

certificate endorsed by a full-time, salaried veterinarian employed by the region of origin stating that the products have been processed in accordance with one of those methods:

(1) Milk or milk products (other than cheese) that are, or are made from, milk that has been treated at an ultra high temperature (298.4 °F (148 °C) for 3 seconds or 284 °F (140 °C) for 5 seconds); or

(2) Milk or milk products (other than cheese) that are, or are made from, milk that has been treated at a high temperature for a short time (HTST) (161.6 °F (72 °C) for 15 seconds) followed by a second HTST (161.6 °F (72 °C) for 15 seconds) treatment. For milk products made with added fat or added concentrates, the treatment temperature must be increased to 167 °F (75 °C); or

(3) Milk products made from HTST milk that is brought to a pH of less than 6 for 1 hour.

(4) Cheese made from raw milk, aged at a temperature of greater than 35.6 °F (2 °C) with a pH of less than 6 for 120 days prior to export from the country of origin; or

(5) Cheese made from HTST milk, aged at a temperature of greater than 35.6 °F (2 °C) with a pH of less than 6 for 30 days prior to export from the country of origin.

* * * * *

(8) Milk and milk products not of classes included within the provisions of paragraphs (a)(1) through (a)(7) of this section may be imported if the importer first applies to and receives written permission from the Administrator, authorizing such importation. * * *

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Done in Washington, DC, this 11th day of February, 2003.

Bill Hawks,

Under Secretary for Marketing and Regulatory Programs.

[FR Doc. 03-3836 Filed 2-14-03; 8:45 am]

BILLING CODE 3410-34-P

FEDERAL ELECTION COMMISSION

11 CFR Parts 100 and 110

[NOTICE 2003-5]

Leadership PACs

AGENCY: Federal Election Commission.

ACTION: Notice of public hearing.

SUMMARY: The Federal Election Commission is announcing a public hearing on proposed rules to address leadership PACs, which are unauthorized committees that are

associated with a Federal candidate or officeholder. Further information is provided in the supplementary information that follows.

DATES: The hearing will be held at 9:30 a.m. on Wednesday, February 26, 2003. The Commission is no longer accepting requests to testify.

ADDRESSES: Commission hearings are held in the Commission's ninth floor meeting room, 999 E Street, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Ms. Mai T. Dinh, Acting Assistant General Counsel, Mr. J. Duane Pugh, Jr., Acting Special Assistant General Counsel, or Mr. Anthony T. Buckley, Attorney, 999 E Street, NW., Washington, DC 20463, (202) 694-1650 or (800) 424-9530.

SUPPLEMENTARY INFORMATION: On December 26, 2002, the Commission published a Notice of Proposed Rulemaking [“NPRM”] proposing three alternative sets of rules addressing political committees that are associated with a Federal candidate or officeholder, and potential limitations to the contributions that such committees may accept and make. 67 FR 78753 (Dec. 26, 2002). The comment period for the NPRM ended on January 31, 2003. Eight sets of comments were received by the Commission in response to the NPRM. Seven commenters, who submitted six of the sets of comments, requested to testify at a public hearing if one is held.

After considering these requests and the other comments received to date in response to the NPRM, the Commission believes a public hearing would be helpful in considering the issues raised in the rulemaking. As the Commission stated in the NPRM, the hearing will be held at 9:30 a.m. on February 26, 2003.

Dated: February 11, 2003.

Ellen L. Weintraub,

Chair, Federal Election Commission.

[FR Doc. 03-3834 Filed 2-14-03; 8:45 am]

BILLING CODE 6715-01-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR PART 1301

[DEA-232P]

RIN 1117-AA70

Controlled Substances Registration and Reregistration Application Fees

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of Proposed Rulemaking.

SUMMARY: DEA is proposing to adjust the current fee schedule for DEA controlled substances registration to adequately recover necessary costs associated with the Diversion Control Program as mandated by the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993.

DATES: Written comments must be submitted on or before April 21, 2003.

ADDRESSES: Written comments should be submitted to the Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

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:

Background

The Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 1993 (Pub. L. 102-395) requires that the Drug Enforcement Administration (DEA) collect fees to ensure the recovery of the full costs of operating the Diversion Control Program. 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.”

