Exhibit A concerning the exhaustion of certain mediation or conciliation procedures made available by FSA prior to bringing an NFA arbitration proceeding; and provided further, that the firm must undertake to provide the customer with information concerning how to commence such procedures and documentation of the commencement of such procedures pursuant to the consent attached hereto as Exhibit A;

(g) Consents to refuse those customers resident in the U.S. that do not satisfy the criteria for being an Eligible Contract Participant, as defined in section 1a(12) of the Commodity Exchange Act, 7 U.S.C. 1a(12), the option of not segregating funds notwithstanding relevant provisions of the U.K. regulatory system;

(h) Consents to provide all customers resident in the U.S. no less stringent regulatory protection than U.K. customers under all relevant provisions of U.K. law; and

(i) Undertakes to comply with the applicable provisions of U.K. law and FSA rules and guidance that form the basis upon which this exemption from certain provisions of the Act and rules thereunder is granted.

As set forth in the Commission's September 11, 1997 Order delegating to NFA certain responsibilities, the written representations set forth in paragraph (2) shall be filed with NFA.[28] Each firm seeking relief hereunder has an ongoing obligation to notify NFA should there be a material change to any of the representations required in the firm's application for relief.

Any material changes or omissions in the facts and circumstances pursuant to which this Order is granted might require the Commission to reconsider its findings that the standards for relief set forth in Commission Rule 30.10 and, in particular, Appendix A thereof, have generally been satisfied. In addition, if experience demonstrates that the continued effectiveness of this Order in general, or with respect to a particular firm, would be contrary to the public interest, or other circumstances to not warrant continuation of the exemptive relief granted therein, the Commission may condition, modify, suspend, terminate, withhold as to a specific firm or otherwise restrict, the exemptive relief granted, as appropriate on its own motion.

■ Accordingly, 17 CFR part 30 is amended as follows:

[28] 62 FR 47792, 47793 (September 11, 1999). Among other duties, the Commission authorized NFA to receive requests for confirmation of Rule 30.10 relief on behalf of particular firms, to verify such firms' fitness and compliance with the conditions of the appropriate Rule 30.10 Order and to grant exemptive relief from registration to qualify firms.

PART 30—FOREIGN FUTURES AND OPTIONS TRANSACTIONS

■ 1. The authority citation for part 30 continues to read as follows:

Authority: 7 U.S.C. 1a, 2, 4, 6, 6c and 12a, unless otherwise noted.

■ 2. Appendix C to part 30 is amended by:

■ A. Removing the entries for:

Firms designated by the Securities and Investment Board;

Firms designated by the Association of Futures Brokers and Dealers;

Firms designated by the Securities Association; and

Firms designated by the Investment Management Regulatory Organization

■ B. Adding the following entry at the end of the appendix:

Appendix C—Foreign Petitioners Granted Relief From the Application of Certain of the Part 30 Rules Pursuant to § 30.10

* * * * *

Firms designated by the Financial Services Authority (''FSA'').

FR date and citation: October 10, 2003, [insert FR citation].

Issued in Washington, DC, on September 30, 2003.

Jean A. Webb,

Secretary of the Commission.

Note: The following Exhibit A will not appear in the Code of Federal Regulations.

Exhibit A—Form of Consent

In the event that a dispute arises between you, _____, and _____ with respect to transactions subject to Part 30 of the Commodity Futures Trading Commission's Rules, various forums may be available for resolving the dispute, including courts of competent jurisdiction in the United States and United Kingdom and arbitration programs made available both in the United States and United Kingdom.

In the event you wish to initiate an arbitration proceeding against the firm to resolve such dispute under the applicable rules of the National Futures Association (''NFA'') in the United States, you hereby consent that you will first commence conciliation in accordance with such procedures as may be made available by the relevant United Kingdom regulator, details of which are provided to you herewith. The outcome of such United Kingdom conciliation is non binding. You may subsequently accept this resolution, or you may proceed either to binding arbitration under the rules of the relevant United Kingdom regulator or to binding arbitration in the United States under the rules of NFA. If you accept the conciliated resolution or elect to proceed to arbitration, or to any other form of binding resolution, under the rules of the relevant United Kingdom regulator or foreign exchange, you will be precluded from subsequently initiating an arbitration proceeding at NFA.

You may initiate an NFA arbitration proceeding upon receipt of documentation from the relevant United Kingdom regulator:

(i) Evidencing completion of the conciliation process and reminding you of your right of access to NFA's arbitration proceeding, or

(ii) Representing that more than nine months have elapsed since you commenced the conciliation process and that such process is not yet complete and reminding you of your right of access to NFA's arbitration proceeding.

The documentation referred to above must be presented to NFA at the time you initiate the NFA arbitration proceeding. NFA will exercise its discretion not to accept your demand for arbitration in the absence of such documentation.

By signing this consent, you are not waiving any other rights to any other legal remedies available under law.

_____

Customer Signature

_____

Date

[FR Doc. 03–25298 Filed 10–9–03; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1301

[Docket No. DEA–232F]

RIN 1117–AA70

Controlled Substances Registration and Reregistration Application Fees

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This final rule establishes the fee schedule for DEA registration and reregistration fees relating to the registration and control of the manufacture, distribution and the dispensing of controlled substances. DEA is required to adequately recover necessary costs associated with the Diversion Control Program (DCP) as mandated by the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993.

EFFECTIVE DATE: December 1, 2003. The new fee schedule will be in effect for all new applications postmarked on or after December 1, 2003 and for all renewal applications postmarked on or after December 1, 2003.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537; Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

I. Introduction and Statutory Authority

The Drug Enforcement Administration (DEA) published a notice of proposed rulemaking in the **Federal Register** on February 18, 2003 (68 FR 7728) to adjust the registration and reregistration fees for controlled substances handlers. 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 and to the registration and control of regulated persons and of regulated transactions.'' Secondly, 21 U.S.C. 958(f) permits DEA to collect ''reasonable fees relating to the registration of importers and exporters of controlled substances or List I chemicals.''

Thirdly and importantly, the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993 (Pub. L. 102–395) requires that DEA collect fees to ensure the recovery of the *full costs* of operating the Diversion Control Program (DCP). Section 111(b)(3) of the act, codified at 21 U.S.C. 886a(3), requires that ''fees charged by the Drug Enforcement Administration under its Diversion Control Program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.'' Section 111(b)(1) of the act also requires that ''there shall be deposited as offsetting receipts into that account all fees collected by the Drug Enforcement Administration, in excess of $15,000,000, for the operation of its Diversion Control Program.''

Following an adjustment in registration fees in 1993, 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. After the district court issued its final order granting the government's motion for summary judgment and disposing of all claims, the AMA appealed. In the ensuing case, *AMA* v. *Reno*, the United States Court of Appeals for the District of Columbia Circuit found DEA's rulemaking to be inadequate and 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). In doing so, however, the court also confirmed the boundaries of the DCP that DEA can fund by registration fees (*AMA* v. *Reno*, 57 F.3d 1129, 1135 (D.C. Cir. 1995)). More specifically, the court found that the current statutory scheme requires DEA to set registration fees to recover the full costs of the DCP, while requiring DEA to charge ''reasonable'' fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and the registration and control of regulated persons and of regulated transactions.

DEA responded to the remand requirement through a notice in the **Federal Register** on December 30, 1996 (61 FR 68624), describing the fee-funded components and activities of the DCP with an explanation of how each satisfies the statutory requirements for fee-funding. A final rule was subsequently published on August 9, 2002 (67 FR 51988).

DEA, therefore, is bound by the above-referenced statutory requirements in setting fees that recover the full cost of the Diversion Control Program and its activities. DEA has developed its rulemaking according to these legislative mandates.

