Installation of Cockpit Placard for RPM Restriction

(f) Within 10 hours time-in-service (TIS) after the effective date of this AD, install a placard on the pilot's console in front of the pilot, that states, in ¼ inch-high or higher characters, ''Continuous propeller operation between 2,350 rpm and 2,450 rpm at 24 inches Hg and higher manifold pressure is prohibited''.

Propellers With Unknown Total Hours TIS, or 10,000 or More Hours Total TIS on the Effective Date of This AD

(g) For propellers that the total TIS is unknown, or that have 10,000 or more hours total TIS on the effective date of this AD, remove the propeller from service within 50 hours TIS after the effective date of this AD.

Propellers With Fewer Than 10,000 Hours Total TIS on the Effective Date of This AD

(h) For propellers with fewer than 10,000 total hours TIS on the effective date of this AD, do the following:

(1) Perform an inspection of the propeller blades and repair if necessary, within 100 hours after the effective date of this AD, using paragraphs 2.B. through 2.F. of Accomplishment Instructions of McCauley ASB No. ASB248, dated January 17, 2005.

(2) At the next propeller overhaul or next major propeller disassembly, life-limit-stamp the letter ''L'' on the propeller hub and blades, using paragraph 3 of Accomplishment Instructions of McCauley Propeller Systems Alert Service Bulletin (ASB) No. ASB248, dated January 17, 2005.

(3) Thereafter, within every 100 hours TIS or at next annual inspection, whichever occurs first, inspect, and repair if necessary, the propeller blades using paragraphs 2.B. through 2.F. of Accomplishment Instructions of McCauley ASB No. ASB248, dated January 17, 2005.

(4) Remove the propeller from service at or before reaching the life limit of 10,000 hours total TIS.

Alternative Methods of Compliance

(i) The Manager, Chicago Aircraft Certification Office, has the authority to approve alternative methods of compliance for this AD if requested using the procedures found in 14 CFR 39.19.

Related Information

(j) None.

Issued in Burlington, Massachusetts, on November 7, 2005.

Peter A. White,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

[FR Doc. 05–22712 Filed 11–15–05; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Parts 47 and 159

[Docket No. RM06–3–000]

Prohibition of Energy Market Manipulation

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: The Federal Energy Regulatory Commission published in the **Federal Register** of October 27, 2005, a document proposing to add a part 47 and part 159 to Title 18 of the CFR. Two clauses in the proposed regulatory language for parts 47 and 159 were inadvertently incorporated into subparagraph text, but were intended to start a new line in the text since they are to modify all three subparagraphs. As such formatting is inconsistent with **Federal Register** requirements, these modifying clauses will be moved to the beginning of the paragraph.

FOR FURTHER INFORMATION CONTACT: Frank Karabetsos, Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426. (202) 502–88133.

SUPPLEMENTARY INFORMATION: The Federal Energy Regulatory Commission published in the **Federal Register** of October 27, 2005 (70 FR 61930), a document adding a part 47 under subchapter B (Regulations under the Federal Power Act) and a part 159 (Regulations under the Natural Gas Act) to Title 18 of the CFR. The proposed regulatory text for the two parts failed to set out certain sentences as modifying clauses. This document corrects that error.

Correction

In proposed rule FR Doc. 05–21423, beginning on page 61930 in the issue of October 27, 2005, make the following corrections:

§ 47.1 [Corrected]

1. On page 61933, in column 2, correct § 47.1(a) to read as follows:

§ 47.1 Prohibition of energy market manipulation.

(a) It shall be unlawful for any entity, directly or indirectly, in connection with the purchase or sale of electric energy or the purchase or sale of transmission services subject to the jurisdiction of the Commission,

(1) To use or employ any device, scheme, or artifice to defraud,

(2) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(3) To engage in any act, practice, or course of business that operates or would operate as a fraud or deceit upon any person.

* * * * *

§ 159.1 [Corrected]

2. On page 61933, in column 3, correct § 159.1(a) to read as follows:

§ 159.1 Prohibition of energy market manipulation.

(a) It shall be unlawful for any entity, directly or indirectly, in connection with the purchase or sale of natural gas or the purchase or sale of transportation services subject to the jurisdiction of the Commission,

(1) To use or employ any device, scheme, or artifice to defraud,

(2) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(3) To engage in any act, practice, or course of business that operates or would operate as a fraud or deceit upon any person.

* * * * *

Dated: November 10, 2005.

Magalie R. Salas,

Secretary.

[FR Doc. 05–22755 Filed 11–15–05; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1301 and 1309

[Docket No. DEA–266P]

RIN 1117–AA96

Controlled Substances and List I Chemical Registration and Reregistration Application Fees

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

ACTION: Notice of proposed rulemaking.

SUMMARY: DEA is proposing to adjust the fee schedule for DEA registration and reregistration application fees relating to the registration and control of the manufacture, distribution and

dispensing of controlled substances and listed chemicals to appropriately reflect all costs associated with its Diversion Control Program as mandated by 21 U.S.C. 822. Specifically, DEA proposes to revise the fee schedule for controlled substances and List I chemical handlers so that all manufacturers, distributors, importers, exporters, and dispensers of controlled substances and of List I chemicals pay an annual fee, by registrant category, irrespective of whether they handle controlled substances or List I chemicals. This action responds to recent amendments to the Diversion Control Fee Account provisions in the Controlled Substances Act (CSA) and will bring DEA's fee collections into line with the new requirements.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before January 17, 2006.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–266'' on all written and electronic correspondence. Written comments sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative/ODL. Written comments sent via express mail should be sent to DEA Headquarters, Attention: DEA **Federal Register** Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be sent directly to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http: //www.regulations.gov* Web site. DEA will accept attachments to electronic comments in Microsoft Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed above.

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 Background

The Controlled Substances Act (CSA) requires that all manufacturers, distributors, dispensers, importers and exporters of controlled substances and List I chemicals obtain an annual registration with DEA (21 U.S.C. 822 and 958(f)). In addition, the CSA, as codified in 21 U.S.C. 821, authorizes the Attorney General, who in turn redelegates this authority to the Administrator of DEA, to ''promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals'' (21 U.S.C. 821 as amended by Pub. L. 108–447).

In October 1992, Congress passed the Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act of 1993 which changed the source of funding for DEA's Diversion Control Program (DCP) from being part of DEA's Congressional appropriation to full funding by registration and reregistration fees through the establishment of the Diversion Control Fee Account (DCFA). The Appropriations Act of 1993 required that ''[f]ees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.'' The legislation did not, however, provide clarification on what constituted the ''Diversion Control Program,'' thus leaving open the issue as to what fee-setting criteria should be used to determine which costs could be reimbursed from the DCFA.

In response to the Appropriations Act of 1993, DEA published a Notice of Proposed Rulemaking (NPRM) in December 1992 to adjust the registration and reregistration fees for controlled substance registrants (57 FR 60148, December 18, 1992). In the absence of guidelines from Congress regarding the specific criteria to be followed in identifying costs and setting the fees, DEA relied on the plain language of the Appropriations Act of 1993 and proposed fees necessary to cover the costs of the activities that were identified within the budget decision unit known as the ''Diversion Control Program.''