Since 1970 the Controlled Substances Act (CSA) has authorized the Attorney General to “charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances.” 21 U.S.C. 821 and 958(f). This fee is collected by the Deputy Administrator of DEA for the Attorney General and is the only fee collected by DEA to support the Diversion Control Program. DEA does collect a user fee to support its listed chemical activities. However, this fee does not fall within the scope of this notice (see below for a further discussion). The fee schedule for the CSA was established in 1971 and was adjusted in 1984 and again in 1993. The fees have remained unchanged since that time.

Following publication in the **Federal Register** of the fee adjustment 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. The district court issued its final order granting the government's motion for summary judgment and disposing of all claims on July 5, 1994. *AMA v. Reno*, 857 F. Supp. 80 (D.D.C. 1994). The AMA appealed, and on July 27, 1995 the United States Court of Appeals for the District of Columbia Circuit remanded, without vacating, the rule to DEA. Specifically, the court required DEA "to identify the components of the fee-funded diversion control program and provide a brief explanation of why it deemed each component to be a part of that program." *AMA v. Reno*, 57 F.3d 1129, 1135 (D.C. Cir. 1995).

DEA responded to the remand requirement through a notice in the **Federal Register** on December 30, 1996, describing the fee-funded components and activities of the DCP with an explanation of how each satisfies the statutory requirements for fee-funding. 61 FR 68624-32. DEA accepted comments on this final rule and, based on these comments, published its final rule on the Drug Diversion Control Fee Account (DDCFA) in the **Federal Register** on August 9, 2002. This rule contains information on the specific DCP activities funded by the DDCFA. Copies of both the December 30, 1996 and August 9, 2002 rulemakings may be found on the Diversion Control Program Web site: <http://www.deadiversion.usdoj.gov>.

This announcement establishes the fee structure under the existing registration system to fully support the operations of the Diversion Control Program for Fiscal Year 2004 through Fiscal Year 2006. Since the last published rule in 1993, the Diversion Control Program has experienced significant growth without any associated increase in registrant fees to support the growth and increased funding needs. DEA is required by law (see below) to collect the full costs of the Diversion Control Program. The amount to be recovered is established by the Congressional appropriations process. The projected amount required to be recovered for Fiscal Year 2004, based on the President's Budget Request, will be \$133.6 million; the estimated amount required to be recovered for Fiscal Year 2005 will be \$157.3 million. The estimated amount required to be recovered for Fiscal Year 2006 will be \$160.3 million. These figures include required program growth

and the mandatory annual \$15 million transfer to the U.S. Treasury.

Statutory Authority to Collect Fees

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." Lastly, the 1993 Appropriations Act added a provision requiring DEA to set a fee schedule "that ensures the recovery of the full costs of operating the various aspects of that program." 21 U.S.C. 886a(3). The United States Court of Appeals for the District of Columbia Circuit noted that in establishing the DDCFA, Congress left intact the fee collection requirements of 21 U.S.C. 821, confirming boundaries of the DCP that DEA can fund by registration fees. *AMA v. Reno*, 57 F.3d 1129, 1135 (D.C. Cir. 1995). Although the court made no specific mention of 21 U.S.C. 958(f), those same boundaries remain intact as well. The court found that the current statutory scheme thus 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, therefore, must examine DCP activities in conjunction with the nexus requirements of 21 U.S.C. 821 and 958(f) to determine whether it can properly fee-fund them while setting fees that recover the full cost of these activities.

Diversion Control Program and Responsibilities

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 CSA, 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 DEA DCP oversight. (The DCP also possesses similar chemical control responsibilities pursuant to the Chemical Diversion and Trafficking Act (CDTA) and subsequent legislation.)

The plain language of the 1993 Appropriations Act requires DEA to set and collect registration fees to cover the full costs of operating its Diversion Control Program. 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 the DDCFA. 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 DDCFA.

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 Division Regulatory Section; certain laboratory service support; DEA Automated Data Processing Systems support (except ARCOS and CSA); Office of Training staff; DEA Management and Administrative Support; Office of Congressional and Public Affairs; Intelligence Support and Diversion Investigators assigned overseas." 61 FR 68631.

In summary, to date fee-fundable DCP activities have included: 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 have included travel, rent, utilities, supplies, equipment and services associated with the above-listed activities. Fee-fundable activities also have included activities related to the control of licit controlled substances in the United States in which the initial source is foreign. For example, smuggling a controlled substance into or introducing it into the United States is importation, albeit illegal, and constitutes an activity for which DEA registration and controls are required under the CSA and its implementing regulations; therefore activities to prevent smuggling fall under the purview of the DCP. Foreign-source substances potentially threaten the integrity of the closed system of distribution and undermine other diversion control efforts by DEA. They also may pose a public health threat and/or unlawful competition to legal, registered U.S. manufacturers and suppliers. The advance of the Internet in particular has made foreign-source substances more accessible in the United States and the diversion of these substances a greater problem. The DCP

now will address the activities that will be funded by the DDCFA as part of its programmatic responsibilities.

