (4).

III. Comments Received

DEA received five comments in response to the December 30, 1996 **Federal Register** notice. One comment was filed on behalf of five professional and trade associations, several of whom were plaintiffs in the legal action: the American Medical Association (AMA), the American Dental Association, the American Veterinary Medical Association (AVMA), the National Community Pharmacists Association and the National Wholesale Druggists' Association (NWDA). A separate comment submitted on behalf of the American Osteopathic Association, also a plaintiff, fully concurred with the multi-party comment. The remaining three comments were filed separately by the AVMA, the NWDA and an individual practitioner. Most of the comments relate to three broad areas of concern: whether particular diversion control activities are properly fee-funded; justification for the current fee schedule; and the accumulation and

disposition of the surplus that had accumulated in the fee account.

The commentors expressed general concern regarding the funding of activities by the DDCFA. They singled out international and enforcement activities as examples of what they considered to be inappropriate funding. Specifically, the commentors asserted that DEA cannot lawfully fee-fund certain international activities, non-registrant drug trafficking investigations, and activities involving controlled substances not lawfully marketed in the United States, such as marijuana and flunitrazepam, because they lack connection or have such attenuated connection to the registration and control of the manufacture, distribution and dispensing of controlled substances. One commentor asked that the Office of Management and Budget (OMB) review various activities to determine whether they are fee-fundable.

Another point raised by commentors regarding DCP funding was that the explanation provided in the December 30, 1996 **Federal Register** notice failed to provide an adequate description of some of the DCP components. One commentor expressed concern regarding fee-funding the National Forensic Laboratory Information System (NFLIS) and Tactical Diversion Squads (TDSs), stating that the final rule described these programs ''too generally.'' Commentors demanded more detailed justification for fee-funding specific DCP activities.

Most of the commentors stated that the current fee schedule is unjustified, asserting that DEA failed to properly determine the costs of appropriate fee-funded activities and overestimated the costs. They asserted that the existence of a surplus is relevant to the issue of whether the registration fees are ''reasonable'' as required by 21 U.S.C. 821, stating that its existence indicates a failure to set appropriate fees. The commentors requested detailed justification for maintaining the fee schedule at current levels. Several also requested that DEA refund the surplus to the fee-paying registrants and/or adjust future fees to prevent surplus funds from accumulating.

In addition, one commentor stated that the rule fails to provide sufficient information on which to meaningfully comment. The same commentor characterized the registration fee as a user fee and claimed that it has been improperly assessed to fund international and other activities from which registrants receive no greater benefit than that received by the general public. Several commentors requested information on the costs of each component of the DCP. Finally, one commentor called for a registration fee structure for practitioners based on their individual controlled substance prescribing or dispensing patterns.

We address each of the points raised by the commentors below.

IV. Requirements for Fee-Funding Diversion Control Activities

DEA's mission with respect to illicit controlled substances like heroin and crack cocaine is to eliminate them outright, but the agency's role is far more complex when it involves licit controlled pharmaceuticals. On one hand, DEA prevents, detects and eliminates the diversion of controlled pharmaceuticals from legitimate channels to illegal use, while at the same time ensuring their availability for legitimate medical and scientific purposes. To facilitate these goals, Congress through the CSA established a closed system of controlled substance distribution encompassing manufacturers, distributors, pharmacies and practitioners. Components of this closed system include scheduling of all controlled substances, registration of all controlled substance handlers, recordkeeping for accountability, security, and manufacturing quotas, all under DEA DCP oversight. The DCP also possesses chemical control responsibilities pursuant to the Chemical Diversion and Trafficking Act (CDTA) and subsequent legislation.

DEA's authority to collect registration fees derives from three statutory provisions. DEA is authorized by 21 U.S.C. 821 to collect reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances. Secondly, 21 U.S.C. 958(f) permits DEA to collect reasonable fees relating to the registration of importers and exporters of controlled substances. Lastly, the 1993 Appropriations Act added a provision requiring DEA to make the DCP self-supporting by setting fees at a level that ensures the recovery of the full costs of operating its ''various aspects''. 21 U.S.C. 886a(3). The United States Court of Appeals for the District of Columbia Circuit noted that in establishing the DDCFA, Congress left intact the fee collection requirements of 21 U.S.C. 821, confirming boundaries of the DCP that DEA can fund by registration fees. *AMA* v. *Reno,* 57 F.3d 1129, 1135 (D.C. Cir. 1995). Although the court made no specific mention of 21 U.S.C. 958(f), those same boundaries remain intact as well. The current statutory scheme thus requires DEA to set registration fees to recover the full costs of the DCP, while limiting DEA to charge ''reasonable'' fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances. DEA, therefore, must examine DCP activities in conjunction with the nexus requirements of 21 U.S.C. 821 and 958(f) to determine whether it can properly fee-fund them while setting fees that recover total program costs.

Much debate regarding which diversion control activities DEA can properly fee-fund has accompanied the establishment of the DDCFA.

The 1993 Appropriations Act specifically mandates that fees ''shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.'' 21 U.S.C. 886a(3). Congress, in using the mandatory term ''shall'' as opposed to the discretionary ''may,'' unambiguously required DEA to increase its then-existing registration fees resulting in registrants fully funding DCP expenses. DEA, therefore, lacks discretion in this matter and must fund its DCP totally from registration fees. Assuming for the sake of argument that there is some doubt as to whether Congress intended DEA to entirely fund the DCP from registration fees due to its use of the phrase ''various aspects'' of the DCP as opposed to something like ''all aspects,'' the House Conference Report notes that the act's language ''requires the Drug Enforcement Administration to set fees to recover the full cost of their Diversion Control Program.'' H.R. Conf. Rep. No. 918, 102nd Cong., 2d Sess. 44 (1992).

The 1993 Appropriations Act directing DEA to set its fees to recover the full costs of its DCP may appear to conflict with the 21 U.S.C. 821 and 958(f) requirements that DEA's fees be reasonable and relate to the control and registration of the manufacture, distribution, dispensing, import or export of controlled substances. Perhaps Congress assumed that all DCP costs are reasonable. Possibly in anticipation of potential conflicts, as a preamble to the provisions establishing the DDCFA, Congress mandated fulfillment of the requirements of the act ''[n]otwithstanding [a]ny [o]ther [p]rovision of [l]aw,'' thus making its provisions supersede all other provisions of law that would otherwise prevent or impede DEA's recovery of the full costs of the DCP through registration fees. H.R. 5678, 102nd Cong., 2d Sess. 111 (1992).

DEA, upon establishment of the DDCFA, wrestled with the determination of which DCP activities it could legally fee-fund. The plain language of the 1993 Appropriations Act

requires DEA to set and collect registration fees to cover the full costs of operating its Diversion Control Program. A broad interpretation of the 1993 Appropriations Act would have resulted in fee-funding all DCP activities, while a narrow interpretation would have restricted the DCP activities that could be fee-funded.

A. Final Rule (March 22, 1993)

DEA examined all activities that relate to the registration and control of the manufacture, distribution and dispensing of controlled substances and to the registration (and control) of importers and exporters. DEA determined that ''activities contained in the [diversion] program which give rise to the fees consist of Diversion Investigators, analysts, technicians, and clerical personnel salaries and expenses; and travel, rent, utilities, supplies, equipment and services associated with these positions for the registration and control of the manufacture, distribution and dispensing of controlled substances.'' 58 FR 15273. DEA determined that it would not fee-fund costs associated with chemical control efforts, clandestine lab efforts, overseas efforts (specifically diversion investigators assigned to foreign posts), DEA's Office of Chief Counsel and executive direction. 58 FR 15273. DEA concluded that these activities were excluded from the Attorney General's budget delineation for the category of ''Diversion Control'' and thus not included in the determination of the fees. *Id.*

B. Federal Register Notice (December 30, 1996)

DEA further excluded from fee-funding in its December 1996 **Federal Register** notice activities that, while supporting the DCP, are funded elsewhere in the DEA Salaries Budget and thus not fee-funded. The notice, mirroring the 1993 final rule, provided the following examples of such activities: Chief Counsel attorney support; laboratory services support; DEA automated data processing systems support; training, management and administrative support; activities conducted by the DEA Office of Congressional and Public Affairs; intelligence support; and diversion investigators assigned overseas. 61 FR 68631.

C. Litigation Statements

The AMA and others brought a complaint in U.S. District Court for the District of Columbia in June 1993 objecting to the fees, and the court granted the government's motion for summary judgment in July 1994. The plaintiffs appealed, and the U.S. Court of Appeals for the District of Columbia Circuit found DEA's rulemaking to be inadequate in July 1995. During the course of these legal proceedings DEA made statements regarding which activities could be fee-funded and which could not. The government statements on fee-fundable activities essentially mirror the criteria set out in the March 1993 Final Rule; *i.e.,* that activities involving chemical control, clandestine laboratories, overseas operations, Chief Counsel and ''executive direction'' were excluded from fee-funding and were paid for by congressionally appropriated funds. DEA subsequently discovered its statements regarding the exclusion of chemical control activities were in part, at least, erroneous.

D. DEA Response to the Senate Appropriations Committee (1998)

In response to questions from the Senate Appropriations Committee regarding fee-fundable activities, DEA stated that in the absence of specific guidance in the Appropriations Act as to which activities were encompassed within the DCP and thus fee-fundable, DEA followed the plain language of the act and used the budget category that had historically been included in the DCP budget request of the Attorney General.

E. DEA Fee Spending Elements

As a matter of note, DCP activities are undertaken by DEA elements other than those within the Office of Diversion Control. While the Office of Diversion Control conducts anti-diversion registration and control activities, other DEA elements undertake activities in support of the DCP in addition to supporting nonfee-fundable activities. As such, these other elements expend fee-funds to support fee-fundable DCP activities. For example, the Office of Administration provides office space, makes appropriate office renovations and supplies the security guard force to the diversion groups. The Office of Administration pays rent and other expenses with fee funds. The Office of Resource Management expends fee funds for payroll and employment benefits for the DCP workforce. The Office of Training trains the DCP workforce and spends fee funds on training in support of fee-fundable activities.

F. Current Fee-Funding

Commentors to the December 1996 **Federal Register** notice focused on several specific activities that DEA has always conducted and has fee-funded under the new fee program since its inception in 1993. In light of the comments, DEA reexamined each questioned activity to determine and explain the extent of its relationship to the registration and control of the lawful manufacture, distribution and dispensing of controlled substances, and the registration for importing and exporting controlled substances.

DEA has reevaluated its fee-funded DCP activities several times since publication of the December 1996 **Federal Register** notice and has concluded that it is proper to fee-fund all activities with the exception of those specifically excluded in the March 1993 and December 1996 **Federal Register** notices. DEA has reached this conclusion because all DCP activities except for those involving chemical control relate to controlled substances lawfully manufactured, distributed, dispensed, imported or exported as required by 21 U.S.C. 821 and 958(f). DEA decided not to fee-fund the remaining excluded activities even though they relate in varying degrees to the criteria enumerated in 21 U.S.C. 821 and 958(f).

Fee-funded activities thus include those relating to controlled substances handled by any DEA registrant (including researchers, analytical laboratories, teaching institutions and narcotic treatment programs) for legitimate medical, scientific or industrial purposes. DEA's ability to fee-fund such activities is derived from the authorizing language of 21 U.S.C. 821. Scheduling activities are also fee-fundable because they, too, relate to the control requirement of 21 U.S.C. 821. Although 21 U.S.C. 958(f) authorizes DEA to collect fees related to the registration, with no explicit mention of ''control'' of importers and exporters of controlled substances, activities related to their control are implicit in the 21 U.S.C. 821 criteria. All controlled substances imported into the United States by DEA-registered importers pursuant to import declarations or permits are distributed to other DEA registrants engaged in the manufacture or distribution of the original substances or of products made from them that are lawfully marketed here. Conversely, DEA-registered exporters are the final point of sale for products manufactured and distributed within the United States by domestic registrants who transfer the products to them for the purpose of export to foreign customers. Activities related to these transactions are, therefore, fee-fundable.

Fee-fundable DCP activities include: scheduling, registration, investigation,

inspection, data collection and analysis, training, establishing production quotas, cooperative efforts with state, local and other federal agencies, cooperative efforts with the regulated industry, international activities, as well as the attendant management, personnel, administrative and clerical oversight for the DCP because they too relate to the fee-funding criteria of 21 U.S.C. 821 and 958(f). For the reasons explained below, DEA has determined that even activities relating to foreign substances unlawfully imported into the United States are fee-fundable as are those relating to counterfeit versions of legitimate controlled substances.