II. Comments Received

Following publication of the Notice of Proposed Rulemaking on February 18, 2003, DEA received 36 comments to the notice, objecting to the fee schedule contained in the proposed rule. Twenty-seven comments were received from physicians (5 comments) and veterinary (22 comments); two comments were received from pharmacists, and seven comments were received from national or state associations representing different registrant groups. Late comments were also sent by another national group after the close of the comment period. Its comments were already raised by other commenters and, therefore, are addressed accordingly in this final rule.

Most commenters objected to the proposed increase in registration and reregistration fees, most noting that the increase was ''too much'' despite the ten-year period since fees were last adjusted; one commenter wrote that he had no problem with the proposed fee increase for practitioners from $70 to $131. One commenter also raised concern that the proposed fees were based on estimated budgets for Fiscal Years 2004–2006 and that, because the fee schedule would extend only to Fiscal Year 2006, DEA could raise the fees again at that time. Several commenters inaccurately characterized the proposed registration fee as either a ''tax'' or as a ''user fee.''

Four commenters expressed concern about the programmatic and operational costs of the DCP that necessitated the proposed increase in fees. Commenters specifically addressed why the DCP budget authority has doubled since Fiscal Year 1994 and what activities, including what new initiatives, would be supported through registration fees.

Three commenters expressed concern about the potential effect of the proposed increase in fees on small businesses, particularly in the current economy.

Three comments were received regarding individual registrations. One commenter wrote that the ability of residents and hospital- and clinic-based physicians to use their employer's registration number instead of being required by DEA to maintain individual registrations causes confusion with pharmacies. Another commenter argued that veterinarians unfairly support a disproportionate share of DCP costs because veterinary clinics as free-standing hospitals must purchase separate DEA registrations unlike physicians and other practitioners affiliated with human hospitals that may work under the hospital's registration under certain circumstances. Comments also noted that a fee increase would encourage practices, especially large practices, to forego licensure of all practitioners in the practice. Similarly, two commenters requested that registration fees be calculated based on the volume of controlled substances used, as usage differs by type of registrant.

Four commenters expressed concern that Internet pharmaceutical companies selling veterinary products at discounted prices are undermining veterinarian revenue. Other areas addressed by commenters included eliminating the mandatory annual $15 million transfer to the U.S. Treasury; finding alternative sources for funding the Diversion Control Program such as fines to violators of controlled substances laws, fines to insurance companies and health care providers that use DEA registrations for identification purposes, ''taxes'' on Internet pharmacies, fees to large drug companies that ''have billions of dollars,'' and Congressional appropriations; and the provision of additional time beyond the 30 days following publication of the final rule for the new fees to go into effect.

Each of the points raised by commenters is addressed below.

III. Objections to Fee Increase

All but one of the commenters objected to the increase in registration and reregistration fees, many characterizing them as ''arbitrary'' and

''exorbitant.'' Multiple commenters noted that physicians and other practitioners have been experiencing declining reimbursements and increasing operating costs, malpractice insurance costs, and costs of complying with other Federal and State requirements combined with high medical school debt. Several commenters suggested that the fee be raised 1.6 percent consistent with the 2003 increase in Medicare reimbursements; others suggested a 3–4 percent annual increase or a flat $5–10 increase. One commenter questioned how the fee increase compares with the rate of inflation. One commenter alleged that DEA was ''arbitrarily'' raising fees, and several others commented that DEA had not provided adequate justification for the fee increase.

As described above, DEA's authority to charge registration fees to support the Diversion Control Program 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.

Thirdly, the 1993 Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act established the Drug Diversion Control Fee Account (DDCFA) and specifically mandated 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 (that is, not from fines, Congressional appropriations or other potential sources). 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).

Congress also mandated fulfillment of the requirements of the Appropriations 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).

Accordingly, while DEA recognizes the economic pressures facing practitioners such as declining Medicaid reimbursements and increasing operating, equipment, and insurance costs, the current statutory scheme 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 does not have the discretion to partially fund the DCP or to find alternative sources of funding for the program. Rather it is mandated by law to fund the DCP fully through registration fees.

DEA has not adjusted the registration and reregistration fees since March 22, 1993 when it published a final rule in the **Federal Register**, establishing registration fees for controlled substances registrants (58 FR 15272). (This fee schedule then went into effect for all registration applications postmarked on April 21, 1993 or later and all renewal applications with an expiration date of May 21, 1993 or later). 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. Following an appeal by the AMA, the United States Court of Appeals for the District of Columbia Circuit found DEA's rulemaking to be inadequate and 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 final rule published in the **Federal Register** on December 30, 1996 (61 FR 68624). DEA then published its Final Rule on the Drug Diversion Control Fee Account and Diversion Control Program funding, responding to comments and clarifying the activities to be funded as part of the DCP, on August 9, 2002 through publication in the **Federal Register** (67 FR 51988).

Over the period of ten years the costs of operating the Diversion Control Program (DCP) have increased, necessitating a review of fees and an increase in those fees that support the program as mandated by statute. Such increase in operating costs, detailed below, include a greater number of diversion investigators, increased investigation costs, additional diversion control efforts such as controlling diversion of licit controlled substances on the Internet, inflation, and increases in salaries and compensation for employees. In setting the fees, DEA is mandated to recover the ''*full costs*'' (emphasis added) of the DCP and does not have the discretion to adjust the fees according to Medicare reimbursements or inflation as suggested by some commenters. DEA is also mandated to charge ''reasonable'' fees. Because the fees do not represent a significant financial burden on registrants (see discussion below regarding the impact on small businesses), DEA has determined that the fees contained in this final rule are reasonable. The individual effect on registrants is minimal, representing from 0.21% to as little as 0.01% of average annual sales (or income) for those registrants qualifying as small businesses. For registrants that are large businesses with higher sales, the impact of the fee is even less.

IV. Fees as a Tax or User Fee

Several commenters inaccurately characterized the registration fee as a tax or user fee. One commenter expressed that the DCP is a program from which the general public benefits and from which physicians do not derive a benefit despite paying a fee. User fees are charges that may be assessed only when a fee-funded service provides special benefits to an identifiable recipient beyond those that accrue to the general public, pursuant to the Independent Offices Appropriations Act (IOAA) (OMB Circular A–25, July 15, 1993). Examples of such services include activities that: Enable the beneficiary to obtain more immediate or substantial gains or values than those that accrue to the general public (*e.g.*, receiving a patent, insurance, or guarantee provision, or a license to carry on a specific activity or business); provide business stability or contributes to public confidence in the business activity of the beneficiary (*e.g.*, insuring deposits in commercial banks); or that are performed at the request of or for the convenience of the recipient, and are beyond the services regularly received by other members of the same industry or group or by the general public (*e.g.*, receiving a passport, visa, airman's

certificate, or a Custom's inspection after regular duty hours).

However, 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). Accordingly, the controlled substances registration fees that are the subject of this rulemaking *do not constitute user fees* because other statutory authority (as described above) set specific criteria and funding guidelines. Moreover, in the 1993 Appropriations Act, 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).

However, with that said, registrants who pay the fees *do* receive special benefits not conveyed on the general public. Specifically by registering with the DEA, registrants are able to handle controlled substances, an immediate ''gain or value'' not provided to the general public. Because of the closed system of drug distribution and the diversion control activities of the DCP, there are some tangential public benefits as well, much in the same way that the system of driver's licenses (by which individual drivers receive a specific benefit not conveyed on the public at large) increases the general safety on public roads thus also conveying an ancillary public benefit.