A more detailed description of the activities funded through the DDCFA is included in DEA's 1996 final rule (61 FR 68631) and amended final rule published on August 9, 2002 (67 FR 51988).

Current Fee-Funding

Since the last published rule in 1993, the Budget Authority for the Diversion Control Program has doubled without any associated increase in registrant fees. Currently, the fees established in 1993 are no longer adequate to recover the "full costs" of operating the DCP as required by law.

The Congressional appropriation for the DCP for Fiscal Year 1994 was \$57.1 million. For Fiscal Year 2004, the expected Budget Authority will be \$118,561,000 (this figure does not include the mandatory \$15 million transfer to the U.S. Treasury). The growth in the DCP has been driven by a number of factors some of which have been reflected in DEA budget submissions such as the creation of Tactical Diversion Squads in Fiscal Year 1997. Other DCP expansions include DEA's response to the diversion of OxyContin®, involving the opening of 247 cases from October 1999 through March 2002 (including 159 cases in Fiscal Year 2001 alone, a 270 percent increase from Fiscal Year 2000). These cases have led to a total of 328 arrests. DEA is also expending increasing time and resources on implementing its initial response to internet-based drug diversion, for which it has opened a number of cases leading to arrests and convictions. DEA has also seen an increase in the number of drug diversion cases leading to arrests. (The number of diversion arrests more than doubled in just five years, from 444 arrests in Fiscal Year 1995 to 941 diversion arrests relating to drug cases alone in Fiscal Year 2000. DEA made 871 diversion arrests relating to drug cases in Fiscal Year 2001, and 341 arrests in the first six months of Fiscal Year 2002. The slight decrease in arrests in Fiscal Year 2001 and the first half of Fiscal Year 2002 is attributable to a greater emphasis on chemical investigative activities.) These additional programmatic needs and responsibilities have required additional investigators, headquarters staff and increased financial resources to support these staff and their efforts to prevent the diversion of licit controlled substances

The following table shows the annual growth in Budget Authority for the DCP

from Fiscal Year 1994 through Fiscal Year 2006 (expected Budget Authority for FY03 and estimated Budget Authority for FY04, FY05, and FY06). The Budget Authority is based on the President's Budget Request. Note, these figures do not include the required annual \$15 million transfer to the U.S. Treasury.

Fiscal year	Budget authority (In 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 (est)	89
FY04 (est.)	118.6
FY05 (est.)	142.3
FY06 (est.)	145.3

In reviewing the activities currently supported by the DDCFA and the relevant legislation and regulatory actions governing the DCP and fee funding, DEA identified several elements of DEA operations that, though not part of the DCP, incidentally support the activities of the DCP and which to date have been funded through Congressional appropriations rather than through the DDCFA. 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; a section within the Office of Training that is specifically dedicated to the DCP; 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 DDCFA, 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 the DDCFA. 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.

Development of the New Fee Schedule

DEA set the current fee schedule for the Diversion Control Program (DCP) through publication in the **Federal Register** on March 22, 1993. This announcement outlined the general categories of cost to be borne by the resulting Drug Diversion Control Fee Account (DDCFA) and delineated the fee categories indicated below:

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

Since this announcement, the fees, which as required by law support the full cost of the Diversion Control Program, have not changed despite growth in the program and additional costs borne by the program (see the previous section). To recover the full costs of the DCP as required by law, DEA plans to incrementally raise the fees in accordance with its existing fee structure as follows:

Registrant class	Annual cost
Manufacturers	\$1,605
Distributors, Importers/Exporters	804
Dispensers/Practitioners	131
Researchers, Narcotic Treatment Programs	131

These increases in fees will go into effect 30 days after the publication of the final rule.

The determination of fees for the Fiscal Year 2004–2006 period covered by this notice is based on the expected Budget Authority for Fiscal Year 2004 (based on the President’s Budget Request) and the estimated budget request and appropriation for each subsequent year plus the annual \$15 million transfer to the U.S. Treasury. 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, 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 DDCFA of \$90 million). However, beginning in Fiscal Year 1999, Congress discontinued this additional appropriation.