At the time that the Appropriations Act of 1993 was passed, 21 U.S.C. 821 did not extend to chemical control activities; accordingly, there were no registration or fee requirements for handlers of List I chemicals. DEA therefore excluded chemical control costs from its Final Rule implementing the requirements of the Appropriations Act of 1993 (58 FR 15272, March 22, 1993). 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); however, despite this amendment, DEA has continued to endeavor to maintain separate funding for its controlled substances diversion control and its chemical diversion control activities.

Following publication of DEA's Final Rule, the American Medical Association (AMA) and others filed a lawsuit objecting to the increase in registration and reregistration fees on the grounds that DEA had failed to provide adequate information as to what activities were covered by the fees and how they were justified. Upon appeal, the United States Court of Appeals for the District of Columbia Circuit remanded, without vacating, the rule to the DEA, requiring the agency to provide an opportunity for meaningful notice and comment on the fee-funded components of the DCP. In doing so, the court confirmed the boundaries of the DCP that DEA can fund by registration fees, finding that the current statutory scheme (21 U.S.C. 821 and 958) required DEA to set reasonable registration fees to recover the full costs of the DCP. (*AMA* v. *Reno,* 57 F.3d 1129, 1135 (D.C. Cir. 1995)).

Thus, in the absence of a simple, objective measure by which DCP costs could be identified and the appropriate fees calculated, both DEA and the courts have looked to 21 U.S.C. 821 and 958 to define the guidelines for determining what costs should be included in the calculation of the fees and from whom the fees might be collected.

On November 20, 2004, Congress passed the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 2005 which provided clarification as to the activities constituting the DCP (Pub. L. 108–447). This Act was included in the Consolidated Appropriations Act of 2005, which was signed into law by the President on December 8, 2004 (Pub. L. 108–447). The Act amends 21 U.S.C. 886a to define the Diversion Control Program as ''the controlled substance and chemical diversion control activities of the Drug Enforcement Administration,'' which are further defined as the ''activities related to the registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed chemicals.'' It also amends the section to provide that reimbursements from the DCFA ''* * * shall be made without distinguishing between expenses related to controlled substances activities and expenses related to chemical activities.''

Finally, the Act amends 21 U.S.C. 821 and 958(f) to make the language of those sections consistent with the definition of the DCP (Pub. L. 108–447). The net effect of the amendments is to allow DEA to deposit all registration and reregistration fees (controlled substance and chemical) into the Fee Account and fund all controlled substance and chemical diversion control activities from the account without distinguishing as to the type of activity (controlled substance or chemical) being funded.

Independent of the passage of the Appropriations Act, DEA undertook an internal reorganization to increase operational efficiencies and overall effectiveness. The resulting internal reorganization removes the focus from the single business decision unit of the DCP to a focus on diversion control activities irrespective of the business decision unit. That is, the diversion control activities of DEA are no longer contained in a single business decision unit identified as the Diversion Control Program. Thus, in identifying the activities that constitute the DCP, DEA must now look across the whole agency at all functions related to the registration and control of the manufacture, distribution, dispensing, importation and exportation of controlled substances and listed chemicals. This approach adheres both to the definition of the DCP contained in 21 U.S.C. 821 and 958 and to the court's requirement that there must be a nexus between the DCP activities funded through fees and the registration and control of the manufacture, distribution, and dispensing of controlled substances and of regulated persons and regulated transactions (now ''listed chemicals'').

In keeping with this organizational and functional change, DEA has re-assessed the diversion control activities to be funded by the Diversion Control Fee Account (DCFA). Accordingly, this Notice of Proposed Rulemaking identifies all of the activities that constitute the DCP irrespective of organizational structure within the agency and in compliance with 21 U.S.C. 821 and 958, and 21 U.S.C. 886a that require that DEA charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, importation and exportation of controlled substances and listed chemicals and that DEA collect fees adequate to fully fund the controlled substances and chemical diversion control activities that constitute the DCP. This rule also proposes a revised fee structure for manufacturers, distributors, dispensers, importers and exporters of controlled substances and List I chemicals, proposing that all handlers of controlled substances and listed chemicals pay an annual fee, by registrant category to support the DCP irrespective of whether they handle controlled substances or List I chemicals. While the Appropriations Act of 2005 specifies changes to the DCP effective immediately, the proposed new fee schedule would not take effect until Fiscal Year 2006. While all DCP activities will be supported by the DCFA, for Fiscal Year 2005 effective February 1, 2005, the combination of available DCFA funds together with the anticipated fee revenues from existing registrants will be sufficient to cover the additional costs being transferred to the fee-fundable aspects of the DCP.

Under the current fee structure, DEA would collect a total of approximately $161,005,104 from registrant fees to support the DCP in Fiscal Year 2006. The estimated Fiscal Year 2006 cost of operating the DCP according to the clarified definition contained in the Consolidated Appropriations Act of 2005 is $201,673,000 as further described below. To this figure, DEA is required to add $15 million to be transferred to the U.S. Treasury (see below for further explanation), necessitating that DEA collect through registrant fees a total of $216,673,000 to ''fully fund'' the DCP in Fiscal Year 2006. Without an increase in registrant fees to support the DCP DEA would fall short by about $55,667,896 and would not have sufficient funds to operate the DCP. Therefore, the following rule proposes to adjust the current registrant fee schedule to ensure the full funding of the DCP through registrant fees.

In addition, because of the statutory clarification that now includes all chemical diversion control activities as part of the DCP, DEA is modifying the fee structure for DCP registrants to include chemical registrants as explained below. To date, chemical registrants have paid fees ranging from a subsidized $116 to $595 (initial registration fee) that covered only the costs of registration and reregistration and not the actual costs of operating the chemical diversion control program.

These fees are user fees in contrast to the fees paid for by controlled substances registrants. User fees are required under the Independent Offices Appropriations act (IOAA) and the guidelines set forth in OMB Circular A–25. User fees are paid when a special benefit is conferred to a particular group, individual, etc. OMB Circular A–25, Section 6 describes a special benefit as a government service which ''enables the beneficiary to obtain more immediate or substantial gains or values (which may or may not be measurable in monetary terms) 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 or various kinds of public land use).''

The section specifies that ''[a] user charge * * * will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.'' The section further requires that the user charge be sufficient to ''recover the full cost to the Federal Government for providing the special benefit.''

Under this definition, a registration to manufacture, distribute, import or export List I chemicals is a special benefit; and therefore, the fees paid by chemical handlers are user fees subject to the IOAA. In contrast, because 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)), the fees paid to date by controlled substances registrants are *not* user fees. That is, because Congress established the DCFA by passing the 1993 Appropriations Act with its collection and spending criteria established by prior law (21 U.S.C. 821 and 958(f)), the registration fees charged by DEA pursuant to the 1993 Appropriations Act are not user fees subject to the IOAA because the act constitutes an independent statutory source for charging the fee and it defines fee-setting criteria, i.e., to cover the full costs of the DCP (*AMA* v. *Reno*, 857 F. Supp. 80 (D.D.C. 1994)).

To comply with the clarified definition of the DCP and the statutory requirement that the operating costs of the DCP be fully funded through registrant fees, DEA must fund all aspects of the DCP, including the chemical diversion program, through fees. Because there is an independent statutory source for charging fees relating to all activities of the DCP (controlled substances and chemical), the fees charged to chemical registrants are no longer considered user fees subject to IOAA provisions, and DEA must collect fees from both chemical and controlled substances registrants to support the DCP.