Because Congress specified in the 1993 Appropriations Act (with collection and spending criteria established by prior law (21 U.S.C. 821 and 958(f)), 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 Drug Diversion Control Fee Account (DDCFA) to fund the DCP will be raised ''in accordance with estimates made in the budget request of the Attorney General'' (21 U.S.C. 886a(3) and (4)), the registration fees charged by DEA pursuant to this act are not user fees subject to the IOAA because the Appropriations Act and related statutory authorities constitute independent statutory sources for charging the fee and define 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). DEA has concluded that the fees meet both of these criteria.

V. Diversion Control Programmatic and Operational Costs

Several commenters wrote that DEA had not provided adequate justification for the fee raise with some requesting detailed descriptions of the costs and expenditures made by the DCP. Commenters questioned the programmatic and operational costs of the DCP and raised concern about the rising costs of DCP activities over the past ten years that necessitated the fee increase.

This section describes fee-fundable activities that constitute the DCP, the budget justification for the fee increase, and how the fees were calculated and addresses related comments regarding the operation of the DCP.

A. Fee-Fundable Activities

DEA's mission with respect to licit controlled pharmaceuticals is to prevent, detect and eliminate 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 Controlled Substances Act, established a closed system of controlled substance distribution encompassing manufacturers, distributors, pharmacies and practitioners; that is, within this closed system a controlled substance can be traced from the time it is manufactured to the time it is dispensed to the ultimate user. This system has proven effective in reducing the diversion of these substances from legitimate channels to the illicit market. 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 the oversight of the DCP. (The DCP also possesses similar chemical control responsibilities pursuant to the Chemical Diversion and Trafficking Act (CDTA) and subsequent legislation. The chemical diversion control program and/or its registration and reregistration fees are outside the domain of this rulemaking and therefore are not affected by this rulemaking.)

The plain language of the 1993 Appropriations Act requires DEA to set and collect registration fees to cover the full costs of operating the DCP. In its 1993 final rule publication setting new registration fees, 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 (see below), clandestine laboratory efforts, overseas staff (specifically diversion investigators assigned to foreign posts), DEA's Office of Chief Counsel or 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.*

At the time this initial rule was published on March 22, 1993, 21 U.S.C. 821 did not extend to chemical control activities (''regulated transactions''). Accordingly, there were no registration or fee requirements for handlers of List I chemicals, and chemical control activities were not included among those to be supported by controlled substances fees. Congress amended 21 U.S.C. 821 on December 17, 1993 to require reasonable fees relating to ''the registration and control of regulated persons and of regulated transactions.'' Domestic Chemical Diversion Control Act of 1993, 3(a), Pub. L. 103–200, 107 Stat. 2333. Despite this amendment, to date DEA's chemical control activities have continued to be supported by appropriated funds and *not* by the controlled substances fees through the Drug Diversion Control Fee Account (DDCFA). Again, DEA's chemical control activities are not the subject of this rulemaking.

In its December 1996 **Federal Register** notice, DEA further excluded from fee-funding those activities that incidentally support the DCP but are funded

elsewhere in the DEA Salaries Budget (and thus not fee-funded). Specific examples listed in the notice include ''support provided by the Attorneys in DEA's office of Chief Counsel Diversion Regulatory Section; certain laboratory service support; DEA Automated Data Processing Systems support (except the Automation of Reports and Consolidated Orders System (ARCOS) and the Controlled Substances Act (CSA) database); Office of Training staff; DEA Management and Administrative Support; Office of Congressional and Public Affairs; Intelligence Support and Diversion Investigators assigned overseas'' (61 FR 68631).

In its August 2002 Final Rule published in the **Federal Register**, DEA reviewed the history and statutory authority of fee-fundable activities in detail and further described what activities would be fee-funded via the DDCFA. These 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 relating to the registration and control of the manufacture, distribution and dispensing of controlled substances, and 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). Fee-fundable activities also include travel, rent, utilities, supplies, equipment and services associated with the above-listed activities (67 FR 51988).

Certain international activities also are supported through fee funds because they relate to the registration and control of the lawful manufacture, distribution and dispensing of controlled substances. 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 Controlled Substances Act'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 Controlled Substances Act 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 Controlled Substances Act 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 Controlled Substances Act 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.

Thus, 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. Among those international activities that are excluded from DDCFA funding are international chemical control activities.

Additional detail on specific international activities supported through fee-funds as part of the DCP is contained in the August 9, 2002 **Federal Register** notice (67 FR 51988).

While diversion control and registration activities are conducted by DEA's Office of Diversion Control, 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 those 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, for example seminars for industry on controlled substances (but not on staff; see below).

Not included among fee-fundable diversion control activities are several elements of DEA operations that, though not part of the DCP, incidentally support the activities of the DCP. To date these activities have been funded through Congressional appropriations rather than through fee funds. Examples of such elements include two sections within the Office of Chief Counsel that (a) litigate administrative actions related to DEA registrants and (b) provide legal support on regulatory policy matters; staff salaries and related staff expenses within a section of the Office of Training that is specifically dedicated to the DCP (note, certain eligible training activities are fee-funded as noted above); a portion of the Office of Forensic Sciences Special Testing Laboratory that supports authentic

sample analyses for licit drugs; and a portion of the budget for DEA's agency-wide computer network, ''Firebird'', related to the work of the DCP. As was discussed more fully in previous rulemakings regarding the use of controlled substances fee funds, while these elements incidentally support diversion control efforts, because their overall function is not primarily devoted to diversion control, they have been included elsewhere in the DEA budget and not as part of fee-fundable activities. In the absence of specific guidance in the 1993 Appropriations Act as to which activities were encompassed within the DCP and thus fee-fundable, DEA has followed the plain language of the act and used the budget categories that had historically been included in the DCP budget request of the Attorney General. As described in DEA's 1996 **Federal Register** notice, for the purposes of budget formulation and appropriation, DEA historically has identified only those resources (with their overhead costs) that were specifically devoted to diversion control efforts as part of the DCP in its annual budget submission to Congress. Other resources which support a broad range of DEA activities, including diversion control, therefore have been included in the budget formulation and appropriation process and not funded through fee funds (61 FR 68631). At this time these activities will continue to be funded through appropriated funds as DEA considers how to better comply with the applicable laws in the future.

B. Budget Justification for Fee Increase

Several commenters questioned the justification for the budget increase necessitating the raise in registration and reregistration fees. Since the fees were last raised in 1993, costs of operating the Diversion Control Program (DCP) have increased. As described above, fee-fundable activities of the DCP 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, certain international activities relating to the registration and control of the manufacture, distribution and dispensing of controlled substances, and attendant management, personnel, administrative and clerical oversight for the DCP. Fee-fundable activities also include travel, rent, utilities, supplies, equipment and services associated with the above-listed activities.

The costs of the DCP have increased due to both the rising costs of ''doing business'' over the past ten years as well as the implementation of a number of new initiatives and programs. One commenter raised concern that the increase in fees seemed to cover the increased costs of operating the DCP with less emphasis on new programs and activities. As summarized below, the increased costs of operating the DCP to date as well as the anticipated costs through Fiscal Year 2006 have included/include a number of new initiatives including: the creation of Tactical Diversion Squads in Fiscal Year 1997, responding to OxyContin® diversion, responding to Internet-based diversion, development of a system to permit electronic transmission of controlled substances prescriptions, development of controlled substances electronic order forms, upgrades to the Automation of Reports and Consolidated Orders System (ARCOS), significant improvements to registration customer/forms service, and increases in the number of diversion investigators.

In Fiscal Year 1994 the Budget Authority for the DCP was $57.1 million. The Budget Authority for Fiscal Year 2004, based on the President's Budget, is $ 118.6 million. The growth in the DCP has been driven by a number of factors some of which have been reflected in the DEA budget submissions such as the creation of Tactical Diversion Squads in Fiscal Year 1997. Other areas of DCP expansion include the costs of responding to the diversion of OxyContin® which involved opening 247 cases between October 1999 and March 2002, including 159 cases in Fiscal Year 2001 alone—a 270 percent increase from Fiscal Year 2000. These cases, for example, have led to 328 arrests.