The expected Budget Authority for Fiscal Year 2004 is \$118,561,000, which 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. Funds include \$12,518,000 for diversion investigation (for 93 positions), including OxyContin® diversion control and implementation of a system to detect Internet sites that may divert controlled substances and investigation of those sites, as warranted. This will permit DEA to conduct additional and more complex investigations into the diversion of pharmaceutical controlled substances. Other funds accounted for include \$12,098,000 (for 40 positions) to develop a system to permit the electronic transmission of controlled substances prescriptions from prescriber to pharmacy and to develop an electronic order form for Schedule I and II controlled substances. 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. The total cost of program enhancements for Fiscal Year 2004 is \$24,873,000. Including the mandatory transfer to Treasury of \$15 million, the total amount required to be recovered for Fiscal Year 2004 is \$133,561,000.

The anticipated President’s Budget Request for Fiscal Year 2005 is \$142,265,000. This figure accounts for increases in program costs due to inflation (including such items as postage rate increase, increases in cost of employee health benefits, increases in GSA rent, etc.), costs of federal staff pay increases, and an additional \$20,578,000 (for 39 positions). This figure includes costs to support the

systems to permit the electronic transmission of controlled substances prescriptions and electronic orders of Schedule I and II controlled substances, the support and operation of DEA’s Internet investigations, a major upgrade to the Automation of Reports and Consolidated Orders System (ARCOS), and significant improvements to registration customer/forms service. 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 \$157,265,000.

The anticipated President’s Budget Request for Fiscal Year 2006 is \$145,307,000 which accounts for inflationary growth from the previous fiscal year estimate and increases in Federal staff salaries. Including the mandatory transfer to Treasury of \$15 million, the total amount required to be recovered for Fiscal Year 2006 is \$160,307,000.

To calculate inflationary growth, DEA used inflation figures of 1.5 percent for Fiscal Year 2004, 1.6 percent for Fiscal Year 2005 and 1.7 percent for Fiscal Year 2006 and salary increase assumptions of 2.0 percent for Fiscal Year 2004 and 3.4 percent for both Fiscal Year 2005 and Fiscal Year 2006, based on the President’s Economic Assumptions. The total amount necessary to collect through fee funds for the Fiscal Year 2004–2006 period is \$451,133,000. Based on the amounts required to be collected for the 2004–2006 period to comply with the law, DEA developed the specific fee levels for each registrant category reflected in the previous table. 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 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 (FY 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 fees above reflect the *total amount* necessary to be collected for the full three-year period (FY 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 fees reflect the total amount necessary to be collected for the Fiscal Year 2004–2006 period, 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.

Regulatory Analyses

Regulatory Flexibility Act

The Deputy 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. While DEA recognizes that this regulation will have a financial effect on registrants with the increase in fees, the change in fees is not significant. Moreover, the fees have not been changed in nine 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 nine 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 proposed 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. 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 proposed in this regulation.

Executive Order 12866

The Deputy Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant regulatory action, but 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 and practitioners is minimal. The majority of the affected entities will pay \$131 per year (or \$391 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 text of the proposed rule.

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. 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 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 \$131 to \$1,605 per year with the majority of affected registrants paying an annual fee of \$131 (or \$391 for three years).

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 proposed to be 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 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	1,605	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.
		Renewal—225a	1,605		
(ii) Distributing	Schedules I-V	New—225	804	1	
		Renewal—225a	804		
(iii) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Teaching Institution).	Schedules II-V	New—224	391	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.
		Renewal—224a	391		
(iv) Research	Schedule I	New—225	131	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.
		Renewal—225a	131		
(v) Research	Schedules II-V	New—225	131	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.
		Renewal—225a	131		
(vi) Narcotic Treatment Program (including compounder).	Narcotic Drugs in Schedules II-V.	New—363	131	1	
		Renewal—363a	131		
(vii) Importing	Schedules I-V	New—225	804	1	May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.
		Renewal—225a	804		
(viii) Exporting	Schedules I-V	New—225	804	1	
		Renewal—225a	804		
(ix) Chemical Analysis	Schedules I-V	New—225	131	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.
		Renewal—225a	131		

Business activity	Controlled substances	DEA application forms	Applica-tion fee (\$)	Registra-tion pe-riod (years)	Coincident activities allowed
(x) Disposer	Schedules I-V	New—225	131	1	
		Renewal—225a	131		

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Dated: February 5, 2003.