Diversion Control Program Responsibilities

The mission of DEA's Diversion Control Program (DCP) is to enforce the provisions of the Controlled Substances Act as they pertain to ensuring the availability of controlled substances and

listed chemicals for legitimate uses in the United States while exercising controls to prevent the diversion of these substances and chemicals for illegal uses.

DCP activities include: Program priorities and field management oversight; coordination of major investigations; drafting and promulgating of regulations relating to the enforcement of the CSA and other legislation; establishment of national policy on diversion; fulfillment of U.S. obligations under drug control treaties; advice and leadership on state legislation/regulation; legal control of drugs and chemicals not previously under Federal control; control of imports and exports of licit controlled substances and chemicals; and program resource planning and allocation, among other activities.

Current Fee-Funding

As described above, in the absence of specific guidance as to which activities were encompassed within the DCP and thus fee-fundable, DEA to date has adhered to the plain language of the Appropriations Act of 1993 and used the budget categories that have historically been included in the DCP budget request of the Attorney General. As described in DEA's 1996 **Federal Register** Final Rule, 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 (to include only its controlled substances activities) in its annual budget submission to Congress (61 FR 68624, December 30, 1996).

DCP activities funded to date through the DCFA have been limited to those in the DCP business decision unit and constituted controlled substances 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. Fee-fundable activities also have included travel, rent, utilities, supplies, equipment and services associated with the above-listed activities and activities related to the control of licit controlled substances in the U.S. in which the initial source is foreign.

DEA had not included the chemical control activities of the DCP among those funded through the DCFA for the reasons outlined previously. However, with the clarification in 21 U.S.C. 886a, as amended by Public Law 108–447, of the activities that constitute the DCP and that must be fully funded through registrant fees, DEA is now proposing to include activities related to the registration and control of the manufacture, distribution, importation and exportation of listed chemicals among those activities to be funded through the DCFA. That is, DEA would no longer distinguish, for the purposes of fee funding, between its diversion control activities relating to controlled substances and those relating to chemicals. These chemical diversion control activities include the overall control of listed chemicals, registration, investigation, inspection, data collection and analysis, cooperative efforts with the regulated industry, related management and administrative positions devoted to diversion control activities, other personnel, and administrative and clerical oversight. Activities also include a portion of the Office of Training (TR) that specifically supports the activities of the DCP. The TR develops, prepares and provides training, guidance and instruction for Diversion Investigators, Diversion Task Force Officers, regulatory agencies, state and local law enforcement, and DCP personnel on controlled substances and chemical diversion control, advance skills and technical knowledge, and systems applications. The total cost of the transfer of chemical diversion control activities to the DCFA in Fiscal Year 2005 was $15,773,000. This figure is specified in the Appropriations Act and excludes $7.6 million in Congressionally-appropriated funds that have been provided for the chemical diversion control activities for Fiscal Year 2005. While the chemical program costs would be transferred to the DCP to comply with the clarification in 21 U.S.C. 886a and therefore paid for out of DCFA (fee) funds, for Fiscal Year 2005 these additional chemical diversion control costs to the DCP would be supported through available DCFA funds combined with anticipated fee collections from existing registrants. That is, while upon enactment the Appropriations Act of 2005 provides for the inclusion of chemical diversion control activities as part of the DCP and therefore subject to fee-funding and support through the DCFA, there will be no changes to registration and reregistration fees for Fiscal Year 2005 to accommodate the transfer of these activities to the DCP.

Beginning in Fiscal Year 2006, DEA proposes to include the additional chemical diversion control costs in the calculation of DCFA registration and reregistration fees, as shown below in the proposed new fee schedule. The chemical diversion control costs that would be supported through the DCFA total $24,499,000 for Fiscal Year 2006, $24,874,000 for Fiscal Year 2007, and $25,223,000 for Fiscal Year 2008, accounting for salary growth and inflation.

In addition to the TR costs described above, these chemical costs also include 188 chemical diversion control positions; 12 overseas diversion investigators dedicated to the DCP; and costs associated with the chemical transaction system (CTRANS). Historically, the DEA has funded diversion investigator positions overseas through appropriated funds, rather than the DCFA, despite the fact that these positions directly support the activities of the DCP. Diversion investigators in foreign posts conduct similar activities to domestic diversion investigators to prevent the diversion of legal controlled substances and listed chemicals to illegal uses. These individuals' activities include, but are not limited to, conducting background investigations of foreign companies involved in the importation into or exportation from the U.S. of controlled substances and listed chemicals; working with foreign governments on matters relating to the international controls on controlled substances and listed chemicals; advise the U.S. mission and DEA management regarding diversion of controlled substances and listed chemicals within foreign territory; training foreign law enforcement and regulatory counterparts to detect, investigate and prevent diversion of controlled substances and listed chemicals and working with foreign law enforcement and regulatory authorities regarding issues involving the illegal exportation from or illegal importation into the United States of controlled substances pharmaceuticals or listed chemicals. (It is the responsibility of the DCP to prevent the diversion of controlled substances and listed chemicals regardless of geographic source.)

The Fiscal Year 2006 cost of the foreign diversion investigator positions described above is $3,107,000. Accounting for inflation and salary growth, the Fiscal Year 2007 cost to be fee-funded would be $3,181,000, and the Fiscal Year 2008 cost would be $3,222,000.

DEA also is proposing to include as fee-fundable activities certain other internal resources that support the DEA's diversion control activities but that have not been considered part of the DCP in the past because of separate budget delineations. As was discussed more fully in previous rulemakings regarding the DCFA, while these elements support diversion control efforts, because the overall functions of the business decision units in which these activities are located are not devoted primarily to diversion control and because they have historically not been included as part of the DCP budget requests of the Attorney General, these elements have been supported by appropriated funds and not by the DCFA (61 FR 68624, December 30, 1996).

DEA identified several of these resources in its Final Rule published on October 10, 2003, including two sections within the Office of Chief Counsel that support DCP activities and a portion of the Office of Forensic Sciences Special Testing Laboratory that supports authentic sample analyses for licit drugs (68 FR 58587, October 10, 2003). Other elements of DEA diversion control operations that support the DCP but have been traditionally funded through appropriated funds, and therefore not through the DCFA, also include diversion investigators assigned to overseas posts.

Following the internal reorganization of the DEA to increase operational efficiencies and shift the focus from business decision units to activities that support the registration and control of the manufacture, dispensing and distribution of controlled substances and listed chemicals and in response to revisions to 21 U.S.C. 886a, DEA reviewed all activities relating to the registration and control of the manufacture, distribution, importation, exportation and dispensing of controlled substances and listed chemicals across the agency. As described above, with the internal reorganization, the agency's diversion control activities are no longer contained in an operational entity or office but rather the DCP now comprises all diversion control activities across the agency. Accordingly, the proposed, new fee structure includes all costs associated with the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals, including some diversion control costs previously funded through appropriated funds and not through registrant fees, regardless of the business decision unit in which these activities are located within the DEA. These costs include portions of the Office of Chief Counsel, the Office of Forensic Sciences Special Testing Laboratory, and the Special Operations Division; 12 foreign diversion investigator positions; additional special agent and intelligence analyst costs not currently supported through the DCFA; and ten new risk management positions to meet new mandates for the DCP. These components and associated costs are described below. A portion of DEA's internal computer system, Firebird, which already is supported through the DCFA, is included in the fee-fundable costs. The total cost of these non-chemical additions for Fiscal Year 2006 is $28,243,000.