DEA also has expended increased time and resources in responding to the diversion of licit controlled substances over the Internet, a concern of several commenters. DEA has opened a number of cases leading to arrests and convictions for illegal diversion over the Internet. In total the number of diversion arrests more than doubled in the five year period of Fiscal Year 1995 (444 arrests) to Fiscal Year 2000 (941 arrests). In Fiscal Year 2001 DEA made 871 diversion arrests. In Fiscal Year 2002 DEA made 714 arrests, and in the first six months of Fiscal Year 2003, DEA made 364 arrests.

The additional investigative and programmatic responsibilities to support investigations have required additional diversion investigators, headquarters staff and increased financial resources to support these staff and their efforts to prevent the diversion of licit controlled substances. Over the past ten years the costs of supporting personnel and the costs of simply ''doing business'' have increased as a result of inflation and general rises in costs. These increases affect staff salaries, benefits, as well as the cost of program-related travel, rent, utilities, supplies, equipment and services associated with diversion control activities. The increasing costs of personnel, activities and general operations— including new initiatives—are shown in the following table that outlines the budget authority for each year from Fiscal Year 1994 to Fiscal Year 2006 (estimated). Note these figures do not include the required $15 million transfer to the U.S. Treasury.

Fiscal year	Budget authority (millions)
FY94	$57.1
FY95	58.4
FY96	62.2
FY97	67.8
FY98	73.2
FY99	76.7
FY00	80.3
FY01	83.5
FY02	86.2
FY03	89
FY04	118.6
FY05 (est.)	139.4
FY06 (est.)	147

C. Use of Estimated Budget Authorities

For Fiscal Years 2005 and 2006 the above budget authority estimates were derived using the President's Budget for Fiscal Year 2004. One commenter expressed concern that DEA was using estimated budget figures in its calculations for the Fiscal Year 2004–2006 period. Use of estimated budgets for future years is a common practice in budgeting to forecast future expenditures and plan future budgets. Because the President's Budget Request for the upcoming fiscal year is typically submitted to Congress in the spring of the prior year with approval following that, if DEA were to wait and use ''actual'', Congressionally-enacted budgets on which to base the fee schedule as suggested by the commenter, significant delays would result in calculating the fees, resulting in potential shortfalls to the fee account which, by statute, must support all activities of the DCP. Importantly too, adjusting the registration and especially the reregistration fees each year would cause significant confusion among registrants as to the correct amount to pay, particularly as the adjustment often would be effective immediately in order to comply with the statute that fees support the ''full costs'' of the DCP. The

process also would result in increased fee calculation, fee collection, and related operating costs for the DCP which would translate to higher registration fees.

D. Calculation of Current Fee

The President's Fiscal Year 2004 budget was calculated using the Fiscal Year 2003 budget as a base and adjusting for inflation, salary increases and programmatic increases or enhancements. The Fiscal Year 2004 budget of $118,561,000 for the DCP was submitted by the President to Congress on February 3, 2003. The Fiscal Year 2004 budget authority of $118,561,000 (that does not include the $15 million transfer to the U.S. Treasury) accounts for increases in program costs due to inflation, increases in federal staff salaries, and additional funds to undertake a number of new initiatives to prevent, detect and eliminate the diversion of controlled substances while ensuring an adequate supply for legitimate medical and scientific purposes. Additional funds would support diversion investigation (93 positions), OxyContin® diversion control, and implementation of a system to detect Internet sites that may divert controlled substances and investigation of those sites, as warranted. Because the registration fees have not been raised since 1993, in recent years the DCP has not been operating with the ideal staffing level of diversion investigators due to budget constraints. The additional funds for OxyContin® and improved Internet diversion control will permit DEA to conduct additional and more complex investigations into the diversion of pharmaceutical controlled substances. Additional funds also would support forty positions and the development of systems to permit the electronic transmission of controlled substances orders and controlled substances prescriptions. These electronic alternatives will provide a similar or higher degree of security/integrity than current paper-based systems and will help DEA to meet its legal mandates under the Government Paperwork Elimination Act. Several commenters highly praised the electronic systems and the increased efficiencies afforded to industry. By increasing reliance on technological resources, the electronic systems also will help to control DCP costs in the future; two commenters raised the issue of streamlining DCP operations and controlling costs through greater reliance on technological resources. The total cost of program enhancements for Fiscal Year 2004 is $27,062,000. Including the mandatory transfer to Treasury of $15 million, the total amount required to be recovered for Fiscal Year 2004 is $133,561,000.

To calculate the anticipated President's Budget Request for Fiscal Year 2005, DEA used a baseline of the Fiscal Year 2004 President's Budget of $118,561,000 (described above) and adjusted the baseline figure for increases in program costs due to inflation (including such items as postage rate increases, increases in cost of employee health benefits, increases in GSA rent, etc.), and costs of federal staff pay increases. The anticipated President's Budget Request for Fiscal Year 2005 is $139,364,000. This figure, revised since the Notice of Proposed Rulemaking in February 2003 because of new guidance on inflationary figures and updated capital asset planning and budgetary information, includes costs to support systems to permit the electronic transmission of controlled substances prescriptions and electronic orders of Schedule I and II controlled substances (systems highly desired and praised by industry, including commenters to the proposed rule), the support and operation of DEA's Internet investigations, a major upgrade to the Automation of Reports and Consolidated Orders System (ARCOS), significant improvements to registration customer/forms service, and 39 additional positions related to these activities. Other funds accounted for include liaison, policy, regulatory, and analytical activities of the Diversion Control Program. Including the mandatory transfer to Treasury of $15 million, the total amount required to be recovered for Fiscal Year 2005 is $154,364,000.

The anticipated President's Budget Request for Fiscal Year 2006 of $147,028,000 was calculated using the same method. This figure also has been revised since the proposed rule based on updated budget figures and reflecting changes in inflationary growth guidance from the Department of Justice. DEA used the anticipated budget request for Fiscal Year 2005 and adjusted that figure for inflationary growth and increases in federal staff salaries, rent and other overhead costs. Including the mandatory transfer to Treasury of $15 million, the total amount anticipated to be required to be recovered for Fiscal Year 2006 is $162,028,000.

In calculating inflationary growth, DEA used inflation figures of 1.5 percent for Fiscal Year 2004, 1.5 percent for Fiscal Year 2005 and 1.6 percent for Fiscal Year 2006 and salary increase assumptions of 4.1 percent for Fiscal Year 2004 and 3.4 percent for both Fiscal Year 2005 and Fiscal Year 2006, based on the Fiscal Year 2005 Department of Justice Modular Cost Standards and the President's Economic Assumptions, respectively.

To calculate the fee schedule for Fiscal Year 2004–2006, DEA used the total amount necessary to collect for the Fiscal Year 2004–2006 period of $449,953,000 and, based on specific statistical calculations, then calculated the fee for each registrant category. To comply with the law that DEA recover the full costs of the DCP, DEA then developed the specific fee levels for each registrant category.

To calculate the fee for each registrant category, DEA first estimated the number of paying registrants for the Fiscal Year 2004–2006 period and then used this figure combined with the full amount required to be collected for this period to set the new fee rate. To calculate the number of paying registrants, DEA used logarithmic regression analysis to project the yearly registrant figures based on historical registrant data for the period of Fiscal Year 1994 through Fiscal Year 2001.

DEA then estimated the number of registrants for each registrant category since different registrant categories pay different fees. Because there were insufficient data for some activities to perform regression analysis, DEA used the percentage for each category using data from the corresponding cycle years in the past.