The final rule published in March 1993 stated that DEA would not fee-fund five particular DCP activities. DEA excluded efforts involving chemical control, clandestine laboratories, overseas activities, Office of Chief Counsel support and executive direction. DEA did not consider their costs in determining the new fees. Although DEA stated that it would fund these activities by other appropriated funds, DEA has subsequently found that agency elements have erred in inappropriately fee-funding some of these at different times since establishment of the DDCFA. DEA is in the process of minimizing the risk of fee-funding these ''excluded'' activities in the future. For a more detailed discussion of the inappropriately fee-funded activities, see Sections X and XIII.

The following sections discuss in greater detail the specific comments questioning various DCP activities, DEA's response to the comments, and how DEA funds them.

V. International Activities

DEA received four comments objecting to fee-funding specific international activities on the ground that they are unrelated or only remotely related to the registration and control of the manufacture, distribution and dispensing of controlled substances or to ''controlling the manufacture, distribution or use of controlled substances by the health care professionals and other registrants on whom the costs of the program have been placed.'' One commentor objected to fee-funding DEA participation in international policy activities such as the development and formulation of United Nations (UN) resolutions, position papers, background documents and briefing materials. Two commentors objected to fee-funding DEA participation in and/or co-sponsorship of international conferences on drug control. These commentors criticized the use of DDCFA funds for meetings with European government officials because they included discussions of, among other topics, the medical use of marijuana, and meetings with Colombian and Mexican officials about flunitrazepam, noting that neither substance is legitimately produced in the United States.

Several commentors objected to use of DDCFA funds to assist foreign authorities with their national systems of control, specifically citing DEA involvement in a conference to improve controlled substance and chemical controls in the Commonwealth of Independent States (CIS) (formerly the Soviet Republics) and for sending a DEA representative to participate in a training seminar to assist African authorities in developing effective national controls. We address these specific concerns later in this section.

A. International Activities Generally

DEA fee-funded certain international diversion control activities when the 1993 Appropriations Act became effective because they relate to the registration and control of the lawful manufacture, distribution and dispensing of controlled substances. As explained above, controlled substances lawfully imported or exported relate to Section 821 requirements because imported substances are subsequently distributed to other DEA registrants, and exported substances are initially manufactured and/or distributed domestically prior to export. As explained in the December 30, 1996 **Federal Register** notice, the CSA's closed system of controls over manufacturing, distribution and dispensing was not established and is not administered within the isolation of our domestic borders. Rather, the controls are part of a global system of national and international laws designed to establish an interrelated, worldwide structure of control over the manufacture, distribution, dispensing, import and export of controlled substances, so that controls or lack of controls in one country do not undermine controls in another. Congress found and declared that illegal importation, along with illegal manufacture, distribution, possession and improper use of controlled substances, has a detrimental effect on the health and welfare of the American people, recognizing that ''[a] major portion of the traffic in controlled substances flows through interstate and foreign commerce.'' 21 U.S.C. 801(2) and (3).

The international drug control treaties to which the United States is a signatory require that each party establish a program of controls relating to the registration and control of the manufacture, distribution, dispensing, import and export of controlled substances. The specific language of the CSA and its implementing regulations recognize the obligations of the United States under the international conventions. *See* 21 U.S.C. 801, 801a, 811(d)(1), 823(a) and 958(a), and 21 CFR 1307.02.

The CSA expressly recognized that the United States is a party to the Single Convention on Narcotic Drugs of 1961 and other conventions ''designed to establish effective control over international and domestic traffic in controlled substances.'' 21 U.S.C. 801(7). Likewise, Congress recognized that the abuse of psychotropic substances has become ''a phenomenon common to many countries'' that ''is not confined to national borders,'' making it ''essential that the United States cooperate with other nations in establishing effective controls over international traffic in such substances.'' 21 U.S.C. 801a(1). Congress further recognized that the United States joined with other countries in executing the Convention on Psychotropic Substances, ''which is designed to establish suitable controls over the manufacture, distribution, transfer, and use of certain psychotropic substances.'' 21 U.S.C. 801a(2). Congress acknowledged that before the Senate could ratify the convention, the CSA required amending to bring it into compliance with the requirements of the convention. Congress thus recognized that the conventions are an integral part of the United States' programs regarding the registration and control of the manufacture, distribution, and dispensing of controlled substances. By implementing and ratifying the international treaties, Congress recognized that a strong domestic program relating to the registration and control of the manufacture, distribution, dispensing, import or export of controlled substances depends on establishing and maintaining strong controls within other individual nations.

As described above, DEA is obligated to conduct, as part of its diversion control program, certain international activities relating to the lawful manufacture, distribution, dispensing, import and export of controlled substances. DEA fee-funds most international diversion control activities that it had historically conducted since 1971, considering each related to 21 U.S.C. 821 and 958(f) criteria. DEA, although not always successful, has

attempted to exclude from fee-funding international chemical control activities, as well as those specified in the March 1993 and December 1996 **Federal Register** notices. Comments responding to the December 30, 1996 **Federal Register** notice raised issues about fee-funding certain international activities, and DEA reexamined the fee-funding criteria in light of the comments. DEA has determined that international programs and activities are an integral part of the DCP, and fee-funding them is appropriate because they relate to the registration or control of the lawful manufacture, distribution or dispensing of controlled substances.

Following is a discussion of the international activities for which comments were received, and justification why DEA fee-funds them.

B. DEA Participation in UN International Policy Activities

The international community, through the UN's International Narcotics Control Board (INCB) and the Commission on Narcotic Drugs (CND), continuously monitors the workings of the treaties and each country's compliance with their diversion control provisions. The UN treaties have mechanisms by which the scope of control may be changed. Such changes are binding upon the United States as a party to the conventions and have a significant impact on those lawfully manufacturing, distributing or dispensing controlled substances here. When new controls are adopted or existing ones amended, DEA must implement the new requirements, and they are binding upon the U.S. registrant community, *i.e.,* all manufacturers, distributors and dispensers. DEA participation in the development and formulation of UN resolutions, position papers and other briefing materials, and its attendance at formal meetings of international experts on drug control ensures that the interests of the United States, including those of its registrants, are represented during the consideration of additional or amended controls.

DEA fee-funds diversion control personnel participation in international policy matters when the activity relates to the lawful manufacture, distribution, dispensing, import or export of controlled substances. For example, DEA has fee-funded international activities relating to the following actual examples: benzodiazepine scheduling; emergency international distribution of controlled substances from the U.S. to countries that have experienced a natural disaster; the manufacture, use, diversion, abuse and scheduling of stimulant drugs, such as methylphenidate, used in the treatment of obesity or Attention Deficit Disorder; preparation of information regarding trade names of U.S.-manufactured products containing Schedule I or II substances; preparation of UN reports, questionnaires and estimates of legitimately produced controlled substances; and the domestic manufacture, distribution or dispensing of controlled substances for pain treatment.

DCP activities involving gamma hydroxybutyrate (GHB) and flunitrazepam on the surface seem to pose a dilemma as to whether DEA may fee-fund them. GHB was originally marketed in health food stores. The U.S. Food and Drug Administration (FDA) issued advisory warnings in 1990 and 1997 declaring GHB unsafe and illicit except under FDA-approved physician-supervised protocols. GHB is currently a Schedule I controlled substance, not approved by FDA for marketing. GHB is under investigation for use in treating narcolepsy under FDA's Orphan Drug program and Schedule III security requirements apply to those conducting these investigations. If FDA approves GHB for medical use in the United States, Congress has directed that DEA place the dosage form, though not the bulk form, into Schedule III. The CSA sets forth the following criteria for drugs or substances placed into Schedule III: the drug or substance has a potential for abuse less than that of the drugs or substances in Schedules I and II; the drug or substance has a currently accepted medical use in the United States; and the abuse of the drug or substance may lead to moderate or low physical dependence or high psychological dependence. 21 U.S.C. 812(b)(3). DEA, therefore, fee-funds GHB activities. DEA must have control and play an active role in the scheduling process prior to FDA approval and scheduling, and to do otherwise would seriously curtail DEA fulfilling its mandated mission. DEA activities prior to scheduling ultimately impact post-scheduling commercial decisions of registrants.

Flunitrazepam, like GHB, is not currently approved for medical use in the United States. However, twenty countries, including Mexico and a number in South America, have approved the drug in tablet form. Roche Pharmaceuticals, a foreign subsidiary of the United States DEA-registered manufacturer, markets the drug under the trade name of Rohypnol®. Smuggling and introducing Rohypnol® into the United States for medical and illicit reasons impacts Roche Pharmaceuticals domestically. DEA has placed flunitrazepam into Schedule IV, while some states have also placed it under control, some in Schedule I, and others in Schedules II to IV. DEA fee-funds flunitrazepam activities because, while more tenuous than those involving GHB, in the case of Rohypnol® they relate to the registration and control of the manufacture, distribution, dispensing and import of at least one U.S. DEA-registered manufacturer. Admittedly, the nexus of non-tableted flunitrazepam to Sections 821 and 958 is less clear and less direct than other Schedule IV controlled substances. DEA determined not to fee-fund activities involving non-tableted flunitrazepam because they are undertaken by non-DCP personnel and are closer to chemical control activities than to traditional DCP activities.

In the event that an international activity or conference meets the fee-funding criteria but also involves excluded activities or substances, DEA attempts to fee-fund the activity on a *pro rata* basis, with the remainder funded by other appropriated funds. The costs of salary, support, travel and other items pertaining to such dual-purpose activities are split-funded and assigned to the appropriate funding source. For example, if an international conference involves fee-funded activities for 90% of the time, and chemical activities for the remaining 10%, then DEA would fee-fund 90% of the conference.

C. Participation In and/or Co-Sponsorship of International Conferences or Bilateral Discussions on Drug Control

DEA participates in and co-sponsors international conferences and meetings with foreign counterparts to gain critical information on drug abuse trends and patterns. DEA considers this information in determining whether these, or pharmacologically similar substances should be controlled in the United States. These activities allow DEA to exchange information regarding diversion and effective (or ineffective) prevention measures and to identify specific problems that the agency must address. Information derived from such activities is essential in protecting the U.S. public health and safety and relates to a broad spectrum of DEA efforts, ranging from information collection and policy formulation to investigative and operational activities.

Several commentors objected to fee-funding meetings with European, Turkish, Colombian and Mexican officials regarding specific control issues, such as the medical use of

marijuana and flunitrazepam. Other international conferences and discussions relate in whole or in part to controlled substances lawfully manufactured, distributed or dispensed. For example, the December 30, 1996 **Federal Register** notice described meetings with European officials to discuss control and policy issues ''relating to pain management, the distribution and use of methylphenidate, narcotic treatment programs, and the medical use of marihuana.'' 61 FR 68628. While the commentor singled out the topic of medical marijuana raised at these meetings, the other subjects clearly relate to serious domestic control issues involving controlled substances lawfully manufactured, distributed or dispensed. DEA carries out the mandates of the CSA related to lawfully manufactured drugs so that controlled substances are available for pain management and other legitimate purposes, while preventing, detecting and investigating their diversion. Methylphenidate is a Schedule II controlled substance, lawfully marketed for Attention Deficit Disorder and narcolepsy, that is in great demand by illicit users and traffickers. Narcotic treatment programs primarily dispense and administer methadone, a highly abusable and sought-after Schedule II controlled substance, to narcotic addicts.

Additionally, and perhaps most importantly, such activities potentially impact U.S. manufacturers, distributors, dispensers, exporters and importers which, if they handle controlled substances legally, are DEA registrants.

The medical uses of marijuana and flunitrazepam have been the subject of much press, policy and medical professional association debate in the United States as to the appropriateness of current CSA controls. Marijuana is a Schedule I controlled substance available and used for research purposes, and those handling it within the closed distribution system including conducting research must be registered with DEA. 21 CFR 1308.11(d)(19) and 21 U.S.C. 823(f). In reviewing and considering U.S. control policy and practices for these substances and activities, it is appropriate and necessary for DEA to research and examine the experience of other nations' control efforts with them. Factors determining whether any substance, including marijuana and flunitrazepam, should be scheduled, re-scheduled or de-scheduled under 21 U.S.C. 811(c), are not limited to the domestic experience of the United States. *See* 21 U.S.C. 811(c). In fact, U.S. firms and practitioners frequently cite the experiences of other nations as a foundation for suggesting modifications to domestic controls. For additional discussion of flunitrazepam, please see Section B directly above.