In the Office of Chief Counsel, two components—the Diversion and Regulatory Policy Section and the Diversion and Regulatory Litigation Section—provide diversion control support through the litigation of administrative actions related to DEA registrants and through legal support on regulatory policy matters. The Diversion and Regulatory Policy Section serves as the principal legal advisor on all policy issues related to controlled substances and chemical diversion control. The Diversion and Regulatory Litigation Section represents DEA in administrative hearings regarding the revocation or denial of DEA registrations to handle controlled substances or listed chemicals and provides legal advice related to the regulation of DEA registrants. DEA has identified 12 positions in these two sections (11 attorneys and one support position) that support the DCP. The Fiscal Year 2006 costs of the Chief Counsel support that would be funded through registrant fees totals $2,085,000, as contained in the President's Budget Request. The Fiscal Year 2007 costs would be $2,118,000, and the Fiscal Year 2008 costs are anticipated to be $2,149,000 to account for inflation and annual salary increases.

DEA's Office of Forensic Sciences Special Testing Laboratory supports authentic sample analyses for licit controlled substances. Fifty-one percent of the current Source Determination receipts handled by the Laboratory relate to licit drugs; that is, 51 percent of the costs of the Laboratory's eight positions directly relate to the control of the manufacture, distribution and dispensing of controlled substances as part of the DCP and therefore would be subject to fee funding under the proposed, revised fee structure. The Fiscal Year 2006 Laboratory costs that would be supported through fee funds total $820,000. The anticipated Fiscal Year 2007 Laboratory costs to be fee-funded would be $832,000, and the Fiscal Year 2008 costs would be $844,000, to account for inflation and annual salary increases.

Based on Fiscal Year 2004 work hour analyses, DEA determined that there were 42 special agent work years utilized on investigations related to the diversion of pharmaceutical drugs. In Fiscal Year 2004, the DCFA funded the equivalent of 13 special agent work years on these investigations. DEA proposes to fully fund through the DCFA the support that is being provided for diversion investigations by including an additional 29 special agent positions. Special agents support the DCP by serving warrants, providing undercover support, making arrests, and providing other functions that diversion investigators are prohibited from executing but that are core elements of diversion control. The additional 29 positions would be added to the DCFA costs and would support both controlled substances and chemical diversion control efforts. The Fiscal Year 2006 cost for these additional special agent positions totals $6,530,000 (as contained in the President's Budget Request). Accounting for inflation and growth in salaries, the Fiscal Year 2007 cost would be $6,627,000, and the anticipated Fiscal Year 2008 cost would be $6,727,000.

In addition, for Fiscal Years 2006, 2007, and 2008 DEA proposes to add a total of 23 special agent positions to the budget supported by the DCFA. These positions include five special agents dedicated to the Office of Enforcement Operations to serve as Diversion Control Enforcement Coordinators for diversion control activities and 18 special agents to serve as part of Diversion Investigation Groups. The Fiscal Year 2006 cost of these positions will be $4,704,000. The Fiscal Year 2007 and Fiscal Year 2008 costs are anticipated to be $4,598,000 and $5,607,000, respectively, accounting for the phase-in of these positions over time and inflation and salary increases.

DEA also proposes to fee-fund a total of 73 intelligence analyst positions of which 67 positions are in the field, four positions are located in the Special Operations Division, and two positions support the Office of Enforcement Operations. Intelligence analysts support the DCP by providing investigative and analytical support for domestic and international diversion control investigations, including the collection and evaluation of investigative intelligence information and the development of innovative techniques and solutions to assist the investigative process. Other duties of

intelligence analysts include researching business records, financial documents and person histories of diversion targets; analyzing emails, and related communications; researching compiling and analyzing import and export data to identify potential diversion targets; and determining associates of criminal targets and criminal organizations. The additional intelligence analysts in the field offices will free up diversion investigators who currently perform much of their own intelligence analysis. Freeing up diversion investigator time will allow them to focus more on investigative activities, including interviewing potential witnesses, conducting pharmacy surveys, conducting audits, and coordinating investigative activities with state and local law enforcement. Among the field positions, 34 intelligence analysts would be phased in during Fiscal Year 2006, and 33 intelligence analysts would be phased in during Fiscal Year 2007. The total cost of the intelligence analyst positions to the DCFA in Fiscal Year 2006 would be $4,465,000, as indicated in the President's Budget Request. As the positions continue to be phased in, the Fiscal Year 2007 fee-fundable intelligence analyst costs would be $8,761,000. The anticipated intelligence analysts cost in Fiscal Year 2008 would be $11,105,000.

DEA also must request DCFA funding for ten risk management positions to support a coordinated, government-wide approach to address prescription drug diversion and abuse. During 2003, more than six million Americans abused prescription drugs. To better address this problem, the Appropriations Act of 2005 created, without funding, 10 risk management positions and directed DEA to work cooperatively with other Federal agencies to ensure that drugs with a high risk of abuse are marketed appropriately (Pub. L. 108–447). The Fiscal Year 2006 cost of these positions to be fee-funded is $1,247,000. The Fiscal Year 2007 cost of these additional 10 diversion control staff for this effort is anticipated to be $1,589,000, and the anticipated Fiscal Year 2008 cost for these positions to be fee-funded is $1,613,000.

In calculating the revised fee schedule, DEA used the DCFA Budget Request for Fiscal Year 2006 and the expected DCFA Budget Requests for Fiscal Year 2007 and Fiscal Year 2008 in addition to the required annual $15 million transfer to the U.S. Treasury as mandated by the CSA (21 U.S.C. 886a). In addition to covering with fee funds all program elements and activities related to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals, DEA must transfer the first $15 million of fee revenue to the General Fund of the Treasury each year (21 U.S.C. 886a(1)). For each fiscal year between Fiscal Year 1993 through Fiscal Year 1998, Congress appropriated an additional $15 million to offset this requirement (a total infusion to the DCFA of $90 million). However, beginning in Fiscal Year 1999, Congress discontinued this additional appropriation.

The Fiscal Year 2006 cost of the DCP is $201,673,000, including a base of $148,931,000 for controlled substances diversion control activities, $24,499,000 in chemical diversion control activities, and $28,243,000 for the additional non-chemical DCP support activities described above; that is:

- 29 existing special agent positions to be dedicated to investigations of trafficking in pharmaceutical controlled substances (FY06 cost of $6,530,000);
- 23 new special agent positions also to be dedicated to diversion control investigations (FY06 cost of $4,704,000);
- 51% of eight Office of Forensic Sciences Special Testing Laboratory positions that support authentic sample analyses for licit controlled substances (FY06 cost of $820,000);
- 12 Chief Counsel positions to provide diversion control support through the litigation of administrative actions related to DEA registrants and through legal support on regulatory policy matters (FY06 cost of $2,085,000);
- 10 new risk management positions, mandated by the 2005 Appropriations Act, to support a coordinated, government-wide approach to address prescription drug diversion and abuse (FY06 cost of $1,247,000)
- 67 field intelligence analysts and 6 Headquarters intelligence analysts to support domestic and international diversion control investigations (FY06 cost of $4,465,000 for 34 of these analysts)
- 1 professional/administrative position and non-personnel support for the Special Operations Division directly related to diversion control efforts (FY06 cost of $4,392,000)
- Firebird operations costs to support communication and infrastructure of the diversion control program (FY06 cost of $4,000,000)

With the addition of the required $15 million transfer to the U.S. Treasury, the total amount necessary to collect through registrant fees in Fiscal Year 2006 is $216,673,000.