Finally, based on the analyses conducted, DEA developed the fees for each registrant category consistent with its current fee structure. In doing so, DEA opted to set the fee level for a three-year period (Fiscal Years 2004–2006) to avoid the heavy burden on registrants and the additional administrative expenses to DEA that resetting the fee each year would impose. Accordingly, the fee schedule (see below) developed reflects the total amount necessary to be collected for the full three-year period (Fiscal Years 2004–2006) divided by projected registrants and accounting for projected registrant growth by category for each fiscal year. Because different categories of registrants pay different amounts, DEA weighted the number of registrants in each category to ensure the appropriate reflection in the fee schedule. Because the registrant fees reflect the total amount necessary to be collected for the Fiscal Year 2004–2006 period, there is the possibility that DEA may accumulate additional funds beyond those necessary for actual program operations in the initial year (Fiscal Year 2004), but in the final year of the period (Fiscal Year 2006) fee collections are anticipated to fall short

of the amount necessary to cover expenditures in that year, so DEA will then draw down the previously collected surplus. The alternatives to this approach would be to reset the fee each year or to set a different fee for each fiscal year; both of these options would cause unnecessary confusion and would impose greater administrative burdens on DEA and registrants.

Because of the updated and slightly reduced budget figures for Fiscal Year 2005 and Fiscal Year 2006, it was necessary for DEA to recalculate the fee levels for each category of registrant. As a result, the resulting fee schedule reflects minor changes to the fee levels as indicated below. For most registrants, this change represents a reduction in fee from that included in the Notice of Proposed Rulemaking.

Registrant class	Annual cost
Manufacturers	$1,625
Distributors, Importers/Exporters	813
Dispensers/Practitioners**	130
Researchers, Narcotic Treatment Programs	130

** The three-year registration and reregistration fee for dispensers (including practitioners, hospitals/clinics, and retail pharmacies) and teaching institutions is $390.

This rulemaking supplants the fee structure proposed in the Notice of Proposed Rulemaking published in the **Federal Register** on February 18, 2003.

E. Other DCP Operational Issues

Several commenters questioned the efficiency of DCP operations as related to the rising cost of operating the program, with some raising the issue of streamlining DCP operations through enhanced use of technology, computer upgrades, and improved business practices to negate the need for a fee increase. The mission of the DCP is to prevent the diversion of licit controlled substances which is done in the most efficient and streamlined manner possible. This mission requires the outlay of funds to support diversion investigations and monitoring of the closed system that was created by the Controlled Substances Act to ensure that registrants maintain controls over their activities with controlled substances to prevent and detect their diversion.

DEA works diligently to achieve administrative efficiencies in all of its programs, including the Diversion Control Program. Through a scheduled, periodic review process, virtually all aspects of the DCP are inspected to detect any waste, fraud or abuse. All expenditures charged to the DDCFA also are reviewed and approved by an independent unit charged with this task. Moreover, each of DEA's annual budget requests to Congress, which contains all components of each DEA program, including the DCP, is available for public review. Each budget request is examined and approved by both the Department of Justice and the Office of Management and Budget. DEA will continue to review expenditures through Fiscal Year 2006 and will adjust the fee schedule as necessary again at that time as a result of budget reviews. In February 2003 DEA also established a separate unit, the Diversion Fee Account Validation Unit, to review, approve, and audit fee-funded expenditures.

DEA has undertaken several initiatives to streamline aspects of the DCP both for the DEA and for registrants. For example, DEA is currently developing a system to permit the electronic transmission of controlled substances prescriptions which will significantly increase the efficiency by which prescriptions are transmitted from prescriber to pharmacy. This system, however, will not reduce the review requirements of DEA employees that monitor the prescription process for controlled substances. DEA also is developing a system to permit the electronic transmission of controlled substances orders which, again, will increase efficiencies for industry. DEA is also pursuing upgrades to the Automation of Reports and Consolidated Orders System (ARCOS) and other technological improvements to its information management systems to increase internal efficiencies. In general, consistent with the performance objectives and goals outlined in its Strategic Plan, DEA is constantly monitoring its operations for areas that can be improved through better use of technology and streamlining of business practices.

One commenter also questioned the exclusion of specific goals and performance standards in the notice of proposed rulemaking. Specific performance goals are included in DEA's Strategic Plan and are therefore not duplicated in rulemaking notices. Moreover, in terms of performance measures, as mandated by the Government Performance and Results Act (GPRA) and the President's Management Agenda, DEA, like all other agencies and components, is required to provide a budget summary that incorporates performance information on a quarterly basis. That is, DEA already integrates budget and performance in order to evaluate the effectiveness of programs relative to long-term, measurable outcome goals.

More specifically, in response to GPRA and the President's Management Agenda, the DCP has restructured its budgetary reporting on the Drug Diversion Control Fee Account (DDCFA) to include performance measures that are consistent with DEA's Strategic Plan and reflect the effectiveness of programmatic activities funded by registrant fees. Among the objectives included in the DEA Strategic Plan is continued support to the registrant population through improved technology, including E-commerce and customer support, while maintaining cooperation, support, and assistance from the regulated industry. These efforts, funded through registration fees, will provide immediate benefits to the registrant population such as streamlined processing and improved access to information. They also will reduce the paperwork burden on small businesses; reduce forged or stolen prescriptions; improve authenticity verification of the prescribing or ordering party and reduce processing time; increase overall security; and improve DEA's data quality, agency efficiency and responsiveness in carrying out its mission.

VI. Effects on Small Businesses

As part of its notice of proposed rulemaking published on February 18, 2003, DEA noted that the rulemaking does not constitute a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. While the actual fee collections as part of the registration fee process (independent of this rulemaking) result in an annual effect on the economy of $100,000,000 or more, the net effect of the fee changes captured in this rulemaking on the economy will be less than $100,000,000 and will not result in a major increase in costs or prices or cause 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. Moreover, the individual effect on small business registrants is minimal ranging from $130 to $1,625 per year with the majority of affected registrants paying an annual fee of $130 (or $390 for three years). In categories of registrants qualifying as small businesses (see below), the fee represents less than 0.21% of average annual sales (or income) based on U.S. Census and Bureau of Labor Statistics data (latest available data from 1997). A breakdown of the effect of the fees on

these categories of registrants is provided below.

Based on an evaluation of U.S. Census data, a certain percentage of manufacturers, hospitals/clinics, and pharmacies, narcotic treatment programs and all practitioners that are registrants with the DEA are likely to be small, as defined by the Small Business Administration. All distributors, importers and exporters are likely to be large. All exporters are likely to be large as they usually are also distributors or manufacturers, and only large manufacturers are likely to be involved in exporting. Researchers, teaching institutions, and analytical labs are assumed to be associated with large institutions or government entities and therefore not qualifying as small businesses.

Manufacturers fall into one of two industry classifications: pharmaceutical preparation or medicinal and botanical manufacturing. Based on DEA data on registered manufacturers, DEA estimates that 381 of the 460 manufacturers registered with DEA qualify as small businesses (Small Business Administration definition of less than 750 employees). For manufacturers in the small business category of 20–49 employees, the fee of $1,625 represents less than 0.02% of the average annual sales of $9.7 million (U.S. Census figures).

There are 61,463 pharmacies registered with the DEA and eligible to handle controlled substances. According to the National Association of Chain Drug Stores (NACDS) and census data on mail order prescription firms, there were 35,428 chain pharmacies, mass merchant pharmacies, supermarket pharmacies, and mail order pharmacies in 2001 (latest data available). It is assumed that the remaining 26,035 DEA registrants are independent pharmacies and that these independent pharmacies are small businesses. The chain drug stores, mass merchant pharmacies, supermarket pharmacies, and mail order pharmacies are assumed to be large establishments. For pharmacies in the $250,000–$499,000 category of annual sales, a fee of $130 per year represents 0.05% of average annual sales. In this category, the mean value of annual sales is $429,853 according to the U.S. Census data of which the annual registration fee represents 0.03%.