D. Assisting Foreign Authorities With Their Diversion Control Systems

One commentor expressed concern about a conference held in Austria to ''improve the design and administration of, and cooperation regarding, controlled substance and chemical controls in the Commonwealth of Independent States' and training African authorities about effective national controls for the manufacture and distribution of controlled substances. The commentor asserted that these activities have ''nothing to do with the legitimate manufacture, distribution and dispensing of controlled substances that are handled by DEA registrants.'' The commentor contended that DEA must explain how these activities legitimately relate to the regulation of DEA registrants.

In addition to the above discussion explaining the interrelationship of effective international controls and treaty requirements with domestic controls, DEA activities to assist other nations in establishing adequate national control mechanisms are crucial in establishing and maintaining the machinery and working procedures that allow the legitimate exportation of controlled substances by U.S. registrants to foreign countries and the legitimate importation of foreign pharmaceuticals by U.S. registrants for distribution and dispensing in the United States. The CSA authorizes registration of importers and exporters of Schedule I or II substances only if consistent with the public interest and with U.S. obligations under the treaties, conventions and protocols. 21 U.S.C. 958(a). The CSA, recognizing the interrelationship between U.S. and foreign controls, makes it unlawful to export Schedule I–IV narcotics and Schedule I and II non-narcotic substances unless the importing country has adequate controls in place and that country has a legitimate medical, scientific or research need for the drug. For example, the foreign-based consignee must hold an appropriate permit or license from the government authority in the importing country that also indicates that a legitimate need for the drug exists in that country. 21 U.S.C. 953(a) and (c). The CSA also restricts the export of the other controlled substances. 21 U.S.C. 953(e).

DEA, jointly with the European Union, organized, sponsored and funded, the Commonwealth of Independent States Policy Conference, held October 1994, in Salzburg, Austria. The purpose of the conference was ''to establish dialogue with policy-level officials of the CIS governments on the problems of illicit drug transit, manufacture, and uncontrolled trade in pharmaceuticals and chemicals used in the clandestine production of drugs.'' DEA, Conference Report, Commonwealth of Independent States Policy Conference on Drug and Enforcement Control 1 (1995). Participants discussed the need for adequate national legislation to enable government authorities to deal with the drug threat, international treaty compliance, establishing or strengthening national frameworks for administering drug and chemical regulatory and enforcement programs, drug trafficking methods and aspects of drug law enforcement. *Id.* As the December 30, 1996 **Federal Register** notice pointed out, DEA's share of the costs of this multi-topic conference was split between the DDCFA and other appropriated funds ''in approximation to the subject matter covered.'' 61 FR 68628.

DEA sent one DCP representative to an INCB training seminar for north and west African drug control administrators held March 1995 in Tunis, Tunisia. Most African countries import controlled substances from American exporters and others to meet their legitimate medical needs. Lack of organization, conflicting authorities and other factors contribute to potential and actual controlled substance diversion in Africa, and the DEA representative provided insight into the business practices and attitudes of importers and exporters of controlled substances and chemicals. Working groups discussed, among other topics, the effectiveness of national and international control measures. Adequate national control measures, as discussed above, are prerequisite for exporting controlled substances from the United States to any foreign country. Training African drug control administrators involved control activities relating to controlled substances lawfully manufactured in, and subsequently exported from, the United States. The total fee account funds expended for this activity totaled $3,775.16.

The adequacy of foreign controls relate to the control of the lawful manufacture, distribution and dispensing of controlled substances for the reasons just cited, and DEA has determined that it will fee-fund these activities based on its extensive reevaluation of the fee-funding criteria.

DEA will continue to fee-fund foreign bilateral and multilateral training, and the development of effective foreign national control systems, unless they do not relate to controlled substances lawfully manufactured, distributed, dispensed, imported or exported in the United States. DEA has attempted to exclude expenses incurred when international activities relate to chemical control but as previously mentioned, has not always been successful.

As a further note, the international activities carried out by personnel assigned to DEA domestic offices are limited in scope. The expenses of DCP personnel assigned to overseas positions are totally funded by other appropriated funds, not by the DDCFA, even though they may conduct activities that fall within the 21 U.S.C. 821 and 958(f) criteria.

VI. Enforcement Activities-Drug Trafficking Investigations

Two comments submitted on behalf of six professional and trade associations stated that the December 30, 1996 **Federal Register** notice indicated that ''much of the [diversion control] program has nothing to do with controlling the manufacture, distribution or use of controlled substances by the health care professionals and other registrants on whom the costs of the program have been placed'' and provided, as an example, ''many of the costs of the agency's efforts to control drug trafficking by non-registrants.''

Narcotic, depressant, and stimulant drugs manufactured, distributed and dispensed for legitimate medical need are sought by abusers and subject to diversion into the illicit traffic. Pharmaceutical drugs are in demand by abusers as a substitute when ''street'' drugs are in short supply (Oxycontin ®, Dilaudid ®, or morphine in place of heroin, for example); as a supplement to ''street'' drugs to enhance or diminish their effect (*e.g.,* tranquilizers to ''smooth out'' a cocaine binge); or even as many abusers'' primary drugs of choice. These legitimate abusable drugs, listed individually in the CSA and its implementing regulations, are ''controlled substances.'' Their street value can be up to a hundred times their original cost, and they are available through theft, fraud or illegal sale from over a million physicians, pharmacies and other registrants.

Abuse resulting from diverted controlled substances is within the DCP's authority to control and prevent since the drugs are lawfully manufactured, distributed and/or dispensed, and the ''sources of supply'' to abusers hold DEA registrations and state licenses. The DCP is responsible for investigations related to lawfully manufactured, distributed and dispensed controlled substances for which registration is required or excepted, and where controls imposed by the CSA and its implementing regulations are circumvented or disregarded. The DCP attempts to ensure that the required controls to prevent diversion are maintained and verifies the *bona fides* of applicants for registration. DCP investigations fall into three general categories: pre-registrant investigations, scheduled regulatory investigations, and complaint investigations. The DCP conducts investigations of individuals and institutions 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 DCP investigates the diversion of legitimate controlled substances to determine where the closed system of controls has been compromised so that corrective action can be taken. When such products are trafficked or sold in the illicit market, it is not always clear how they were diverted, but the illicit source of supply must by virtue of the closed distribution system requirement be a person subject to the CSA's registration and control requirements. The person responsible for the diversion could be a doctor, pharmacist, employee of a DEA registrant or other source. The controlled substances could be smuggled or stolen.

The closed system created by the CSA was designed to ensure that registrants maintain controls over their activities with controlled substances to prevent and detect their diversion. When drug abusers and traffickers obtain controlled substances from registrants, the DCP investigates the registrants to determine whether their controlled substance registration is consistent with the public interest. The DCP also investigates non-registrants such as prescription forgers and ''doctor shoppers.'' All of these activities relate ''to the * * * control * * * of the dispensing of controlled substances'' since the originating source of the drugs is a DEA registrant or an individual whose activities is subject to DEA's registration requirements.

DEA identified six categories of DCP complaint investigations in the December 30, 1996 **Federal Register** notice and described how each relates to 21 U.S.C. 821. Following review of the comments received, DEA reevaluated these investigations and how they relate to 21 U.S.C. 821 and 958(f). DEA fee-funds these investigative activities because they relate to the registration and control of lawfully manufactured, distributed or dispensed controlled substances. Some have asserted that DEA should not fee-fund investigative activities involving other than lawfully manufactured, distributed or dispensed controlled substances, such as counterfeit or illegally imported versions of legitimate controlled substances. While the nexus of some investigative activities with controlled substances under the 21 U.S.C. 821 and 958(f) criteria may not appear as evident or as clear as others, DEA believes that it is sufficient to justify fee-funding investigative activities except when they involve chemicals. (The activities within the areas specifically excluded by the March 1993 and December 1996 **Federal Register** notices, while currently excluded from fee-funding, may have sufficient nexus for fee-funding under 21 U.S.C. 821 and 958(f) criteria.) The language of 21 U.S.C. 821 requires only that the activities listed therein ''relate to'' the registration and control of the manufacture, distribution, and dispensing of controlled substances. The primary targets and types of complaint investigations conducted by the DCP (which is a major emphasis of the DCP program) are identified below, with an explanation of how each relates to the fee-funding requirements:

1. Registrants and their employees or agents who are suspected of diverting controlled substances from legitimate channels. Investigations of registrants relate to the ''registration and control'' criteria of 21 U.S.C. 821 and/or the ''registration'' criteria of 958(f). Although employees of registrants are exempt from individual registration as agents of a registrant, their access to lawfully manufactured, distributed or dispensed controlled substances remains subject to the controls of the CSA and is the responsibility of the registrant. Registrants are required under 21 CFR 1301.71(a) to provide effective controls and procedures to guard against theft and diversion of controlled substances, including that by their employees and agents.

2. Persons who engage in pharmaceutical controlled substance smuggling, theft, robbery or trafficking. Such investigations can include, where appropriate, identifying and immobilizing the sources of supply, whether domestic or foreign, through enforcement of controls relating to the lawful manufacture, distribution or dispensing of controlled substances. These activities relate to the registration and control responsibilities of 21 U.S.C.

821 and 958(f). For example, theft or robbery may be the result of a registrant's failure to maintain required security controls or even collusion with a thief or robber, and the investigation will ensure that the deficiencies are corrected and determine whether the registrant's continued registration is in the public interest. In another example, if controlled substances lawfully manufactured or distributed in the United States are exported to avoid stringent U.S. control and then smuggled back into the United States, DEA will investigate to determine if the U.S. exporter should be prosecuted, its registration revoked or future export authorizations denied.

DEA fee-funds these investigative activities because they relate to lawful controlled substance manufacture, distribution or dispensing. Among smuggling, theft, robbery or trafficking pharmaceutical controlled substances, smuggling is perhaps the activity area with the most unclear nexus with 21 U.S.C. 821 and 958(f) criteria. Smuggling a controlled substance into, or introducing it into, the United States is importation, albeit illegal, and constitutes an activity for which DEA registration and controls are required under the CSA and its implementing regulations. Smuggling investigations relate to the registration for importing controlled substances under 21 U.S.C. 958(f) and their subsequent control once in the United States under 21 U.S.C. 821. Some smuggled pharmaceutical controlled substances are manufactured, distributed or dispensed by foreign subsidiaries of DEA registrants. Smuggled substances potentially threaten the integrity of the closed system by introducing foreign-source or even counterfeit substances into the domestic market. It is to the benefit of manufacturers and distributors that these products are eliminated from competition with their products to pharmacies, and prescribers for the assurance that they are handling only legitimate products and to the public health. The presence of these smuggled substances potentially impacts the domestic market for controlled substances manufactured, distributed and dispensed by DEA registrants.

3. Persons, both registered and non-registered, who conduct controlled substance activities without the required DEA registration or state authorization. DEA registration and state licensure are prerequisites for lawfully manufacturing, distributing, dispensing, importing and exporting controlled substances, including handling Schedule I substances in industrial, analytical or research applications. Proper registration is the keystone of the CSA's closed distribution system. Investigations to maintain the integrity of the CSA registration system directly relate to the registration and control of the manufacture, distribution and dispensing of controlled substances under 21 U.S.C. 821 and to the registration for importing and exporting controlled substances under 21 U.S.C. 958(f). DCP authority to investigate extends to registered persons who lack required state or other authorization which is a prerequisite for DEA registration, non-registered persons who are conducting controlled substance activities for which registration is required, including those who have had a registration revoked yet continue to misrepresent that they are registered, and registrants conducting activities with controlled substances not authorized by their registration. DEA fee-funds investigations of DEA registrants authorized to handle, or persons seeking registration to handle, a controlled substance that is not commercially available in the United States, but for which registration is required for its use in industrial, analytical or research applications. Investigations of these activities relate to the registration and control requirements under 21 U.S.C. 821.