The anticipated costs of the DCP for Fiscal Year 2007, including all activities relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals, is $213,723,000. DEA used an inflation figure of 1.5 percent, based on the President's Economic Assumptions, to account for increases in costs against the Fiscal Year 2006 costs described above. Including the required $15 million transfer to the U.S. Treasury, the total amount necessary to collect through registrant fees in Fiscal Year 2007 is $228,723,000. The anticipated costs of the DCP for Fiscal Year 2008, including all activities relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals, is $219,964,000. Including the required $15 million transfer to the U.S. Treasury, the total amount necessary to collect through registrant fees in Fiscal Year 2008 is $234,964,000.

The total amount necessary to collect through fee funds for the Fiscal Year 2006–2008 period to fully fund the DCP as mandated by statute is $680,360,000. Under the current fee structure (without the proposed changes included in this rule), DEA would collect only $491,944,464 for the Fiscal Year 2006–2008 period through registrant fees and would therefore fall short by $188,415,536 of the necessary costs of operating the DCP. DEA's proposed new fee structure, therefore, would provide the necessary additional funds to ensure that the operational costs of the DCP are fully funded through registrant fees as mandated by statute.

Based on the total amount necessary to collect for Fiscal Years 2006–2008, DEA developed the specific fee levels for each registrant category reflected in the table below. To calculate these fees, DEA first estimated the number of paying registrants for this period and then used this figure combined with the amount required to be collected (with the new fees) 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 2004 combined with conservative estimates for future registration activity.

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 and fee-paying ratios that have been in existence since the inception of registrant fees. During this time, DEA has evaluated other options to apportion registrant fees, including, for example, basing fees on the usage level of controlled substances or listed chemicals. However, in each case, DEA determined that any potential benefits to an alternative fee structure system would be more than offset by greater administrative costs and burdens which must be borne by registrants. For more discussion on this topic, please see DEA's 2002 Final Rule (67 FR 51988, August 9, 2002) and its 1996 Final Rule (61 FR 68624, December 30, 1996).

In developing the proposed fee schedule, DEA opted to set the fee level for a three-year period (FY 2006–2008) for two reasons. First, the vast majority of registrants are practitioners who pay a three-year registration fee. These registrants are divided into roughly three separate groups who pay their three-year registration fees on alternate year cycles. Accordingly, the fees below reflect the *total amount* necessary to be collected for the full three-year period (FY 2006–2008), 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 fees reflect the total amount necessary for collection over a three year period (Fiscal Years 2006–2008) and because the type and number of registrants varies from year to year, the total amount of fees collected may not equal the requested budget level for any given year. Surplus fees collected in one year are used to offset fee collection shortfalls in another year. In no case are fees spent in excess of the levels enacted by Congress.

In evaluating options to structure the fee schedule, DEA opted to remain with the current fee structure to reduce reporting burdens on registrants and operational costs associated with the DCP which would then be passed on to registrants through annual fees. One option suggested in the past by registrants is to structure fees based on total usage of controlled substances and/or listed chemicals. Such an option would require significant reporting by registrants and oversight by DEA and would greatly increase the administrative costs of operating the DCP.

Current Fees Paid by Registrants

Currently, both handlers of controlled substances and of List I chemicals pay annual registration and reregistration fees. Under the current structure and prior to the passage of the Consolidated Appropriations Act of 2005 which clarified the activities constituting the DCP, fees paid by controlled substances registrants fully supported all costs of the DCP which to date have excluded chemical diversion control activities and other activities that support the DCP but have traditionally been funded through Congressional appropriations. In contrast, fees paid by chemical registrants supported only the costs associated with registration and reregistration and the administration of the chemical diversion control program—that is *not* the full costs of chemical diversion control activities.

Currently, handlers of controlled substances pay annual registration and reregistration fees ranging from $130 to $1,625 depending on the category of registrant. Practitioners, mid-level practitioners, dispensers, researchers, and narcotic treatment programs pay an annual registration or reregistration fee of $130 (practitioners pay a three-year registration fee of $390). Distributors, importers and exporters pay an annual fee of $813, and manufacturers pay an annual fee of $1,625. The DEA last adjusted the fee schedule for controlled substances handlers in October 2003 (68 FR 58587, October 10, 2003). DEA anticipates that even without the statutory changes prompting the proposed fee adjustments contained in this rule, the agency would have needed to adjust the fees for controlled substances registrants to account for inflation and normal growth in operational costs in Fiscal Year 2006. Approximating a 15 percent increase in fees due to inflation and increases in program costs would have raised the annual practitioner fee, for example, from $130 to $150.

Chemical handlers pay different annual fees for initial registration and subsequent reregistrations and depending on the category of registrant. Manufacturers, non-retail distributors, importers and exporters of List I chemicals currently pay $595 for each initial annual registration and $477 for each subsequent annual reregistration. Retail distributors pay an annual fee of $248 plus a $7 application processing fee for each initial registration to conduct business and $116 per year for each reregistration (60 FR 32447, June 22, 1995). Since October 1997, non-retail distributors of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products have been required to pay only $116 of the initial $595 registration fee (62 FR 53958, October 17, 1997). Fees for chemical registrants have not been adjusted since passage of the DCDCA in 1995, and DEA has not revisited the fees except with regard to the waiver of a portion of the fees in 1997 (62 FR 53958).

The current chemical fees reflected only the operational costs of registering and reregistering List I chemical handlers and *not* the full costs of the chemical diversion control program; however, with the revisions to 21 U.S.C. 886a that specifically defines the DCP to include both controlled substances and chemical diversion control activities, the DEA must collect fees from both controlled substances and chemical registrants at a level sufficient to fully fund the operations of the DCP (21 U.S.C. 886a). DEA estimates that if chemical registrants were required to pay for the full operating costs of the chemical diversion control program, registration and reregistration fee for all categories of non-retail chemical registrants would be in excess of $6,400. This calculation is based on the current population of registered non-retail chemical handlers.

Development of the Proposed New Fee Schedule

To recover the full costs of the DCP as required by statute and as outlined in the preceding sections, DEA proposes to incrementally raise the fees in accordance with its existing fee structure as shown in the following table. The table also includes the current fees paid by each category and the total increase in fees.

Registrant class	Proposed new annual fee	Current annual fee	Difference
Manufacturers (controlled substances)	$2,386	$1,625	$761
Manufacturers (chemical)	2,386	**595	1,791
Distributors, Importers/Exporters (controlled substances), including reverse distributors	1,193	813	380
Distributors, Importers/Exporters (chemical)	1,193	**595	598

Registrant class	Proposed new annual fee	Current annual fee	Difference
Chemical Retail Distributors	1,193	**255	938
Dispensers/Practitioners*	191	130	61
Researchers, Narcotic Treatment Programs	191	130	61

*Practitioners, mid-level practitioners, pharmacies, hospitals/clinics, and teaching institutions would pay a fee of $573 for a three-year registration period.
**Registration.