There are 14,796 hospitals registered with DEA to handle controlled substances. U.S. Census data indicate there are 6,590 hospitals; thus the remaining 8,206 registrants are assumed to be clinics. Census data also indicate there are 4,434 large hospitals; therefore, assuming all hospitals are registered with the DEA, DEA estimates there are 2,156 small hospitals. There are 3,260 clinics that can be defined as large. Thus, assuming that all large clinics are registered with DEA, DEA assumes that the remaining 4,946 clinics that are DEA registrants are small. For hospitals in the small business category of $1 million–$2.5 million in annual revenue, the annual fee of $130 represents less than 0.01% of average annual revenues. For clinics and narcotic treatment programs with annual revenues of less than $100,000 the annual fee of $130 represents 0.13% of annual revenue. Or for entities with the mean annual revenue of $61,909 in this group, the fee represents 0.21% of annual revenue. There are 1,166 narcotic treatment programs registered with the DEA.

Finally, there are 1,038,000 practitioners registered with the DEA to handle controlled substances—the largest registrant category. Because practitioners may hold multiple registrations and because practitioners register for three-year cycles, this figure may double count some practitioners and, accordingly, represents a high estimate. The majority of registered practitioners are physicians, followed by dentists and veterinarians. As of May 2003, there are 736,449 physician registrants, 164,630 dentist registrants, 51,101 veterinarian registrants, 44,800 nurse practitioner registrants, and 24,077 physician assistant registrants. Other practitioner registrants include optometrists, nursing homes, animal shelters, ambulances, naturopaths, euthanasia technicians, certain pharmacists in the state of Washington, certain veterinarian technicians in the state of California, and doctors of oriental medicine.

For the three largest groups of registrants in this category, data from the Bureau of Labor Statistics (2001 survey data) indicate the average annual salary of physicians to be $110,020, of dentists to be $110,790 and of veterinarians to be $69,150. For practitioners with average annual salaries of less than $100,000 the annual fee of $130 represents 0.13% of annual revenue. Of the mean annual salary of practitioners in this category ($63,688 per U.S. Census data), the fee represents 0.20%. For physicians and dentists which account for 87% of practitioner registrants, the fee represents 0.12% of annual average salary.

In summary, while the changes in fee structure will affect a substantial number of individual entities that qualify as small businesses, the impact will be minimal when evaluated as a percentage of average annual sales, revenue or income. Consequently, this rule does not create a significant adverse effect on a substantial number of small entities. In addition, the rule is not a discretionary action but rather responds to a statutory mandate to fully fund the costs of the Diversion Control Program through registrant fees.

VII. Registration Fee

A. Effective Date of New Fee Structure

Based on the methodology described in section V–D of this rulemaking and current calculations, to recover the full costs of the DCP as required by law, DEA plans to incrementally raise the fees in accordance the fee structure summarized in Section V. This fee structure replaces the fee structure proposed in the February 18, 2003 Notice of Proposed Rulemaking.

This fee schedule will go into effect on December 1, 2003. To be as clear as possible about the effective date and to ease processing, this effective date represents the first day of the month following the mandatory 30 days after the publication of the final rule in the **Federal Register**. The new fee schedule will be in effect for all new registration applications postmarked on or after December 1, 2003 and all reregistration applications postmarked on or after December 1, 2003. Registration or reregistration applications postmarked on or after this date must, therefore, include the new fee payment.

Because DEA is required by statute to recover through fees the ''full costs'' of the DCP, DEA will continue to monitor the costs and expenditures of the DCP and will revise the fee structure as necessary. DEA does not expect to revise the fee structure again until Fiscal Year 2006 (to be effective Fiscal Year 2007); however, DEA cannot anticipate events or other catalysts that may necessitate major diversion control initiatives by the DEA in future years.

B. Individual Registrations

Several comments were received relating to the use of individual registrations for practitioners as opposed to clinics or medical facilities. One pharmacist commenter objected to the ability of residents and hospital- and clinic-based physicians to use their employer's registration number instead of being required by DEA to maintain individual registrations. The commenter noted that use of an employer's number leads to confusion among pharmacists when the computer, cross-checking the number against the practitioner's name, indicates that they do not match. The commenter argued that the ability to use employer's registration numbers is

unfair to those who must pay individual registration fees and suggested that before registration fees are increased that DEA require all prescribers of controlled substances to be individually registered. Two commenters noted that it is expensive to license multiple practitioners in a practice and that a fee increase would encourage practitioners to forego licensure of all practitioners especially in large practices. One also noted that it would be beneficial if practitioners could work under an umbrella license for the whole clinic.

The Controlled Substances Act requires that every person who manufactures, distributes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance obtain an annual registration. 21 U.S.C. 822(a)(1) and 822(a)(2). However, the Controlled Substances Act also provides for certain exceptions, including ''an agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.'' 21 U.S.C. 822(c)(1).

More specifically, ''an individual practitioner who is an agent or employee of another practitioner (other than a mid-level practitioner) registered to dispense controlled substances'' may be exempted from securing his or her own registration but may ''when acting in the normal course of business or employment, administer or dispense (other than by issuance of prescription) controlled substances if and to the extent that such individual practitioner is authorized or permitted to do so by the jurisdiction in which he or she practices, under the registration of the employer or principal practitioner in lieu of being registered him/herself.'' 21 CFR 1301.22. That is, within a group practice, for example, one DEA-registered physician may take the responsibility for ordering a stock of controlled substances from which other physicians in the practice could dispense. However, only the DEA-registered physician would be authorized to issue prescriptions for controlled substances. That is, prescriptions written under a particular DEA number may *only* be written by the physician possessing that registration number.

Additionally, an individual practitioner who is an agent or employee of a hospital or other institution also may administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself (much like a pharmacist operates under the pharmacy's DEA registration). However, such registration is permissible only if: (1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice; (2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing; (3) The hospital or other institution by which he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction; (4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution; (5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized; and (6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner (21 CFR 1301.22). Other registrants would include pharmacies wishing to verify the identity and authority of individual practitioners to prescribe controlled substances. Note, state laws differ with regard to clinic registration and the use of ''umbrella'' registration numbers for employees of such clinics.

A separate registration is required for each principal place of business or professional practice at one general physical location where controlled substances are manufactured, distributed, imported, exported, or dispensed by a person (21 U.S.C. 822(e)).

C. Allocation of Fee Based on Usage

Four commenters raised issues related to allocation of the registration fee according to usage of controlled substances. Three commenters wrote that, because veterinarians use a limited amount of controlled substances, they should not be expected to be equal partners with other practitioners in funding the DCP. Another commenter stated that, as staff write only 12 controlled substances prescriptions per year, the fee increase would dramatically increase the cost of each of these prescriptions per unit.

The Controlled Substances Act mandates that ''every person'' who manufactures, distributes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance obtain an annual registration (21 U.S.C. 822(a)(1) and 822(a)(2)). This statute mandates such registration irrespective of the extent such persons handle controlled substances. Accordingly, DEA may not alter the fee structure to account for the extent to which registrants handle controlled substances.

VIII. Enforcement of Controlled Substances Act

Several commenters expressed concern that Internet pharmaceutical companies selling veterinary products at discounted prices are undermining veterinarian revenue, with one commenter alleging that Internet and catalog pharmacies sell prescription medications directly to consumers without a prescription from a veterinarian. Three commenters wrote that it is ''not in my profession['s] best interest to pay such exuberant fees * * * while the internet companies undercut the veterinarian.'' Another commenter stated that Internet pharmacies selling controlled substances to consumers without a prescription should be fined severely.