4. Persons who obtain controlled substances from registrants through fraud, deceit or circumvention of the manufacturing, distribution, dispensing, importing or exporting controls, such as by fraudulent use of another person's DEA registration number, ''doctor shopping'' or prescription forgery. The CSA system of registration and control was created to prevent diversion from registrants and ideally permits detection when diversion occurs. Investigations of this type of diversion focus on the activities of non-registrants in order to determine the source of the diversion, the degree of registrant culpability (if any) and appropriate corrective action. Investigative activities involving non-registrants who obtain legitimate controlled substances are fee-funded to the extent they involve lawfully manufactured, distributed or dispensed controlled substances.

5. Drug trafficking by non-registrants of controlled substances that are fraudulently promoted as legitimate (such as herbal remedies that actually contain a controlled substance). Investigations involving products that are not lawfully marketed in the United States, but which contain a controlled substance that is lawfully marketed here, on the surface appear to be too tenuous to relate to 21 U.S.C. 821 and 958(f) criteria. ''Black Pearls'' is an example of one herbal remedy sold in health food stores that contains a controlled substance (diazepam). An example of a product trafficked as having been lawfully produced is smuggled or counterfeit anabolic steroids. Trafficking of these products sometimes occurs within the otherwise legitimate medical/pharmaceutical environment.

For investigations involving products such as smuggled anabolic steroids, the nexus to 21 U.S.C. 821 and 958(f) is discussed and described under Number 2 directly above. DEA concedes that the nexus of counterfeit substances promoted as legitimate to 21 U.S.C. 821 and 958(f) criteria seems more tenuous in comparison with other DCP activities. Counterfeit versions of controlled substances manufactured, distributed or dispensed compete with legitimate versions of that substance, thus impacting registrants lawfully handling them under the CSA. Additionally, Congress explicitly recognized the problem created by the distribution and dispensing of counterfeit controlled substances. *See* 21 U.S.C. 841(a)(2). While ''distribution'' may entail any controlled substance, ''dispensing'' by definition involves controlled substances lawfully marketed in the United States and subject to the CSA's closed system of distribution. 21 U.S.C. 802(10). Dispensing is an activity that requires DEA registration.

6. Persons who use their DEA registrations to assist in the diversion or misuse of legitimate controlled substances. The CSA provides that controlled substances may only be administered or dispensed by a practitioner in the normal course of professional practice. Unlawful registrant practices such as selling or trading controlled substances for non-medical purposes, health care fraud or self-abuse are outside the scope of activity authorized by their DEA registration. Investigative activities of such practices meet the fee-funding criteria because DEA registration enables the registrants to divert controlled substances from the CSA's closed distribution system.

To summarize, DEA fee-funds investigative activities of registrants and non-registrants when they relate to the registration and/or control of the lawful manufacture, distribution or dispensing of controlled substances.

VII. National Forensic Laboratory Information System

One commentor objected to fee-funding the National Forensic Laboratory Information System (NFLIS),

concerned that DEA did not provide adequate information demonstrating whether the analyzed drug evidence involves licit or illicit controlled substances, resulting in registrants not knowing whether DEA is inappropriately fee-funding a system for illicit drugs.

The NFLIS is a computerized database of analyzed diverted and trafficked drug information from non-federal state and local forensic crime laboratories in the United States. The information obtained through the NFLIS, when combined with data from other sources, will present a more accurate and complete indicator of the extent of the abuse, diversion and trafficking of specific substances on a regional and national basis, providing early warning of new and changing trends. Prior to establishment of the NFLIS, DEA had to laboriously collect this data manually through separate contacts with individual laboratories nationwide.

DEA will use the NFLIS primarily for classifying and scheduling substances, setting production quotas, determining enforcement priorities and establishing drug control priorities for controlled substances lawfully manufactured, distributed or dispensed under the CSA. The CSA authorizes DEA to schedule, reschedule or deschedule substances according to specific scheduling criteria. 21 U.S.C. 811(a). The CSA requires DEA to conduct a comprehensive study of a substance, including collecting data on abuse and abuse potential before initiating any scheduling actions. 21 U.S.C. 811(b). The DCP is the DEA element responsible for conducting drug evaluations and gathering the necessary data for scheduling purposes regardless of the type of substance under consideration. The NFLIS will provide DEA with accurate, chemically verified data that will be used to support these DCP activities. *See* Section IX below for a discussion of how scheduling and production quotas relate to 21 U.S.C. 821 and 958(f).

Scheduling actions establish which substances are subject to the registration and control provisions of the CSA. There are no ''legal'' or ''illegal'' substances, only activities with controlled substances that are either legal or illegal under the CSA, depending upon their actual use. For example, there are numerous researchers registered to handle Schedule I substances (LSD, heroin, etc.,). There is obviously extensive illicit trafficking in Schedule I substances. Scientifically acceptable and meaningful use of the NFLIS for any and all scheduling actions requires the collection of data on all types of abused, diverted and trafficked substances. Data collected by the NFLIS is necessary to conduct a complete and thorough scheduling review of a substance. The analyzed drug evidence reported to NFLIS will include controlled substances that are lawfully manufactured, distributed or dispensed, as well as non-controlled but lawfully marketed substances subject to pending scheduling actions, illicit controlled substances and non-controlled substances that are purported to be controlled substances. DEA concedes that that only first type of evidence falls within the 21 U.S.C. 821 and 958(f) criteria.

As most new drugs of abuse begin as local problems, it is almost impossible to quickly detect new drugs of abuse or changes in national drug abuse trends based on DEA's STRIDE system, the database of drug analysis information of drugs purchased and seized in DEA cases. Systematic collection and analysis of non-federal forensic data are critical for the DCP to discharge its scheduling responsibilities efficiently.

Licit and illicit controlled substance data are not as separate from one another as one might believe. Existing indicators, such as the Drug Abuse Warning Network (DAWN) and the Drug Use Forecasting System (DUF), demonstrate that the majority of licit controlled substance abuse is in combination with illicit substances. In addition, lawfully marketed controlled substances have been trafficked as illicit drugs, and non-controlled substances have been sold as controlled substances. For example, traffickers have distributed diverted Dilaudid® as heroin, and substances sold as anabolic steroids have been determined to be non-controlled counterfeits. Information related to these activities that is analyzed and compiled as a result of the NFLIS will enhance overall DCP efficiency in determining which substances pose threats to the public health and safety.

While the primary purpose of the NFLIS will be for control activities related to the lawful manufacture, distribution or dispensing of controlled substances, there will be instances in which data will be used for activities unrelated to the fee-funding criteria. Most of the funding for the NFLIS thus far has occurred in establishing the system's infrastructure. As later costs to collect data or to generate a report for non-fee-fundable activities are minimal, there will be occasions when DEA provides NFLIS data for non-related regulatory and law enforcement activities. DEA will monitor NFLIS activities, and if after a reasonable period it appears that non-fee-fundable activities occur on more than a minimal basis, DEA will reevaluate its fee-funding of the NFLIS.

In summary, DEA fee-funds the NFLIS because the system will be used primarily for drug scheduling actions, setting production quotas and other diversion control activities related to 21 U.S.C. 821 and 958(f) fee-funding criteria.

VIII. Tactical Diversion Squads (TDSs)

One commentor objected to fee-funding DEA's Tactical Diversion Squads (TDSs), concerned that DEA described them too generally in the final rule and did not adequately explain their connection to the activities of DEA registrants.

Authority for the TDSs derives from the statutory directive to the Attorney General to cooperate with local, state and federal agencies to combat controlled substance trafficking and abuse. 21 U.S.C. 873(a). The CSA authorizes the Attorney General to assist state and local governments ''in suppressing the diversion of controlled substances from legitimate medical, scientific, and commercial channels'' by establishing cooperative investigative efforts and to enter into contractual agreements with state and local law enforcement agencies providing for cooperative enforcement and regulatory activities. 21 U.S.C. 873(a)(6) and (7). TDSs are cooperative teams of DEA diversion personnel and other federal, state and local authorities established to identify and investigate the diversion of licit controlled substances from registrants. DEA has established multi-agency TDSs in eight cities.

TDSs combine efforts by DEA and other federal, state and local law enforcement and regulatory agencies to combat the diversion of lawfully marketed controlled substances from registrants primarily at the retail level within a given geographic area. The mission of the TDSs is to concentrate a dedicated workforce to detect, investigate, disrupt and refer for prosecution, violators of federal and state controlled substance statutes pertaining to drug diversion. The TDSs develop investigative leads from information and intelligence from participating agencies, through undercover operations and the use of informants. The multi-agency efforts help coordinate the various jurisdictional responsibilities of the agencies that otherwise may hinder investigations and prosecutions, and combine program and personnel expertise to maximize resources and

enhance efforts at all levels of diversion control investigations.

Information gleaned from work of the TDSs also contribute to classification and scheduling activities, as well as to the establishment of production quotas, by generating data essential to these functions. Classification, scheduling and production quota activities relate to the control of the manufacture, distribution and dispensing of controlled substances as required by 21 U.S.C. 821. For additional justification regarding classification, scheduling and production quota activities, *see* Section IX below. Data gathered about the number of persons diverting licit controlled substances and the specific substances involved help identify drug abuse trends and patterns.

DEA fee-funds the salaries of DEA personnel, office space, travel, investigative equipment and costs, and training and overtime for state and local officers. The member agencies provide representative personnel and fund their salaries. Fee-funding TDSs is appropriate because the investigative and prosecutorial activities are directed solely against registrants and others mishandling controlled substances otherwise lawfully manufactured, distributed or dispensed.

IX. Classification and Identification of Controlled Substances and Establishment of Production Quotas

One commentor questioned activities ''that appear to exceed the bounds of a program for which DEA registered practitioners should be expected to pay.'' The comment noted that the classification and identification of controlled substances and the establishment of production quotas appear to be ''indirect or collateral'' activities having more to do with controlled substance manufacturing and marketing than with diversion control. The commentor requested that the Office of Management and Budget (OMB) review these activities.

The DDCFA budget request and the DEA appropriated funds budget request are submitted each year to OMB through the Attorney General, the White House and Congress, which approves the requests and authorized the funding of the programs at the requested levels. Prior to publication, the December 18, 1992 **Federal Register** notice proposing to adjust the registration fee schedule and the March 22, 1993 **Federal Register** notice of the final rule establishing the fee schedule were submitted to OMB for review. 57 FR 60148 and 58 FR 15274. Therefore, the diversion control budget provisions and **Federal Register** notices relevant to the DDCFA have been submitted for review consistent with OMB's authority and jurisdiction. DEA did not submit the December 30, 1996 **Federal Register** notice describing DCP components and fee-funded activities to OMB because it was merely the publication of additional information for public comment and was not a new rule. Moreover, this notice has been reviewed by OMB.

Classification and scheduling substances relate to more than just controlled substance manufacturing and marketing. The authority to classify and schedule substances of abuse is central to the effective application of the CSA and DEA Diversion Control Program relating to the registration and control of the lawful manufacture, distribution, dispensing, import and export of controlled substances. The term ''classification'' as used in the CSA equates to the term ''scheduling.'' Classification, with its related activities, is the initial step constituting the threshold that must be met for any change of status of a substance within the five schedules, which in turn dictates the CSA controls to which it is subsequently subjected. Classification or scheduling affects all registered manufacturers, distributors and dispensers who lawfully handle the controlled substance within the closed distribution system. The DCP collects, monitors and analyzes data for recommendations to add substances to, delete substances from, or transfer substances between schedules and maintains a highly educated staff of pharmacologists and scientists to perform this work. They are experts in controlled substance pharmacology, and their opinions are sought by state, national and international officials involved in drug abuse studies. This DCP staff is responsible for ensuring that objective and comprehensive studies are undertaken on the actual and potential abuse of substances to find the balance between protecting the public health and safety, yet allowing necessary medication to be readily available for legitimate medical and scientific purposes. Each study requires an examination of the scientific literature regarding the properties of the drugs, the current controls over the drugs, data regarding annual production and consumption, and information from law enforcement, regulatory and medical sources regarding drug diversion, trafficking and abuse.

The CSA provides for the classification of substances of abuse into one of five schedules when appropriate. Such classification determines the level of controls that all registrants must then comply with when handling the controlled substance. Classification of a substance thus impacts not only how it will be handled by registered manufacturers, distributors and importers and exporters, but also how it will be administered, prescribed and dispensed by registered practitioners such as pharmacies, hospitals, physicians, dentists and veterinarians.