Although these fees did not go into effect on October 1, 2005, the first day of Fiscal Year 2006, DEA will publish a Final Rule in as timely a manner as possible. Under the proposed, new fee schedule, controlled substances registrants and chemical registrants in the same registrant category (e.g., manufacturers) would pay the same fee regardless of the substance or chemical being handled. Moreover, by this Notice, DEA proposes to remove differentiation between retail and non-retail distributors of List I chemicals; that is, both retail and non-retail distributors would pay the same fee as described above.

The fee structure above would supplant the current fee structure for controlled substances and for chemical registrants. To clarify further, in establishing the new fee structure above, DEA also would be withdrawing, by this notice, its Notice of Proposed Rulemaking issued on December 1, 1999, which proposed changes in registration and reregistration fees for manufacturers, distributors, importers, exporters and retail distributors of List I chemicals (64 FR 67216, December 1, 1999). DEA also would be rescinding, by this notice, the 1997 Notice of Fee Waiver published on October 17, 1997 (62 FR 53958). By this notice DEA had waived a portion of the registration fee for non-retail distributors of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products.

DEA also is removing the registration waiver for persons who distribute, import or export a product containing a List I chemical if that person is registered with the DEA to manufacture, distribute or dispense, import or export a controlled substance, since the registration to handle List I chemicals and the registration to handle controlled substances, while both supporting the DCP and therefore subject to the same fees per the Appropriations Act of 2005, cover different regulatory, legal and business requirements and also relate to different customer bases.

With the changes to 21 U.S.C. 821 and 958, and 21 U.S.C. 886a (summarized above) that require that DEA charge reasonable fees relating to the registration and control of the manufacture, distribution, dispensing, importation and exportation of controlled substances and listed chemicals and that DEA collect fees adequate to fully fund the controlled substances and chemical diversion control activities that constitute the DCP, the DEA must calculate the full costs of the DCP based on the full operating costs of its controlled substances diversion activities and its chemical diversion activities. Accordingly, persons who handle (manufacture, dispense, distribute, import or export) both controlled substances and List I chemicals must maintain a separate registration for each business activity.

Regulatory Analysis

The rulemaking actions contained in this notice are necessary to ensure the full funding of the DCP through registrant fees as required by 21 U.S.C. 886a(3). Recent statutory clarification as to what constitutes the DCP and an internal reorganization of the DCP to improve operational efficiencies prompted DEA to conduct a review of the activities and costs constituting the DCP and to recalculate the registrant fees accordingly. This action was necessary despite the last fee adjustment on October 10, 2003.

By registering with the DEA to handle controlled substances and List I chemicals (as required by 21 U.S.C. 822) and paying the annual registration fee (or three-year registration fee for some registrants), registrants receive the benefit of being able to manufacture, distribute import, export, and/or dispense controlled substances and/or listed chemicals. Entities that have not registered or do not maintain a current registration with the DEA to handle controlled substances and/or List I chemicals are, in general, not permitted to handle these substances (certain exceptions apply as delineated in 21 U.S.C. 822(c)).

Registration of controlled substances and List I chemical handlers is a key element of the system of controls related to the manufacture and distribution of these substances. Congress established this system of controls through the Controlled Substances Act, the Chemical Diversion and Trafficking Act, and subsequent legislation in an effort to prevent, detect and eliminate the diversion of controlled pharmaceuticals and listed chemicals from legitimate channels to illegal use, while at the same time ensuring their availability for legitimate purposes. This system has proven effective in reducing the diversion of these substances from legitimate channels to the illicit market. Components of this system include the registration of all controlled substances and listed chemicals and their handlers (Handlers of List II chemicals exclusively are not required to register with the DEA), recordkeeping, security, and manufacturing quotas, all under DEA DCP oversight. This proposed rule does not change the requirement to register to handle controlled substances and/or List I chemicals but rather changes the annual fee associated with registration and reregistration.

Regulatory Flexibility Act

The Regulatory Flexibility Act as amended (5 U.S.C. 601–612), requires agencies to determine whether a proposed rule will impose a significant economic impact on a substantial number of small entities. The proposed fees affect a wide variety of entities. The following table indicates the sectors affected by the proposed rule.

TABLE 1.—INDUSTRIAL SECTORS OF DEA REGISTRANTS

Sector	NAICS code	Controlled substance	Chemical
Chemical Manufacturing (organic, inorganic)	3251		X
Medicinal and Botanical Manufacturing	325411	X	X

TABLE 1.—INDUSTRIAL SECTORS OF DEA REGISTRANTS—Continued

Sector	NAICS code	Controlled substance	Chemical
Pharmaceutical Manufacturing	325412	X	X
Adhesive Manufacturing	325520		X
Toilet Preparation Manufacturing	325620		X
Other Chemical Manufacturing	325998		X
Drugs and Druggist Sundries Wholesalers	424210	X	X
General Line Grocery Wholesalers	424410	X	X
Confectionary Merchant Wholesalers	414450		X
Chemical Wholesalers	424690		X
Tobacco Wholesalers	424940		X
Miscellaneous Wholesalers	424990		X
Supermarkets	445110	X	X
Drug Stores	446110	X	X
Discount Stores	452112	X	X
Warehouse Clubs and Superstores	452910	X	X
Testing Labs	541380	X	X
Packaging and Labeling Services	561910		X
Colleges, Universities, Professional Schools	611310	X	
Ambulatory Health Care Services	621	X	
Hospitals	622	X	

Controlled substances are prescription drugs; firms manufacturing and distributing them usually specialize in prescription pharmaceuticals. The supermarkets, discount stores, warehouse clubs, and superstores handle controlled substances through their distribution centers and their pharmacies. The listed chemical registrants are more diverse for two reasons. First, most of the listed chemicals have non-drug uses, such as chemical intermediates, flavorings, fragrances, and adhesives. Second, the drug products containing List I chemicals are primarily over-the-counter (OTC) medicines. These are distributed by drug wholesalers who specialize in non-prescription drugs, wholesalers who supply convenience stores, and grocery, pharmacy, and discount stores (e.g., superstores) that operate their own distribution centers. Of the 460 registered manufacturers, importers, exporters, and distributors who hold multiple registrations, only 70 hold both a controlled substance and a chemical registration.

As of December 2004 there are 1,178,361 controlled substances registrants and 2,998 chemical registrants, as shown in Table 2.

TABLE 2.—NUMBER OF REGISTRANTS BY BUSINESS ACTIVITY

	Controlled substances	Chemicals
Practitioners	984,271	
Midlevel Practitioners	103,239	
Retail Pharmacy	62,865	*
Hospital/Clinic	15,650	
Teaching Institution	443	
Manufacturer	485	208
Distributor	823	2,413
Researcher	7,458	
Analytical Laboratory	1,541	
Importer	159	195
Exporter	253	181
Narcotic Treatment Program	1,174	
Total	1,178,361	2,998

*Retail distributor.