The mission of the Diversion Control Program, as outlined above, is to prevent the diversion of licit controlled substances in conformance with the Controlled Substances Act. All manufacturers, distributors and dispensers of controlled substances are required to obtain a registration with the DEA (21 U.S.C. 822(a)(1) and 822(a)(2)). This requirement includes Internet-based pharmaceutical companies that dispense controlled substances. No dispenser, including Internet-based companies, is permitted to dispense controlled substances without the prescription of a registered physician or other appropriate practitioner. DEA investigates and prosecutes violations of the Controlled Substances Act, including the dispensing of controlled substances without a legal prescription from an authorized and registered practitioner.

Four commenters, three from the same institution, objected to the ability of Internet pharmaceutical companies to sell veterinary products directly to consumers thus affecting sales directly through the veterinary clinics. Commenters expressed concern that clients were purchasing veterinary pharmaceutical supplies through the Internet companies when veterinarians ''must write prescriptions,'' thus eroding pharmaceutical sales by veterinarians and undermining the

veterinarian-client relationship. One commenter also alleged that Internet pharmacies are selling pharmaceuticals without prescriptions from authorized practitioners. Three commenters from the same institution suggested that the DEA tax the Internet drug companies to fund the DCP and leave the current controlled substance handlers fees at the same level.

DEA assures the commenters that any violations of the Controlled Substances Act, including the unauthorized dispensing of controlled substances, are subject to prosecution to the fullest extent of the law. Over the past several years, DEA has undertaken a number of concerted initiatives to control and prevent the diversion of licit controlled substances over the Internet, with the number of diversion arrests more than doubling between Fiscal Year 1995 and Fiscal Year 2000. DEA's diversion control actions do not cover legal commerce transactions such as the legal dispensing of controlled substances through Internet sites or the sale of non-controlled substances (such as other veterinary products) which is outside the purview of the DEA. DEA also notes that Internet pharmaceutical companies, like other dispensers of controlled substances, must register with the DEA in order to handle controlled substances and as such already pay a registration fee like other registered dispensers.

IX. Miscellaneous Issues

A. Mandatory $15 Million Transfer to U.S. Treasury

One commenter objected to registrant fees supporting the mandatory transfer of $15 million to the U.S. Treasury, noting that this burden should not be placed on registrants and requesting that DEA petition Congress to appropriate the required $15 million, so that all fee funds are used to support DCP activities.

DEA is required by the Appropriations Act of 1993 to transfer the first $15 million of fee revenue to the General Fund of the Treasury each year (21 U.S.C. 886a(1)). Calculation of the fees, therefore, must account for this mandated transfer. That is, DEA has no discretion in that matter, and the fees collected by DEA must represent the total amount necessary to ''fully fund'' the DCP by law *plus* an additional $15 million. For the period of Fiscal Year 1993 through Fiscal Year 1998, Congress appropriated an additional $15 million to offset the transfer requirement (a total infusion to the DDCFA of $90 million). However, beginning in Fiscal Year 1999, Congress discontinued this additional appropriation, and the additional $15 million became an additional net expense to the DCP at that time. Congress has not agreed to appropriate the additional $15 million towards the mandatory transfer since that time.

B. Alternative Funding Sources for DCP

Seven commenters raised the issue of finding alternative sources of funding for the DCP to replace the registration fees, including congressional funding and collecting fees from other non-registrant entities (*e.g.*, health insurance companies). As has been detailed above, DEA's authority to charge registration fees to support the DCP derives from three statutory provisions. Of these provisions, the Appropriations Act of 1993 specifically mandates that DEA collect through fees an amount sufficient to ensure the recovery of the ''*full costs*'' (emphasis added) of the DCP (21 U.S.C. 886(a)(3)). That is, DEA is required by statute to fully fund DCP expenses *through registration fees.* For the period of Fiscal Year 1993 through Fiscal Year 1998, Congress appropriated an additional $15 million to the DDCFA to offset the annual mandatory $15 million transfer to the U.S. Treasury described in the previous section. Such appropriations were discontinued beginning in Fiscal Year 1999, and the DCP remains entirely funded through registration fees.

C. Clarification of Fee Amount

Certain registrants pay a single fee for a three-year registration period. Such registrants include dispensers (including practitioners, hospitals/clinics, and retail pharmacies) and teaching institutions. Since publication of the February 18, 2003 notice of proposed rulemaking, DEA has finalized a number of other regulatory actions which affect the CFR sections amended by this final rule. On June 24, 2003, DEA finalized regulations regarding the use of central fill pharmacies to fill controlled substances prescriptions on behalf of retail pharmacies (68 FR 37405). This final rule amended 21 CFR 1301.13(e)(1)(iii) to add ''central fill pharmacy'' as a business activity under dispensing (effective July 24, 2003). Consequently, central fill pharmacies are subject to the same fee as all other dispensers, including pharmacies and teaching institutions. Effective with this rulemaking, the registration/reregistration fee for dispensers, including central fill pharmacies, and teaching institutions is $390 for a three-year period.

Because other categories of registrants secure a registration on an annual basis, much of the discussion in this rulemaking addressed the value of annual registration. In such discussions, DEA often referred to an annual value of $130 which is one-third of $390.

The annual registration and reregistration fee for researchers, narcotic treatment programs (including compounders), effective with this rulemaking, is $130. These categories of registrants obtain a registration and pay the associated fee on an annual basis.

This rulemaking also establishes new annual registration/reregistration fee amounts for manufacturers of $1,625, for distributors of $813, for importers of $813, and for exporters of $813. Reverse distributors are subject to the same annual fee of $813 as distributors as a result of an interim rule published by DEA on July 11, 2003 defining ''reverse distributor'' and establishing reverse distributor as a new category of registration. (68 FR 41222). This interim rule amended 21 CFR 1301.13 by redesignating paragraph (e)(1)(iii) which contained dispensing activities as paragraph (e)(1)(iv) and adding a new paragraph (e)(1)(iii) ''reverse distributors''. In its February 18, 2003 **Federal Register** notice proposing new registration and reregistration application fees, DEA inadvertently included language in the regulatory text regarding fees to be assessed to reverse distributors (referred to as ''disposers'' in the proposed rulemaking), although regulations establishing reverse distributor as a new registration category had not yet been established. As regulations establishing reverse distributors as a new category of registration have now been established, the fees included in this final rule are now accurate and apply as delineated above to this category of registrants. In its February 18, 2003 proposed rule DEA also inadvertently assigned an incorrect annual fee of $131 to disposers. As described above, reverse distributors or disposers, like other distributors, are subject to an annual fee of $813.

Regulatory Analyses

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. DEA recognizes that this regulation will have a financial effect on a substantial number of registrants with the increase in fees; however, DEA believes that, based on the length of time between fee

adjustment, the program growth and cost increases, and the overall size of the increase in fees, the change in fees is not significant, and the economic impact of the fees on individual registrants is not significant. The fee represents from 0.21% to as little as 0.01% of average annual sales (or income) for registrants qualifying as small businesses. Moreover, the fees have not been changed in ten years, and DEA is legally mandated to collect fees to cover the full costs of the Diversion Control Program. The appropriations process was used to determine the budget on which the fees are based. The increase in fees after ten years covers both inflation and enhancements to address additional responsibilities assumed by the Diversion Control Program.