The language of 21 U.S.C. 821 refers to ''the registration and control * * * of controlled substances,'' and classification and scheduling of substances of abuse are the initial steps in the ''control * * * of controlled substances'' criteria of 21 U.S.C. 821. Thus, these activities meet one of the legal requirements for fee funding. DEA believes that it is reasonable to fee-fund classification/scheduling activities, and to fund the same classification/scheduling activities from different sources depending upon whether the substance of abuse is controlled or non-controlled at the start would be unworkable and not feasible. DEA has determined, therefore, that it is appropriate to fee-fund classification and scheduling activities of controlled substances and substances of abuse that are not yet controlled.

In conjunction with the classification of substances, the CSA and international treaties require that controlled substance containers include certain identifying symbols, warnings and seals. These symbols, warnings and seals identify for all legitimate handlers a controlled substance's level of control under the CSA and alert them as to how they must handle it. In clarifying how to handle the substance, the identifying symbols, warnings and seals help maintain the integrity of the closed system of controls, minimizing the risk of diversion when the substances are properly handled and securely stored. The CSA makes it unlawful to remove, alter or obliterate a required symbol or label, illustrating the importance of controlled substance identification. 21 U.S.C. 842(4).

The CSA and international treaties require DEA to determine the total quantity of certain controlled substances necessary for medical, scientific, research and industrial use in the United States and limit the manufacture of such substances to the quantity necessary for legitimate use through a system of production quotas. In recent years, DEA has issued approximately 850 quotas annually to over 200 manufacturer registrants. DEA's scientific staff works closely with the regulated industry to identify medical trends, new drugs entering the market, and manufacturing issues in order to allow U.S. manufacturers to meet

legitimate patient and distribution needs. The DCP scientific staff collects and analyzes information regarding the legitimate use, trafficking and abuse of Schedule I and II controlled substances in the United States from such sources as manufacturing and distribution reports, treatment and prescription utilization data, case data, drug abuse indicators and Department of Health and Human Services (HHS) estimates of medical use. In response to requests from controlled substance manufacturers, DCP staff conducts training sessions throughout the United States to assist these registrants in understanding the operation and goals of the quota system.

Although manufacturers are the registrants who, by virtue of their role in the closed manufacturing and distribution system, directly apply the provisions of the production quotas issued, it is inaccurate to characterize the establishment of quotas as an indirect or collateral activity primarily related to manufacturing and marketing. The establishment of production quotas is a key component in the closed system of controls. Establishing production quotas for controlled substances impacts not only the quantity manufactured and distributed by registered non-practitioners but also the availability of those substances for administering and prescribing by physicians and veterinarians, and dispensing by pharmacies. Production quotas help to ensure adequate availability of controlled substances for legitimate use by handlers at each level of the closed system. Additionally, quotas limit overproduction, minimizing diversion and abuse and ultimately reducing the need for enforcement activities against registrants and others.

The classification and identification of controlled substances and the establishment of quotas relate to the control of the lawful manufacture, distribution, dispensing, import and export of controlled substances by practitioners and other registrants. Therefore, funding these activities through fees collected from registrants is consistent with the requirement that they relate to the registration and control requirements of 21 U.S.C. 821 and 958(f).

X. History of the Current Fee

In response to the 1993 Appropriation, DEA published a rulemaking in the **Federal Register** on March 22, 1993 to announce a new fee schedule for the Diversion Control Program (DCP) (58 FR 15272). This announcement outlined the general categories of cost to be borne by the resulting Drug Diversion Control Fee Account (DDCFA) and excluded from such outline certain DCP costs, including the cost of the Chemical Control Program. This program is responsible for the regulation and monitoring of activity involving chemicals used in illicit manufacture of controlled substances and for the investigation of the diversion of these chemicals. Following the March 22, 1993 announcement, several registrant groups filed a complaint in the United States District Court for the District of Columbia. On July 5, 1994, the district court disposed of all claims, but one of the plaintiffs, the American Medical Association (AMA), appealed to the United States Court of Appeals for the District of Columbia Circuit. In this case, *AMA* v. *Reno,* 57 F. 3d 1129 (D.C. Cir. 1995), the District of Columbia Circuit held that DEA ''was required to identify the components of the fee-funded Diversion Control Program and provide a brief explanation of why it deemed each component to be a part of that program.'' Id. At 1135. DEA has attempted to fulfill the court's mandate through a second announcement, which appeared in the **Federal Register** on December 30, 1996 (61 FR 68624).

The second announcement provided a more detailed discussion of the DCP costs to be included in, and excluded from, DEA's DDCFA charges. A table summarizing these costs follows.

Included	Excluded
• All direct support of drug diversion control efforts, including: Diversion investigators, analysts, technicians, and clerical personnel; equipment and services associated with these positions for the registration and control of the manufacture, distribution and dispensing of controlled substances. • Salaries and expenses, benefits. • Travel, rent, utilities, supplies. • Training.	• All direct support of chemical diversion control efforts, including payroll, benefits, travel, training, supplies and equipment.
Specific Activities: • Development and refinement of regulations and rules re: registration and control of the manufacture, distribution and dispensing of controlled substances.. • Preparation for and conduct of meetings and national conferences with registrants, registrants' representatives (*e.g.,* associations, etc.), law enforcement representatives, and other interested parties.. • Responding to inquiries from industry, law enforcement, regulatory personnel, Congress, and federal agencies.. • Classification and scheduling of substances, including the collection and analysis of necessary data, providing information to international, national and state entities re: scheduling of substances, responding to scheduling petitions, providing testimony and expert guidance and assistance, and working with law enforcement agencies, the scientific community, industry, the public and other interested parties.. • Identification of controlled substances for the control of the lawful manufacture, distribution, dispensing, and export of controlled substances by practitioners and other registrants.. • Establishment of quotas for certain controlled and substances for medical, scientific, research and industrial use and monitoring of the manufacture, utilization, trafficking an abuse of controlled substances against the quotas.. • Conduct of training seminars for industry on controlled substances, including quotas, etc..	Specific Activities: • Chemical control. • Clandestine laboratories. • Overseas positions. • Chief Counsel support. • Executive Direction. • DEA automated data processing systems and support (except ARCOS and CSA). • Office of Training staff. • DEA management and administrative support. • Office of Congressional and Public Affairs support. • Intelligence support. • Development of non-drug related materials such as the Chemical Handlers Manual. • Chemical Laboratory Services Support.

Included	Excluded
• Registration of persons authorized to manufacture, distribute, dispense, import, or export controlled substances, including registration of persons conducting research with Schedule I controlled substances in conjunction with FDA and distribution of registrant information to other DEA elements , Federal, state and local regulatory personnel, and registrants as necessary.. • Conduct of other investigations including pre-registrant investigations and cyclic investigations of registrants' records/inventories.. • Participation in any civil or criminal action resulting from above-referenced investigations.. • Operation of system of declarations and permits for importers and exporters of controlled substances to comply with CSA and international treaties. This includes examining request for permission to import or export controlled substances and maintenance of records, monitoring of imports of controlled substances to ensure they are consistent with domestic need, and preparation of reports.. • Participation in international policy activities re: the manufacture, distribution, dispensing, import and export of controlled substances and the strengthening of controls in these areas to comply with CSA and international treaties/conventions, including participating in United Nations policy activities and international meetings/conferences; developing and formulating policy; and developing substantive materials and research papers. Note, fee-funded activities in this area are limited to domestic personnel (personnel assigned to overseas positions are supported through appropriated funds).. • Providing assistance to foreign authorities and governments with their diversion control systems to improve the design and administration of, and cooperation regarding, controlled substances and chemical controls.. • Participation in cooperative efforts with other officials involved in diversion control activities (*e.g.,* Federal, state, local, and national and local pharmaceutical and health care organizations) and maintenance of an active liaison program.. • Development of information manuals and materials for industry such as Pharmacist's Manual, Practitioner's Manual, Mid-Level Practitioner's Manual, and the Security Outline to the Controlled Substances Act.. • Enforcement of the Anabolic Steroid Control Act.. • Operation of ARCOS and CSA data systems.. • Establishment and operation of National Forensic Laboratory Information System.. • Establishment and operation of Tactical Diversion Squads..	

The increased detail of the December 30, 1996 announcement did not address all concerns, however. Several of the commentors asserted that DEA failed in the first DDCFA rulemaking and in the December 1996 **Federal Register** notice to articulate how it had arrived at the amount for the registration fee increase in 1993 and failed to provide adequate justification for the increase. One commentor concluded that ''[t]he thing that bothers many of us is that it appears the amount of increase was ''picked out of the air'' and there was no justification for that much of an increase.''

The 1993 Appropriations Act mandates: (a) That DEA deposit each fiscal year's fee revenue in excess of $15 million into an account for ''offsetting receipts'' (*i.e.,* the first $15 million collected must remain in the General Fund of the Treasury); (b) that revenue deposited into such account ''remain available until expended''; (c) that the fees funding this account ''be set at a level that ensures the recovery of the full costs of the various aspects'' of the DCP; (d) that DEA ''be refunded in accordance with estimates made in the budget request of the Attorney General''; and (e) that the Attorney General ''prepare and submit annually to the Congress, statements of financial conditions of the account''. 21 U.S.C. 886a.

The 1993 Appropriations Act augments DEA's previously established authority, pursuant to 21 U.S.C. 821, to collect offsetting fees by requiring that DEA fund the entire DCP with registration fees. Because previously established fees were insufficient to recover the full cost of operating the DCP, the 1993 legislation made a fee increase unavoidable. Because the law required recovery of the ''full costs'' of the program and because the law required all fee revenue to ''remain available until expended,'' DEA knew that any excess or surplus collected would remain in the fee account until it could be used for an appropriate DCP purpose.

DEA's method for estimating the full cost of the DCP has been a traditional approach: modular costing. This approach is required under the Department of Justice (DOJ) Instructions for the Preparation of Budget Estimates and is consistent with Office of Management and Budget (OMB) Circular A–11, Section 30.5; and both DOJ and OMB review the cost modules presented with each of DEA's three annual budget drafts. A modular cost is the total organizational burden of each incremental employment position in an organization. Such burden extends beyond the salary and benefits of a new position and includes all other resource requirements (including supplies, utilities, rent, training, etc.) resulting from the position's existence. Cost estimation may also accommodate fixed program increases: such fixed costs are incorporated into each budget request under the separate heading ''Non-Personnel Costs''. The modular costing method is useful because it enables budget formulators to project the cost of additional resources without recalculating the base cost of the underlying program. If the underlying program is modified or broken into components, however, the base cost of the resulting program(s) must be calculated afresh. The DCP's division into one appropriation-funded component and one fee-funded component made just such a base cost recalculation necessary.

In 1992, prior to passage of the 1993 Appropriation Act, DEA's FY94 budget

request for the DCP was represented partially under the Drug and Chemical Diversion Control Decision Unit and partially under other decision units. These decision units were not developed to enable DEA to track such individual programs as the DCP, and even the Drug and Chemical Diversion Control Decision Unit was not identical with the DCP. Many of the costs of the DCP were managed under other decision units. The cost of DCP budgeting and accounting, for example, was borne under DEA's Management and Administration decision unit. DEA was therefore unprepared to collect a fee recovering the full costs of a program which (a) could not be disaggregated in the DEA Accounting System (DEAAS, the automated accounting system in use at the time) and (b) was managed by several offices within the agency. Yet, with the passage of the 1993 Appropriation DEA was obliged to develop a new estimate of total DCP cost, including costs of the program not previously budgeted under the Drug and Chemical Diversion Control Decision Unit.

To achieve such a first-time, full cost estimation of the DDCFA-funded portion of the DCP, DEA assigned each object group (or general cost element, such as salaries, benefits, training *etc.*) a budgeted cost based on the ratio of projected DDCFA workyears (one workyear equals 2,080 hours worked by an individual) to projected Salary and Expense Appropriation (S&E) workyears. The budgeted cost of items intended for both DCP and non-DCP use (*e.g.,* utilities, postal expenses, office services, and furniture) was prorated between DDCFA and the S&E account in proportion to the ratio of projected DDCFA workyears to projected S&E workyears. The budgeted cost of such dedicated DCP activities as the Administrative Law Judges' office, on the other hand, was assigned entirely to the DDCFA because 100 percent of that office's activities were related to drug diversion control at that time. When DEA prepared the initial estimate of FY94 DDCFA cost, budgeted DDCFA workyears totaled 555, in comparison with 6,602 total budgeted DEA workyears. The ratio of DDCFA workyears to total DEA workyears, accordingly, was 8.31 percent (555 divided by 6,602). DEA also prorated payroll costs and non-foreign space rent and alterations in proportion to the projected workyears billable to the DDCFA as a percentage of DEA's total projected workyears.