Not all registrants listed in Table 2 are subject to the fees. Publicly owned institutions, law enforcement agencies, and military personnel are exempt from fees. In addition, DEA waives fees for charitable organizations, some of which are registered as chemical distributors (OTC medicines are distributed by some food banks and exported by aid organizations).

The number of registrations overstates the number of individual registrants. The CSA requires a separate registration for each location where controlled substances are handled and a separate registration for each business activity; that is a registration for activities related to the handling of controlled substances and a registration for activities relating to the handling of List I chemicals. Some registrants may conduct multiple activities under a single registration (e.g., manufacturers may distribute without being registered as a distributor), but firms may hold multiple registrations for a single location. Individual practitioners who prescribe, but do not store controlled substances, may use a single registration at multiple locations within a state, but need separate registrations for each state in which they practice and are authorized to dispense controlled substances. Firms with multiple locations must have separate registrations for each location.

Small Entities. Most DEA registrants are small entities under the Small Business Administration (SBA)

standards. Almost all practitioners would be considered small (annual revenues of less than $6 million to $8.5 million, depending on specialty). Narcotic treatment programs and many clinics would be considered small (revenues of less than $8.5 million). According to the American Hospital Association, there are currently 5,764 registered hospitals; 1,360 are operated by Federal, state, or local governments and are exempt from fees. Of the remaining hospitals, the rural hospitals (2,166 including publicly owned hospitals) are more likely to be small (revenues less than $29 million). About 20,000 of the pharmacies are independent and are likely to be small (revenues less than $6 million); some of the small chain pharmacy firms may also be considered small. The teaching institutions and researchers are generally associated with large institutions and are not expected to be small. Importers and exporters are frequently manufacturers; these are likely to be the larger companies. The remaining importers and exporters, however, will generally be classified as wholesalers and would probably be small under the SBA standard for wholesalers (100 employees). The manufacturing sector includes the major companies, but many of the firms are small under SBA standards (500 to 1,000 employees). The distributors have the widest variety of sizes, from the few large wholesalers that handle almost 90 percent of drugs to very small wholesalers handling an array of products. In general, because of the cost of security for controlled substances, controlled substances manufacturers and distributors are larger than chemical manufacturers and distributors. DEA has no basis for estimating the total number of small entities affected, but it is clearly a substantial number.

Impacts. As noted above, the proposed new registration fees range from $191 to $2,386 annually. These fees are per location and per registered business activity. DEA data indicate that 63 percent of controlled substances manufacturers hold at least two registrations (as a manufacturer, importer, exporter, or distributor); the highest number of registrations identified for a manufacturer was 67. For chemical manufacturers, 66 percent hold at least two registrations, with the highest number being 30. The percent of multiple registrations for controlled substance importers is 91 percent, for exporters, 88 percent, for distributors 55 percent; for chemical importers it is 77 percent, exporters 95 percent, and distributors 29 percent. The chain pharmacies hold registrations for each of their locations. The largest chain holds retail pharmacy registrations for more than 5,000 locations as well as almost 40 registrations for its distribution centers. The fees paid to DEA will range from $191 for dispensing registrants holding a single registration to more than $900,000 for the largest chain pharmacy with multiple locations. Most small registrants are expected to pay a single registration fee of either $191, $1,193 or $2,386 per year (or per year equivalent).

To assess whether the fees could impose a significant economic impact on a small entity, DEA considered whether the fees represent more than one percent of annual revenues for the registrant groups. For dispensers, the annual revenues would have to be below $17,900 to have the registration represent more than one percent of revenues. Medical practitioners granted authority to handle controlled substances have annual incomes well above that level; physician assistants, the mid-level practitioner with the lowest average salary, have annual salaries of about $65,000. The average independent pharmacy has sales of almost $2 million according to the National Association of Chain Drug Stores. The smallest clinics have revenue streams higher than $17,900. Consequently the higher fees will not impose a significant burden on dispensers.

For manufacturers, the 2002 Census data indicate that the value of shipments for the smallest chemical manufacturers (including drugs) ranged from $477,000 to $1.1 million per location (establishment). For this registrant group, therefore, the fee of $2,386 does not represent more than one percent of revenues and will not impose a significant burden.

The one registrant group for which the fees could exceed one percent of revenues is chemical distributors. Controlled substance distributors are generally larger drug wholesalers in part because of the cost of security they need to prevent theft of controlled substances and other prescription drugs. According to 2004 Duns data, between one percent and 11 percent of the wholesale sectors handling listed chemicals have revenues below $100,000. DEA does not collect financial data on its registrants, but it is possible that some chemical distributor registrants have revenues below $100,000. The proposed increase in annual reregistration fee for chemical distributors (from $477 to $1,193) could impose a significant burden on these registrants. The proposed increase in the initial registration fee (from a subsidized $116 to $1,193 annually) also could be a barrier to entrance for these very small firms. Based on its experience, however, DEA considers it unlikely that any firm that lacked the resources to pay the initial registration fee would be granted a registration because it would be unlikely to have the resources to maintain the records and provide the security necessary to prevent diversion of the products. Moreover, the proposed new registration fees for all wholesale level activities are far less than the estimated annual fee of $6,400 that chemical registrants would be charged if they were required to independently fund the chemical portion of the diversion control program. Combining all diversion control activities into a single Diversion Control Program, as mandated by the Consolidated Appropriations Act of 2005, results in scale efficiencies and overall reduced costs to all registrants.

The Deputy Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)) and has provided above detailed regulatory analysis on the effects of this rulemaking on small entities. While DEA recognizes that this regulation will have a financial effect on registrants with the increase in fees, the change in fees is necessary to fully comply with 21 U.S.C. 886a and related statutes governing the Diversion Control Program and the Diversion Control Fee Account by which DEA is legally mandated to collect fees to cover the full costs of the Diversion Control Program as defined by all activities relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals.

Executive Order 12866

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 1(b). DEA has determined that, because the proposed increased fees will result in a total increase of less than $70 million annually to be collected through fees (that is the difference between the amount collected annually under the current fee structure and the amount proposed to be collected under the proposed, new fee structure), this is not a significant regulatory action; however, it has been reviewed by the Office of Management and Budget. The fees to be collected represent only an increase of less than $70 million each year for the Fiscal Year 2006–2008 period (based on estimated fee collection figures) and are required to fully support the President's

budget for the DCP, as approved by Congress through the appropriations process. Therefore, DEA has no discretion in the establishment of the new fees and is required by law to collect registration and reregistration fees of sufficient amount to fully support the DCP.

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 $115,000,000 or more in any one year, and will not significantly or uniquely affect small governments. The proposed increase in fees for private sector entities and individuals will result in a total increase of less than $70 million annually to be collected through fees (that is the difference between the amount collected annually under the current fee structure and the amount proposed to be collected under the proposed, new fee structure). Moreover, the effect on individual entities and practitioners is minimal. The majority of the affected entities will pay a fee of $573 for a three year registration period (the equivalent of $191 per year) which equates to about 0.14 percent of annual income for most practitioners (the vast majority of all registrants). This rule is promulgated in compliance with 21 U.S.C. 886a that the full cost of operating the DCP be collected through registrant fees.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. While this rule will result in an annual effect on the economy of $100,000,000 or more, it 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 U.S.-based companies to compete with foreign-based companies in domestic and export markets. This rule is not a discretionary action but rather responds to statutory clarification as to the activities constituting the DCP which, by law, must be fully funded through registrant fees (21 U.S.C. 821 and 21 U.S.C. 886a, respectively). Moreover, the individual effect on small business registrants is minimal. The majority of registrants considered to be small businesses are practitioners who will pay a three-year registration fee of $573 or the equivalent of $191 per year. For the majority of these practitioners, who compose the vast majority of registrants and registrants qualifying as small businesses, this fee represents about 0.14 percent of their annual mean salary. The impact on other small business entities is described in greater detail in the preceding regulatory analysis.