In considering options for collecting the full costs of the Diversion Control Program as mandated by law (21 U.S.C. 886a(3)), DEA considered several alternatives to the approach used in this regulation. One alternative would be to reset the fee each year for each category of registrant according to the budget authority. Another alternative would be to set a different fee for each fiscal year. Commenters suggested both of these approaches. DEA determined that both of these options would cause unnecessary confusion with fee changes each year and would impose greater administrative and financial burdens on DEA and registrants than the approach used in this regulation. Moreover, resetting the fee each year, for example, would unfairly affect practitioners differently depending on their registration renewal year; some practitioners would pay more than others. Using actual budget authority figures instead of estimated budget authority figures, as used in this rulemaking, would not give registrants sufficient notice as to fee changes. Doing so also could result in DEA not collecting the full costs of the DCP as required by law in a timely manner. In calculating the fees contained in this rule, DEA used estimated budget authorities based on expected inflation and program enhancements as is standard government practice for forecasting future budgets.

Executive Order 12866

The Deputy Assistant Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). This action has been reviewed by the Office of Management and Budget.

Executive Order 12988

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

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate of $100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. While it will affect the private sector in excess of $100,000,000 per year, the effect on individual entities is minimal. The majority of the affected entities will pay $130 per year (or $390 for a three-year registration period). Moreover, this rule is promulgated in compliance with Congressional mandate that the full cost of operating the DCP be collected through registrant fees as stipulated in the 1993 Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act (Pub. L. 102–395) and codified in 21 U.S.C. 886a(3). Detailed estimates and analyses, including specific fee amounts for individual registrants, are included in the preamble text.

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. The net effect of the fee changes captured in this rulemaking on the economy will be less than $100,000,000 and will not result in a major increase in costs or prices or cause 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. This rule is not a discretionary action but rather responds to the Congressional mandate that the full operating costs of the DCP be collected through registrant fees as described above. The individual effect on small business registrants is minimal ranging from $130 to $1,625 per year with the majority of affected registrants paying an annual fee of $130 (or $390 for three years). As discussed in detail in the preamble, the fee represents less than 0.21% of annual sales or income for the smallest categories of registrants qualifying as small businesses according to Small Business Administration definitions.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

■ For the reasons set out above, 21 CFR part 1301 is amended as follows:

PART 1301—[AMENDED]

■ 1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

■ 2. Section 1301.13 is amended by revising paragraph (e)(1) to read as follows:

§ 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.

* * * * *

(e) * * *

(1)

Business activity	Controlled substances	DEA application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(i) Manufacturing	Schedules I–V	New—225 Renewal—225a	1,625 1,625	1	Schedules I–V: May distribute that substance or class for which registration was issued; may not distribute or dispose any substance or class for which not registered. Schedules II–V: except a person registered to dispose of any controlled substance may conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a mfg. Was issued.
(ii) Distributing	Schedules I–V	New—225 Renewal—225a	813 813	1	
(iii) Reverse distributing.	Schedules I–V	New—225 Renewal 225a	813 813	1	
(iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Central Fill Pharmacy, Teaching Institution).	Schedules II–V	New—224 Renewal—224a	390 390	3	May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II–V in a proportion not exceeding 20% of the complete solution, compound or mixture. A retail pharmacy may perform central fill pharmacy activities.
(v) Research	Schedule I	New—225 Renewal—225a	130 130	1	A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in Section 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.
(vi) Research	Schedules II–V	New—225 Renewal—225a	130 130	1	May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purposes of dosage form development; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities or research with such substances, and to persons exempted from registration pursuant to Section 1301.24; and conduct instructional activities with controlled substances.
(vii) Narcotic Treatment Program (including compounder).	Narcotic Drugs in Schedules II–V.	New—363 Renewal 363a	130 130	1	
(viii) Importing	Schedules I–V	New—225 Renewal—225a	813 813	1	May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.
(ix) Exporting	Schedules I–V	New—225 Renewal—225a	813 813	1	

Business activity	Controlled substances	DEA application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(x) Chemical Analysis	Schedules I–V	New—225 ..... Renewal—225a	130 130	1	May manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to section 1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws related to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.

* * * * *

Dated: October 7, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 03–25817 Filed 10–9–03; 8:45 am]

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DEPARTMENT OF THE TREASURY

Alcohol and Tobacco Tax and Trade Bureau

27 CFR Part 73

[T.D. TTB–5; Notice No. 5]

RIN 1513–AA61

Electronic Signatures; Electronic Submission of Forms (2000R–458P)

AGENCY: Alcohol and Tobacco Tax and Trade Bureau (TTB), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: The Alcohol and Tobacco Tax and Trade Bureau (TTB) amends its regulations to permit industry members to use electronic technology to reduce the need for and storage of paper documents. In order to accomplish our goals, we are adding a new part 73 that will allow you to use electronic, rather than handwritten, signatures to sign certain forms, and to submit certain forms to TTB electronically through a TTB-approved electronic document receiving system.

EFFECTIVE DATE: October 10, 2003.

FOR FURTHER INFORMATION CONTACT: Lisa M. Gesser, Regulations and Procedures Division, Alcohol and Tobacco Tax and Trade Bureau, P.O. Box 128, Morganza, MD 20660; telephone 301–290–1460.

SUPPLEMENTARY INFORMATION:

What Will This Final Rule Do?

This final rule amends the regulations to allow you to:

- Use electronic signatures to sign certain forms you submit to us instead of using traditional handwritten signatures; and
- Submit certain forms to TTB electronically through an electronic document receiving system that we approve.

Why Does TTB Want To Allow You To Submit Certain Forms Electronically?

We believe that by giving you the option to submit certain forms electronically, instead of requiring paper documents, we can:

- Reduce the costs associated with submitting and maintaining large volumes of paper documents;
- Improve the quality and accessibility of data;
- Allow for the faster review and approval of a variety of documents; and
- Allow for a variety of our documents to be available around the clock.

What Is TTB's Authority To Implement These Regulations?

Our authority to implement these regulations comes from:

(1) *Government Paperwork Elimination Act (GPEA).* GPEA was signed into law on October 21, 1998. GPEA directs Federal agencies to provide for the optional use and acceptance of electronic documents and signatures, and electronic recordkeeping, where practical, by October 2003. (*See* Secs. 1702–1710 of Pub. L. 105–277.)

(2) *Internal Revenue Code of 1986 (26 U.S.C.)* The Internal Revenue Code of 1986 authorizes the Secretary of the Treasury to, by regulation, encourage electronic filing, address what constitutes a timely filed electronic document, and develop procedures for the acceptance of signatures in digital or other electronic form. (*See* 26 U.S.C. 6011, 6061, and 7502.)

(3) *Electronic Signatures in Global and National Commerce Act of 2000 (E–SIGN).* E–SIGN provides that no contract, signature, or record relating to a transaction shall be denied legal effect solely because it is in electronic form, nor may a document be denied legal effect solely because an electronic signature or record was used in its formation. E–SIGN applies to documents that are created in a commercial, consumer, or business transaction. It does not cover transactions that are uniquely governmental such as a compliance report. (*See* Public Law 106–229.)

(4) *Office of Management and Budget Circular A–130.* OMB's Circular A–130 requires agencies to employ electronic information collection techniques where such means will reduce the burden on the public, increase efficiency, reduce costs, and help provide better service. (*See* Circular A–130, Para. 8.a.1(k).)

How Does TTB Plan on Implementing Electronic Filing?

We are creating a new part 73 in title 27 CFR, chapter I, entitled ''Electronic Signatures; Electronic Submission of Forms.'' Part 73 explains our overall policy regarding electronic signatures and the electronic submission of certain forms to TTB.

Electronic Signatures

Upon the effective date of this final rule, we recognize electronic signatures executed to certain electronic forms as the full equivalent of, and having the same legal effect as, traditional handwritten signatures executed on paper. We will notify you, by publishing a general notice in the **Federal Register** and on our Web site (*http://*