The amount DEA originally projected as the total operating cost of the DCP for FY94 was $62,917,000. Yet this estimate included the cost of ''chemical'' diversion control: the regulation and monitoring of activity involving chemicals used in the illicit manufacture of controlled substances and the investigation of the diversion of these chemicals. Because DEA had independently determined not to fee-fund the cost of ''chemical'' diversion control, it reduced its request for DDCFA obligating authority (and thereby its minimum fee revenue target) to $57,123,000. The remaining $5,794,000 of the DCP's projected FY94 cost fell under the modified (and still S&E-funded) Chemical Diversion Control Decision Unit.

DEA's original estimation of the DDCFA-billable portion of the DCP was, if anything, too conservative, especially inasmuch as it did not capture a significant non-programmatic item. In addition to the direct program elements discussed in the December 30, 1996 **Federal Register** announcement and outlined above, DEA must transfer the first $15 million of fee revenue to the General Fund of the Treasury each year. 21 U.S.C. 886a(1). DEA's failure to include this surcharge (which is not driven by the number of DCP employees and is therefore not captured in DEA's DCP cost modules) in its calculation of the DDCFA fee did not impede cash flow until FY99, however, because Congress had appropriated an offsetting $15 million supplement to the DDCFA for every year from FY93 (the year of the DDCFA's inception) through FY98. Indeed, because of the offsetting appropriation of $15 million from FY93 through FY98 (a total infusion to the DDCFA of $90 million), the DDCFA had spent $21 million more than its cumulative revenue but was still showing a $69 million surplus ($90 million minus $21 million) in FY99. The DDCFA surplus, even at its peak of $69 million in FY99, in other words, was artificial and predicated on a supplemental appropriation not provided for in 21 U.S.C. 886a.

The DDCFA's actual cash flow has turned negative with (a) the discontinuation of the $15 million supplemental appropriation in FY99 and (b) the growth of DCP responsibilities. Some DCP growth has been reflected in DEA budget submissions, as when DEA requested and received authority (in FY97) to create Tactical Diversion Squads (TDSs) in various field locations. Other DCP expansions have not been reflected in DEA budget submissions, as when DEA implemented its initial response to internet-based drug diversion, or when DEA increased the number of drug diversion cases leading to arrest. (The number of diversion arrests more than doubled in just five years, from 444 arrests in FY95 to 935 diversion arrests relating to drug cases alone in FY00.) Yet, notwithstanding such growth due to both budgeted and unbudgeted DCP expansions, DEA has not increased the fee supporting the DDCFA since FY93.

In the meantime, DEA has also faced a management challenge extending beyond the DDCFA. Before Fiscal Year 1998 (FY98), DEA relied upon DEAAS. DEAAS was adequate for the purposes of a law enforcement organization with a single funding source and streamlined agenda, but as both enforcement and diversion control mandates began to expand in the 1990s (and in order to comply with laws requiring auditable financial statements) DEA replaced DEAAS with a better-suited accounting system.

The replacement, DEA's current Federal Financial System (FFS), is more flexible and has enabled DEA to track all obligations and expenditures (not merely those incurred under the DDCFA) through a greater variety of cost centers and programs. But this improved accounting capability was not available until FY98. Prior to FY98, a deficiency of accounting controls throughout DEA's management structure resulted in the inadequate tracking of all DEA funds—not just the DDCFA. For FY97 and before, accordingly, DEA's annual independent financial audit resulted in an unsatisfactory opinion of DEA's accounts and financial statements. Yet even in FY93 DEA attempted to comply with the law establishing the DDCFA.

XI. Accumulation and Distribution of Surplus

Each of the five commentors addressed the surplus, with all but one asserting that DEA must either issue a refund to the fee-paying registrants or reduce future fees. As noted in the December 1996 **Federal Register** notice, this surplus (or positive cash balance) began to accrue shortly after the establishment of the DDCFA. The surplus totaled $45 million as of September 1996 and had risen to $69 million by February 1999. Note in the table below that the bottom line ''Carryover'' figure represents the DDCFA surplus at the end of a given fiscal year. This surplus grew through FY98 (the last fiscal year during which DEA received a supplemental $15 million appropriation for the DDCFA) and has declined through the present. Because the surplus is expected to become a deficit shortly after the end of FY02, there are no funds to support a

refund to registrants, as all remaining DDCFA funds will be expended.

DRUG ENFORCEMENT ADMINISTRATION DIVERSION CONTROL FEE ACCOUNT (DDCFA)

[Cash flow summary (dollars in thousands)]

	FY93	FY94	FY95	FY96	FY97	FY98	FY99	FY00	FY01	FY02 (Est.)	FY03 (Est.)
DDCFA Authority [1]	12,000	42,123	57,178	62,188	67,824	73,268	76,710	80,330	83,543	86,021	[2] 116,462
Carry over from Prior Year		7,201	28,939	37,230	45,284	61,724	69,313	53,168	44,699	36,072	10,018
Rescinded Authority							(7,000)	(35,000)	(8,000)		
Net Carryover [3]		7,201	28,939	37,230	45,284	61,724	62,313	18,168	36,699	36,072	10,018
Revenue:											
Collections [4]	19,201	69,609	61,258	65,160	75,003	69,668	69,301	75,232	75,099	74,967	74,967
Supplemental Appropriation	15,000	15,000	15,000	15,000	15,000	15,000					
Less: General Treasury Surcharge	(15,000)	(15,000)	(15,000)	(15,000)	(15,000)	(15,000)	(15,000)	(15,000)	(15,000)	(15,000)	(15,000)
Net Revenue	19,201	69,609	61,258	65,160	75,003	69,668	54,301	60,232	60,099	59,967	59,967
Obligations:											
Gross Obligations [4]	12,000	47,871	53,294	57,106	61,951	62,961	71,772	74,121	77,272	86,021	116,462
Adjustments & Deobligations			(327)		(3,388)	(882)	(1,326)	(5,420)	(8,546)		
Net Obligations	12,000	47,871	52,967	57,106	58,563	62,079	70,446	68,701	68,726	86,021	116,462
Fiscal Year End Balance	7,201	28,939	37,230	45,284	61,724	69,313	46,168	9,699	28,072	10,018	(44,795)
Restored Authority							7,000	35,000	8,000		
Carryover	7,201	28,939	37,230	45,284	61,724	69,313	53,168	44,699	36,072	10,018	(44,795)

[1] Estimate of DDCFA-funded program is provided to Congress two years before execution and is subsequently authorized (but not appropriated).
[2] The collection of $116,462 in FY03 will require prior implementation of a revised fee structure.
[3] Carryover equals the Unobligated Balance shown on the final FMS Form 2108, after release of which Adjustments & Deobligations are shown in the subsequent year.
[4] Gross Obligations and Collections are based on DEA's most recent Financial Management System (FMS) Form 133, prior to availability of which an estimate is provided.

A second series of tables on subsequent pages, entitled ''Validated vs. Actual DCP Program Charges to the DDCFA'', shows the accumulation and subsequent depletion of the DDCFA surplus.

The commentors stated that in (ostensibly) failing to project the costs of the DCP accurately, DEA overestimated initial program costs and calculated an excessive fee, which resulted in a significant surplus. Yet, rather than overestimating DCP costs, DEA appears, as discussed above, to have underestimated such costs drastically. DEA has followed the OMB-approved DOJ Instructions for the Preparation of Budget Estimates to project future DCP costs from the inception of the DDCFA through the present. Indeed, for all fiscal years since FY93, DEA's programmatic requirements of the DDCFA are defended in this section, below. Unfortunately, DEA has not charged the DDCFA for all fee-fundable costs, including the mandated annual $15 million transfer to the General Treasury. Thus the surplus accumulated between FY93 and FY98 was attributable not to *overestimations* of future DDCFA need but to subsequent *underbilling* of actual DDCFA-fundable activity and costs.

Perhaps confusingly, DEA's general underbilling of the DDCFA has accompanied occasional instances of DDCFA overcharge within a particular cost category. In FY96, for example, rent charges to the DDCFA appear to have exceeded a reasonable amount by at least $2.1 million. Yet for the same year DEA's estimate of valid DDCFA information technology charges (*e.g.* for Diversion Investigators' desktop computers, as distinct from network infrastructure charges provided for under DEA's Salaries and Expenses appropriation) is greater than actual DDCFA information technology charges by $3.3 million. DEA appears to have overcharged the DDCFA for rent in FY96, in other words, but other allowance centers were undercharging the DDCFA to an even greater degree during the same period.

A particular area of confusion between legitimate and illegitimate uses of the DDCFA has been the boundary separating ''chemical'' from ''non-chemical'' DCP activities. This boundary crosses through a range of cost categories, from payroll to training. In its 1993 **Federal Register** notice, and during the course of the *AMA* v. *Reno* litigation, DEA stated it was not charging the costs of enforcing the Chemical Diversion and Trafficking Act to the DDCFA. DEA has since discovered these statements to have been in error. DEA has identified numerous examples of chemical costs erroneously charged to the DDCFA and of DDCFA-fundable items erroneously charged to the Chemical Decision Unit. Such errors resulted from a failure in some DEA offices to understand (and therefore implement) internal directives to use multiple fund sources for obligations with both a chemical and a non-chemical purpose. Because the errors resulted from a failure of understanding, however, they resulted, in turn, in mischarges to both the DDCFA and to the appropriation for the Chemical Decision Unit. The analysis presented below was performed in order to quantify the full extent of such funding errors and to determine whether there was any net overcharge to the DDCFA.

Before FY00, a common cause of chemical mischarges was erroneous ''split-funding.'' Items purchased in support of the entire DCP—for both chemical and non-chemical activities—were not consistently prorated by purpose (*i.e.,* ''split-funded'') until FY00. Such items (including photocopiers and automobile repairs) should have been charged to the DDCFA in proportion to the ratio of non-chemical to chemical activity, but such ''split funding'' was not effectively instituted (despite earlier guidance) until FY00. The analysis below takes these and other DDCFA mischarges into account by imputing a legitimate DDCFA burden based on workyear consumption. The results of this calculation suggest that DDCFA overcharges are *more than offset* by DDCFA undercharges.

DEA has acted in good faith to address and resolve accounting and managerial deficiencies connected with both the DDCFA and other programs. The replacement of DEAAS with FFS arose not just from DDCFA challenges but also from the need to isolate the cost of such major appropriation-funded DEA programs as Source Country Interdiction and Mobile Enforcement Teams. To validate DDCFA charges

under the abandoned DEAAS system, DEA has performed two independent retrospective analyses of actual DDCFA billings since FY93. Both of these analyses have confirmed (a) that DEA's original projections of DDCFA need (as presented to Congress and subsequently used as the basis for fee collections) were overly conservative and (b) that the DEA also should have charged the DDCFA more in the aggregate for every year through FY00.

DEA began its first analysis with a calculation of the ratio of DDCFA to non-DDCFA work years consumed. Only domestic, non-chemical DCP work years (as broken out in DEA's budget submissions to Congress) were included in this calculation. These work years correspond to DCP positions assigned to drug diversion control efforts. DEA multiplied the resulting ratio by non-DDCFA actual expenditures (a figure also provided in DEA's Congressional budget submissions and consistently greater than 90 percent of DEA's total expenditures). The resulting total for FY93 through FY00, $672,745,000, was then multiplied by 67 percent to reflect the relatively lower cost of a DEA Diversion Investigator (the core position supporting DEA's DDCFA-funded activities) in comparison with a DEA Special Agent (the core position supporting DEA's appropriation-funded activities). The result of this last calculation was $449,227,000: $8,129,000 more than the $441,098,000 actually charged to the DDCFA for FY93 through FY00. This calculation is not a traditional budget estimation technique, yet it corroborates the actual charges originally provided for in the official budget process. It answers the commonsense question, ''What if DEA had never developed a DCP budget: was the money spent from the DDCFA proportional to the number of Diversion Investigators assigned to drug diversion control efforts?'' The resulting estimate of total drug diversion control cost is approximately $8 million greater than the actual charges to the DDCFA (as recorded in DEA's accounting system) during the same period, even before adding the $15 million annual surcharge (required transfer to the U.S. Treasury).