List of Subjects

21 CFR Part 1301

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

21 CFR Part 1309

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

For the reasons set out above, 21 CFR Parts 1301 and 1309 are proposed to be amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS AND DISPENSERS OF CONTROLLED SUBSTANCES

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, 951, 952, 953, 956, 957.

2. Section 1301.13 is proposed to be 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	2,386 2,386	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	1,193 1,193	1	
(iii) Reverse distributing	Schedules I–V	New—225 Renewal—225a	1,193 1,193	1	

Business activity	Controlled substances	DEA application forms	Application fee ($)	Registration period (years)	Coincident activities allowed
(iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Central fill pharmacy, Teaching institution).	Schedules II–V	New—224 ..... Renewal—224a	573 573	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 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	191 191	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 § 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 1	191 191	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 § 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	191 191	1	
(viii) Importing	Schedules I–V	New—225 ..... Renewal—225a	1,193 1,193	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	1,193 1,193	1	
(x) Chemical Analysis	Schedules I–V	New—225 ..... Renewal—225a	191 191	1	May manufacture and import controlled substances for analytical activities 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 § 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.

* * * * *

PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS, AND EXPORTERS OF LIST I CHEMICALS [AMENDED]

3. The authority citation for Part 1309 is proposed to be amended to read as follows:

Authority: 21 U.S.C. §§ 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 958.

4. Section 1309.11 is proposed to be revised to read as follows:

§§ 1309.11 Fee amounts.

(a) For each application for registration or reregistration to manufacture for distribution the applicant shall pay an annual fee of $2,386.

(b) For each application for registration or reregistration to distribute (either retail distribution or non-retail distribution), import, or export a List I chemical, the applicant shall pay an annual fee of $1,193.

5. Section 1309.12 is proposed to be revised to read as follows:

§§ 1309.12 Time and method of payment; refund.

(a) For each application for registration or reregistration to manufacture for distribution, distribute (either retail distribution or non-retail distribution), import, or export a List I chemical, the applicant shall pay the fee when the application for registration or reregistration is submitted for filing.

(b) Payment should be made in the form of a personal, certified, or cashier's check or money order made payable to ''Drug Enforcement Administration.'' Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

6. Section 1309.24 is proposed to be revised to read as follows:

§§ 1309.24 Waiver of registration requirement for certain activities.

(a) The requirement of registration is waived for any agent or employee of a person who is registered to engage in any group of independent activities, if such agent or employee is acting in the usual course of his or her business or employment.

(b) The requirement of registration is waived for any person whose activities with respect to List I chemicals are limited to the distribution of red phosphorus, white phosphorus, or hypophosphorous acid (and its salts) to: another location operated by the same firm solely for internal end-use; or an EPA or State licensed waste treatment or disposal firm for the purpose of waste disposal.

(c) The requirement of registration is waived for any person whose distribution of red phosphorus or white phosphorus is limited solely to residual quantities of chemical returned to the producer, in reusable rail cars and intermodal tank containers which conform to International Standards Organization specifications (with capacities greater than or equal to 2,500 gallons in a single container).

(d) The requirement of registration is waived for any retail distributor whose activities with respect to List I chemicals are limited to the distribution of below-threshold quantities of a pseudoephedrine, phenylpropanolamine, or combination ephedrine product that is regulated pursuant to § 1300.02(b)(28)(i)(D) of this chapter, in a single transaction to an individual for legitimate medical use, irrespective of whether the form of packaging of the product meets the definition of ''ordinary over-the-counter pseudoephedrine or phenylpropanolamine product'' under § 1300.02(b)(31) of this chapter.

(e) The requirement of registration is waived for any manufacturer of a List I chemical, if that chemical is produced solely for internal consumption by the manufacturer and there is no subsequent distribution or exportation of the List I chemical.

(f) If any person exempted under paragraph (b), (c) or (d) of this section also engages in the distribution, importation or exportation of a List I chemical, other than as described in such paragraph, the person shall obtain a registration for such activities, as required by § 1309.21 of this part.

(g) The Administrator may, upon finding that continuation of the waiver would not be in the public interest, suspend or revoke a waiver granted under paragraph (b), (c), or (d) of this section pursuant to the procedures set forth in §§ 1309.43 through 1309.46 and §§ 1309.51 through 1309.55 of this part.

(h) Any person exempted from the registration requirement under this section shall comply with the security requirements set forth in §§ 1309.71–1309.73 of this part and the recordkeeping and reporting requirements set forth under parts 1310 and 1313 of this chapter.

Dated: November 8, 2005.

Michele M. Leonhart,

Deputy Administrator.

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DEPARTMENT OF JUSTICE

28 CFR Part 16

[AAG/A Order No. 015–2005]

Privacy Act of 1974; Implementation

AGENCY: Department of Justice.

ACTION: Proposed rule.

SUMMARY: The Department of Justice, Tax Division, proposes to amend 28 CFR part 16 to exempt a newly revised Privacy Act system of records entitled ''Files of Applicants For Attorney and Non-Attorney Positions with the Tax Division, Justice/TAX–003,'' as described in today's notice section of the **Federal Register**, from 5 U.S.C. 552a(c)(3), (d)(1), and (e)(1). The exemptions will be applied only to the extent that information in a record is subject to exemption pursuant to 5 U.S.C. 552a(k)(2) and (k)(5). The exemptions are necessary to protect the confidentiality of employment records. The Department also proposes to delete as obsolete provisions exempting two former Tax Division systems of records: ''Freedom of Information/Privacy Act Request Files, Justice/TAX–004;'' and ''Tax Division Special Project Files, Justice/TAX–005.'' The records in Tax-004 are now covered by a Departmentwide system notice, ''Freedom of Information Act, Privacy Act, and Mandatory Declassification Review Requests and Administrative Appeals, DOJ–004''. The relevant records in TAX–005 are now part of the revised system entitled ''Criminal Tax Case Files, Special Project Files, Docket Cards, and Associated Records, Justice/TAX–001.''

DATES: Submit any comments by December 27, 2005.

ADDRESSES: Address all comments to Mary Cahill, Management and Planning Staff, Justice Management Division, Department of Justice, Washington, DC 20530 (1400 National Place Building), Facsimile Number (202) 307–1853. To ensure proper handling, please reference the AAG/A Order No. on your correspondence. You may view an electronic version of this proposed rule at *http://www.regulations.gov*. You may also comment via the Internet to the DOJ/Justice Management Division at the following e-mail address: *DOJPrivacyACTProposedRegulations@usdoj.gov*; or by using the *http://www.regulations.gov* comment form for this regulation. When submitting comments electronically, you must include the AAG/A Order No. in the subject box.

FOR FURTHER INFORMATION CONTACT: Mary Cahill, (202) 307–1823.