This first analysis addresses the possibility of DDCFA overcharges at the bottom line. The analysis assigns all DEA costs to one of two categories (DDCFA or non-DDCFA) based on the number of work years reported for each category. This analysis leaves untested the cost elements adding into the bottom line. To validate these components, DEA designed a second test of the DDCFA charges in FFS for FY99. In this second diagnostic, DEA met with each headquarters office holding DDCFA obligation authority and verified actual procedures and obligations. DDCFA obligations found not to comport with DEA's announcements in the **Federal Register** were removed from the obligating office's validated total, while DDCFA charges provided for (but not made because of accounting and managerial errors) in the same announcements were added. For field offices, whose authority to obligate DDCFA funds is limited, the principle problem identified was a failure to split-fund (*i.e.,* draw a proportional amount from more than one fund source for a single item) non-travel items.

DEA next sought to extend this analysis of FY99 FFS data back to the beginning of the DDCFA (in FY93). To develop this extrapolation, DEA identified actual drug diversion control work hours stored in the Workhour Reporting System (WRS, a system tracking both the drug diversion control and chemical diversion control work hours reported by Diversion Investigators on DEA Form 351) and the wage and non-wage cost inflators reported to Congress in each fiscal year's budget request. DEA then projected valid DDCFA charges in reverse for FY93 through FY98 by carrying the directly validated FY99 data backward and adjusting for inflation and WRS data in each year. Finally, DEA compared this retrospective projection with the certified actual accounting data stored for the same fiscal years and offices.

The result was striking. In every year of this analysis, the actual DDCFA charges recorded in DEA's accounting system are significantly lower than what an inflation-adjusted, workhour-proportional projection generates. In the earlier years (FY93 through FY95), the difference is greater than $40 million per year. Later, as DEA began to make further legitimate use (even after invalidation of selected misuses) of the DDCFA, this annual difference recedes to just over $16 million. But in every year, DEA undercharged the DDCFA to a greater degree, and in more allowance centers, than the total of particular overcharges ultimately identified. The tables showing the results of this analysis follow.

Validated vs. actual DCP program charges to the DDCFA—Item	Validated	Obligated/incurred	Undercharge (overcharge)
	Fiscal year 1993		
Diversion Control Work Hours	.....	274,960	.....
Drug Diversion Control Work Hours	.....	253,946	.....
Split-Funding Drug Portion	.....	92%	.....
Wage Inflation Factor Used for DEA Budget	.....	2.0%	.....
Non-wage Inflation Factor Used for DEA Budget	.....	2.6%	.....
Payroll/Benefits	20,736,431	12,000,000	8,736,431
Rent/Utilities	6,982,552	.....	6,982,552
DCP Management	3,787,819	.....	3,787,819
Information Systems	3,214,756	.....	3,214,756
Staff Relocation	2,197,040	.....	2,197,040
Field Operations	1,187,364	.....	1,187,364
Staff Training	912,791	.....	912,791
Investigative Tech	791,779	.....	791,779
Facility Security	531,529	.....	531,529
Health Services	161,259	.....	161,259
Forensic Sciences	140,117	.....	140,117
Interest Penalties	71,552	.....	71,552
Administrative Law	40,297	.....	40,297
Total	40,755,287	12,000,000	28,755,287

Validated vs. actual DCP program charges to the DDCFA—Item	Validated	Obligated/incurred	Undercharge (overcharge)
Field Split-Funding Mischarges (NonTravel)	.....	.....	.....
Net Undercharge (Overcharge)	.....	.....	28,755,287
Cumulative Net DDCFA Undercharge from FY93	.....	.....	28,755,287
	Fiscal year 1994		
Diversion Control Work Hours	.....	493,982	.....
Drug Diversion Control Work Hours	.....	466,200	.....
Split-Funding Drug Portion	.....	94%	.....
Wage Inflation Factor Used for DEA Budget	.....	2.0%	.....
Non-wage Inflation Factor Used for DEA Budget	.....	2.6%	.....
Payroll/Benefits	38,829,816	30,681,201	8,148,615
Rent/Utilities	13,152,027	12,662,303	489,724
DCP Management	7,134,570	752,964	6,381,605
Information Systems	6,055,172	546,115	5,509,057
Staff Relocation	4,138,249	483,060	3,655,188
Field Operations	2,236,466	1,298,223	938,242
Staff Training	1,719,293	449,291	1,270,002
Investigative Tech	1,491,360	1,068,591	422,769
Facility Security	1,001,165	451,073	550,092
Health Services	303,740	67,957	235,783
Forensic Sciences	263,919	.....	263,919
Interest Penalties	134,773	.....	134,773
Administrative Law	75,901	56,760	19,141
Total	76,536,451	48,517,539	28,018,912
Field Split-Funding Mischarges (NonTravel)	.....	.....	46,723
Net Undercharge (Overcharge)	.....	.....	27,972,188
Cumulative Net DDCFA Undercharge from FY93	.....	.....	56,727,475
	Fiscal year 1995		
Diversion Control Work Hours	.....	485,937	.....
Drug Diversion Control Work Hours	.....	461,089	.....
Split-Funding Drug Portion	.....	95%	.....
Wage Inflation Factor Used for DEA Budget	.....	2.0%	.....
Non-wage Inflation Factor Used for DEA Budget	.....	2.6%	.....
Payroll/Benefits	39,172,203	29,874,828	9,297,375
Rent/Utilities	13,346,044	13,616,909	(270,865)
DCP Management	7,239,818	1,003,812	6,236,006
Information Systems	6,144,497	1,943,983	4,200,514
Staff Relocation	4,199,295	1,833,917	2,365,379
Field Operations	2,269,458	1,665,859	603,598
Staff Training	1,744,656	534,204	1,210,452
Investigative Tech	1,513,361	1,070,050	443,311
Facility Security	1,015,934	480,750	535,184
Health Services	308,221	109,170	199,051
Forensic Sciences	267,812	.....	267,812
Interest Penalties	136,761	.....	136,761
Administrative Law	77,021	69,721	7,300
Total	77,435,081	52,203,202	25,231,878
Field Split-Funding Mischarges (NonTravel)	.....	.....	57,293
Net Undercharge (Overcharge)	.....	.....	25,174,585
Cumulative Net DDCFA Undercharge from FY93	.....	.....	81,902,060
	Fiscal year 1996		
Diversion Control Work Hours	.....	468,677	.....
Drug Diversion Control Work Hours	.....	430,032	.....
Split-Funding Drug Portion	.....	92%	.....
Wage Inflation Factor Used for DEA Budget	.....	2.2%	.....
Non-wage Inflation Factor Used for DEA Budget	.....	3.0%	.....
Payroll/Benefits	37,337,472	31,120,120	6,217,352
Rent/Utilities	12,820,525	14,921,408	(2,100,883)
DCP Management	6,954,740	1,083,346	5,871,394
Information Systems	5,902,548	2,602,958	3,299,591
Staff Relocation	4,033,942	1,759,553	2,274,389
Field Operations	2,180,095	1,822,990	357,104
Staff Training	1,675,958	1,026,738	649,220
Investigative Tech	1,453,770	1,287,820	165,950

Validated vs. actual DCP program charges to the DDCFA—Item	Validated	Obligated/incurred	Undercharge (overcharge)
Facility Security	975,930	442,216	533,714
Health Services	296,084	141,197	154,887
Forensic Sciences	257,267	.....	257,267
Interest Penalties	131,376	32,374	99,002
Administrative Law	73,988	43,659	30,329
Total	74,093,694	56,284,378	17,809,316
Field Split-Funding Mischarges (NonTravel)	.....	.....	107,017
Net Undercharge (Overcharge)	.....	.....	17,702,299
Cumulative Net DDCFA Undercharge from FY93	.....	.....	99,604,360
	Fiscal Year 1997		
Diversion Control Work Hours	.....	443,458	.....
Drug Diversion Control Work Hours	.....	397,002	.....
Split-Funding Drug Portion	.....	90%	.....
Wage Inflation Factor Used for DEA Budget	.....	3.0%	.....
Non-wage Inflation Factor Used for DEA Budget	.....	3.1%	.....
Payroll/Benefits	35,503,736	31,009,637	4,494,099
Rent/Utilities	12,202,713	14,358,276	(2,155,563)
DCP Management	6,619,596	4,649,140	1,970,455
Information Systems	5,618,109	4,655,344	962,765
Staff Relocation	3,839,549	2,180,000	1,659,549
Field Operations	2,075,037	1,987,268	87,770
Staff Training	1,595,195	1,534,400	60,794
Investigative Tech	1,383,714	628,795	754,919
Facility Security	928,901	560,178	368,723
Health Services	281,816	146,499	135,317
Forensic Sciences	244,869	.....	244,869
Interest Penalties	125,045	.....	125,045
Administrative Law	70,422	242,833	(172,410)
Total	70,488,701	61,952,370	8,536,332
Field Split-Funding Mischarges (NonTravel)	.....	.....	133,277
Net Undercharge (Overcharge)	.....	.....	8,403,054
Cumulative Net DDCFA Undercharge from FY93	.....	.....	108,007,414
	Fiscal year 1998		
Diversion Control Work Hours	.....	501,861	.....
Drug Diversion Control Work Hours	.....	386,771	.....
Split-Funding Drug Portion	.....	77%	.....
Wage Inflation Factor Used for DEA Budget	.....	3.1%	.....
Non-wage Inflation Factor Used for DEA Budget	.....	2.8%	.....
Payroll/Benefits	35,661,034	36,426,300	(765,266)
Rent/Utilities	12,221,111	13,926,300	(1,705,189)
DCP Management	6,629,576	3,209,600	3,419,976
Information Systems	5,626,580	3,092,800	2,533,780
Staff Relocation	3,845,338	1,949,900	1,895,438
Field Operations	2,078,166	2,316,600	(238,434)
Staff Training	1,597,600	921,700	675,900
Investigative Tech	1,385,800	200,300	1,185,500
Facility Security	930,301	1,060,900	(130,599)
Health Services	282,241	118,600	163,641
Forensic Sciences	245,238	.....	245,238
Interest Penalties	125,233	.....	125,233
Administrative Law	70,529	95,800	(25,271)
Total	70,698,748	63,318,800	7,379,948
Field Split-Funding (Non Travel)	.....	.....	324,747
Net Undercharge (Overcharge)	.....	.....	7,055,201
Cumulative Net DDCFA Undercharge from FY93	.....	.....	115,062,615
	Fiscal year 1999		
Diversion Control Work Hours	.....	484,083	.....
Drug Diversion Control Work	.....	386,171	.....
Split-Funding Drug Portion	.....	80%	.....
Wage Inflation Factor Used for DEA Budget	.....	3.0%	.....
Non-wage Inflation Factor Used for DEA Budget	.....	2.1%	.....
Payroll/Benefits	36,673,884	38,484,803	(1,810,919)

Validated vs. actual DCP program charges to the DDCFA—Item	Validated	Obligated/incurred	Undercharge (overcharge)
Rent/Utilities	12,458,398	16,111,600	(3,653,202)
DCP Management	6,758,297	6,402,810	355,487
Information Systems	5,735,826	3,831,504	1,904,322
Staff Relocation	3,920,000	1,397,306	2,522,694
Field Operations	2,118,516	2,895,754	(777,238)
Staff Training	1,628,619	1,139,564	489,055
Investigative Tech	1,412,707	11,549	1,401,158
Facility Security	948,364	.....	948,364
Health Services	287,721	121,800	165,921
Forensic Sciences	250,000	249,861	139
Interest Penalties	127,665	149,517	(21,852)
Administrative Law	71,898	71,898	(0)
Total	72,391,895	70,867,965	1,523,930
Field Split-Funding Mischarges (NonTravel)	.....	.....	438,812
Net Undercharge (Overcharge)	.....	.....	1,085,118
Cumulative Net DDCFA Undercharge from FY93	.....	.....	116,147,733

The preceding tables of ''Validated vs. Actual Charges'' show three quantitative columns for each fiscal year from FY93 through FY99. The first quantitative column shows the ''Validated'' amount, or the dollars that should have been charged (in accordance with the aforementioned itemized review of all FY99 DDCFA charges) to the DDCFA. The second quantitative column shows the ''Obligated/Incurred'' amount, or the dollars which actually were charged to the DDCFA. (Note that, given the deficiencies of DEAAS, this column does not necessarily reflect the accurate subtotal of each item listed; but the column does show exactly what was spent bottom line level for the years in question.) The third column (the first column minus the second column) shows the ''Undercharge (Overcharge)'' amount or dollars that should have been charged over and above what was charged to the DDCFA. The rows of the preceding tables represent the DCP's major items, from Payroll/Benefits to Regulatory Law. Two item names which may not be immediately self-evident are ''Interest Penalties'' (which are required by law to accompany late vendor payments) and ''Administrative Law'' (which, as distinct from the DEA executive administration chief counsel's office, is the independent function required under 21 CFR 1316.41 *et seq.* whereby DEA hears and resolves disputes regarding potential registrant violations).

For each fiscal year, the ''Validated'' charges shown above are adjusted to reflect (a) the wage and non-wage inflation factors for that year (shown at the top of each table) and (b) the ratio of Drug Diversion Control Work Hours to Diversion Control Work Hours, or Split-Funding Drug Portion (also shown at the top of each table). Note that adjustment (b) is based on work hours stored in WRS (DEA's system for tracking the purpose (drug or chemical) of Diversion Investigator hours worked). Thus, in FY93, DEA charged the DDCFA $12 million for salaries and benefits but did not bill the DDCFA for DCP administrative law functions, even though the cost of such functions is provided for in DEA's 1996 **Federal Register** announcement. When all such undercharges (together with consideration that FY93 payroll should have been over $20 million) are tallied, the result is a DDCFA undercharge exceeding $28 million in FY93 alone, even before adding the non-programmatic $15 million surcharge for that year.

While DEA is confident that the DDCFA was not overcharged in total between FY93 and the present, the agency is still moving toward a more precise accounting standard. In FY01 DEA created a task force to review each obligation of DDCFA funds for which the total cost to be incurred is $500 or greater. This task force also works closely with each DDCFA-funded office to establish a clear understanding of proper procedure and documentation, and its efforts will enable DEA to publish a more accurate accounting of total DCP costs than has heretofore been possible.

In the meantime, the $15 million annual offsetting transfer by Congress into the DDCFA was discontinued as of FY98, and the remaining revenue (from fee payments) is proving inadequate to address legitimate programmatic needs. Even during the period when Congress was providing an offsetting $15 million transfer (FY93 through FY98), the DCP received a cumulative funding supplement of $90 million but amassed a surplus which never exceeded $70 million. With the discontinuation of this supplement in FY99, the DDCFA surplus has declined rapidly and will turn deficit before the end of FY03.

XII. Status of the Current Fee

This notice does not change the current fee schedule, and the fee schedule currently supporting the DCP remains the same as the schedule announced at the inception of the DDCFA in 1993:

Registrant class	Annual cost
Manufacturers	$875
Distributors, Importers/Exporters	438
Dispensers/Practitioners	70
Research, Narcotic Treatment Programs	70

XIII. Miscellaneous Issues

A. Registration Fee as User Fee

One commentor stated that registration fees imposed on domestic registrants should not fund ''international and other activities from which the registrant receives no greater benefit than the public at large.'' Yet DEA does not fund the costs of Diversion personnel stationed overseas through the DDCFA although certain overseas activities such as those relating to the import and export of controlled substances satisfy the requirements of 886a and 821 and are properly funded through the DDCFA. In addition, certain other activities from which ''the registrant receives no greater benefit than the public at large'' (*e.g.,* the review for potential scheduling of new substances) are allowable DDCFA burdens. The commentor referred to the standard applicable to user fees. User fees, or charges imposed pursuant to the Independent Offices Appropriations Act (IOAA), may be assessed only when a fee-funded service provides special benefits to an identifiable recipient

beyond those that accrue to the general public. OMB Circular A–25, July 15, 1993. The IOAA applies ''only when there is no independent statutory source for the charging of a fee or where a fee statute fails to define fee-setting criteria.'' *AMA* v. *Reno*, 857 F. Supp. at 84 (D.D.C. 1994). Congress established the DDCFA by passing the 1993 Appropriations Act with its collection and spending criteria established by prior law (21 U.S.C. 821 and 958(f)). This statute specified that ''[f]ees 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'' and funds from the DDCFA will be raised ''in accordance with estimates made in the budget request of the Attorney General.'' 21 U.S.C. 886a(3) and (4). Therefore, registration fees charged by DEA pursuant to the 1993 Appropriations Act are not user fees subject to the IOAA because the act constitutes an independent statutory source for charging the fee and it defines fee-setting criteria, i.e., to cover the full costs of the DCP. *AMA* v. *Reno,* 857 F. Supp. 80 (D.D.C. 1994).

Thus, the appropriate test for fee-funding DCP activities is not whether they convey a special benefit to registrants, but whether the fees are ''reasonable'' and ''relat[e] to the registration and control of the manufacture, distribution, and dispensing of controlled substances'' or relate to the registration of importers and exporters, and are set ''at a level that ensures the recovery of the full costs of operating the various aspects of [the diversion control] program.'' 21 U.S.C. 821, 958(f) and 886a(3).

B. Costs of the Components of the DCP

Two commentors contended that DEA should have provided an explanation of the costs of the DCP components. One commentor argued that registrants are entitled to an accurate accounting of the expenses for each of the program's components and demanded that DEA publish an explanation of its expenditures. Another commentor asked that DEA document the comparative costs of activities included within the DCP and subject the proposed rule to review by OMB.

DEA acknowledges both commentors' concerns and has referred all parties of such a mind to DEA's annual budget request to Congress. This document breaks down the components of each DEA program, including the DCP, and shows both prior-year actual data and future-year projections. For budget submissions relating to FY98 and earlier, DEA retains little, and sometimes no, supporting documentation and is therefore unable to provide some of the cost detail. Yet each DEA budget is based on itemized cost modules which were developed using the most recent (*i.e.,* best) accounting data available at the time. And the review of each DEA budget submission by both the Department of Justice and OMB includes a thorough examination and approval of the underlying cost modules and all other supporting documentation.

C. Fee Schedules Based on Prescribing Practices

One commentor expressed disappointment ''at DEA's refusal to establish a fair and equitable fee schedule based on actual prescribing or use records.'' DEA addressed this issue in the December 30, 1996 **Federal Register** notice, noting the various alternative fee structures that it had considered and the problems associated with each. 61 FR 68632. As DEA stated in that notice, establishing a fee based on the volume of drugs handled by individual practitioners would be impractical since there is no way of determining such drug volumes. In addition, the volume of drugs handled can change due to considerations of market, health care, and competition, thus requiring frequent changes in the fees and making program budgeting impractical. Whatever benefit such a plan may offer would be offset by significantly increased costs, which must be borne by registrants, to monitor the prescribing and dispensing practices of practitioners and determine the appropriate fee, based on the volume of drugs prescribed or dispensed.

XIV. Conclusion

Since FY93, DEA has attempted to manage the DCP in compliance with the following statutes: 21 U.S.C. 821 (which authorizes reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances); 21 U.S.C. 958(f) (which authorizes reasonable fees relating to the registration of importers and exporters of controlled substances); and 21 U.S.C. 886a(3) (which requires a fee structure sufficient to recover the full costs of operating the DCP). Such management has included: (a) the submission to Congress of a DCP budget based on historic actual costs, in accordance with both DOJ and OMB guidelines and (b) the internal promulgation of guidelines governing the uses of the DDCFA.

DEA has endeavored to avoid charging the DDCFA for three categories of DCP cost: (1) Costs associated with the regulation and monitoring of activity involving chemicals used in the illicit manufacture of controlled substance and the investigation of the diversion of these chemicals; (2) costs associated with the stationing of Diversion personnel overseas; and (3) portions of the DCP's indirect cost. Of these three cost categories, the first two (chemical and foreign diversion control activities) may be included in future Congressional requests for DDCFA funding authority. The third category includes DCP items which should have been (and, as of FY01, have indeed been) obligated against the DDCFA. Specifically, these items consist of health services and physical security requirements connected with DCP operation. Although DEA did not begin charging the DDCFA for such items until FY01, their funding out of the DDCFA is consistent with the provisions of 21 U.S.C. 821, 21 U.S.C. 886a, and all applicable public representations of DEA.

Yet DEA has also mischarged the DDCFA on numerous occasions. Some mischarges have been simple overcharges, as when DEA charged an excessive portion of its rent to the DDCFA. In such cases, DEA was correct to charge a portion of the total cost to the DDCFA; but the amount charged appears in retrospect to have been unreasonably high. Other mischarges fall into the ''inappropriate'' category. Such charges were explicitly proscribed either in 21 U.S.C. 886a or in DEA's subsequent public announcements.

DEA regrets being unable to itemize each instance of excessive and inappropriate charge to the DDCFA. DEA retains a full, certified public accounting record of all DDCFA charges, but the underlying documentation is largely unavailable and/or insufficient for the period in question. DEA's best effort to analyze this period in retrospect has nevertheless revealed two important insights: (1) DEA's FY93–FY98 accounting shortfall regarding the DDCFA resulted from a lack of familiarity with the funding mechanism and its managerial/accounting implications, and (2) the sum of all retrospectively identifiable potential mischarges *is exceeded* by the sum of all corresponding undercharges. DEA therefore acknowledges a failure in fully accounting for its early use of the DDCFA but concludes that such failure had no adverse impact on the registrants. With every year since the DDCFA's inception, DEA has improved its management of this vital source of

funds. DEA has made accounting errors, especially early on, when the very idea of a fee fund was new and unfamiliar to the law enforcement organization. But such errors have proven, upon subsequent inspection, both unintentional and financially offset by other errors. The accumulation of a DDCFA surplus, moreover, resulted not because DEA's cost projection and fee setting method was overly generous but because DEA's subsequent charges to the DDCFA did not include all actual DDCFA-billable costs of the DCP and because of an unexpected supplemental annual appropriation of $15 million by Congress. In light of such errors, DEA has intensified its efforts to transform the DDCFA from a management problem into the platform for a higher standard of managerial excellence. Beginning with FY99, DEA has retrospectively reviewed each office's use of the DDCFA to verify propriety. In FY01, DEA proceeded to validate (or reverse) each obligation of DDCFA funds totaling $500 or more. And in FY02, DEA will be validating both obligations and subsequent expenditures according to the highest standard of traceability. For these latest years, any auditor will be able to find a stand-alone document supporting every DDCFA-funded item costing $500 or more.

XV. Regulatory Analysis

Regulatory Flexibility Act

The 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 initially finalized on March 22, 1993 (58 FR 15272) was $50.00 per registrant. Further, the total annual impact of the fee increase for the entire registrant population was less than $50 million.

Since 1971, the Controlled Substances Act 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(f)). 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 regulations to implement the Controlled Substances Act which were finalized in 1971. The ratio of fees was: a distributor's fee is 50% of the manufacturer's fee and a dispenser's 16–20% of a distributor's fee.

In its December 30, 1996 **Federal Register** notice (61 FR 68624), DEA considered a number of alternate approaches to the fee schedule. Among these alternative were: establish a fee based on volume of drugs handled by individual registrants; establish a fee based upon DEA work hours expended per class of registrant; establish a different fee for various types of practitioner activities (*i.e.,* hospital, medical doctor, dentist, veterinarian, narcotic treatment program, teaching institution); and, charge for order forms (DEA 222) used to order Schedule I and II controlled substances. Each of these alternative approaches was rejected for a variety of reasons, including, but not limited to, the impracticability of the alternative, an inability on the part of DEA to determine controlled substance utilization by individual registrants, and an inability to adequately budget due to fluctuating registration fees which would be created under certain alternatives. Therefore, although various fee approaches have been considered in the past, none offered a feasible alternative to the present approach.

Executive Order 12866

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is a significant rulemaking action. Therefore, this action has been reviewed by the Office of Management and Budget. This document responds to the remand requirement of the United States Court of Appeals for the District of Columbia Circuit, and the notice and comments received subsequent to that remand requirement.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

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.

Paperwork Reduction Act

This rulemaking imposes no recordkeeping or reporting requirements on registrants. No information collection request is necessary.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and will 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 $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Dated: July 30, 2002.

John B. Brown III,

Deputy Administrator.

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