John B. Brown III,

Deputy Administrator.

[FR Doc. 03-3765 Filed 2-14-03; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF AGRICULTURE

Forest Service

36 CFR Part 242

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 100

RIN 1018-A188

Subsistence Management Regulations for Public Lands in Alaska

AGENCIES: Forest Service, Agriculture; Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the U.S. Forest Service and U.S. Fish and Wildlife Service, are proposing to amend the regulations governing subsistence use of wildlife in Alaska by clarifying how old a person must be to receive a Federal Subsistence Registration Permit or Federal Designated Harvester Permit and by removing the requirement that Regional Councils must have an odd number of members. These changes are viewed as noncontroversial and are designed to ensure that the regulations for the Federal Subsistence Management Program in Alaska are easy for the public to understand and reflect current policies.

DATES: We must receive your written public comments no later than April 4, 2003.

ADDRESSES: Submit written comments to Office of Subsistence Management, 3601 C Street, Suite 1030, Anchorage, AK 99503. Submit electronic comments to *Bill_Knauer@fws.gov*. For electronic comments, please submit as either WordPerfect or MS Word files, avoiding the use of any special characters and any form of encryption.

FOR FURTHER INFORMATION CONTACT: For Forest Service questions, contact Ken

Thompson, Regional Subsistence Program Manager, USDA-FS Alaska Region, at (907) 786-3592. For Fish and Wildlife Service questions, contact Thomas H. Boyd at (907) 786-3888.

SUPPLEMENTARY INFORMATION:

Background

The regulations at 36 CFR part 242 and 50 CFR part 100 (referred to below as “the regulations”), authorized by Title VIII of the Alaska National Interest Lands Conservation Act (16 U.S.C. 3101-3126), implement the Federal Subsistence Management Program on public lands in Alaska.

On May 7, 2002, we published in the **Federal Register** (67 FR 30559-30571) a final rule that made certain changes to the regulations. In that final rule, we clarified how old a person must be to receive a Federal Subsistence Registration Permit or Federal Designated Harvester Permit, and we retained, without change, a long-held requirement that Regional Councils must have an odd number of members.

At the request of other agencies, in the final rule, we added language to § __.6(b) of the regulations to clarify that, “In order to receive a Federal Subsistence Registration Permit or Federal Designated Harvester Permit or designate someone to harvest fish or wildlife for you under a Federal Designated Harvester Permit, you must be old enough to have reasonably harvested that species yourself (or under the guidance of an adult).” Since the publication of the final rule, we have determined that this language could be misleading and should be further clarified. Therefore, we are proposing editorial changes to this paragraph to make it easier to understand.

In addition, in the final rule, we retained, without change, a long-held requirement in § __.11(b)(1) stating, “The number of members for each Regional Council shall be established by the Board, and shall be an odd number.” We retained the requirement that Regional Councils have an odd number of members to prevent the possibility of a tie during Council votes. Since the publication of the final rule, however, the Deputy Secretary of the Department of the Interior approved a Federal Subsistence Board recommendation to increase the size of Regional Councils to

10 or 13 members. These increases will help achieve better balance, as required by the Federal Advisory Committee Act (5 U.S.C. App.1), in Regional Councils. Further, we have learned that in Regional Council meetings, if a vote count is tied, that motion fails; therefore, our reason for requiring an odd number of members does not apply. In light of this new information, we are proposing to revise § __.11(b)(1) to remove the requirement that Regional Councils must have an odd number of members. This change would bring this paragraph into accord with current policies.

Elsewhere in today’s **Federal Register**, we have published a direct final rule to promulgate the same regulatory changes to 36 CFR 242 and 50 CFR 100 proposed here. We published the direct final rule because we believe these changes are noncontroversial and anticipate no adverse public comment on them. If we receive no adverse comments regarding these amendments within 45 days, then these changes become effective 60 days from today, and we will withdraw this proposed rule. If we do receive adverse comments, then this proposed rule initiates the normal notice-and-comment rulemaking proceedings. We are opening this comment period for 45 days instead of 60 days because we need this regulatory change in place prior to the councils’ recruitment and appointment process for the winter 2004 meeting cycle. This entire process normally takes a year to complete.

Required Determinations

Regulatory Planning and Review (E.O. 12866), Regulatory Flexibility Act (5 U.S.C. 601 et seq.), and Small Business Regulatory Enforcement Fairness Act (5 U.S.C. 804(2))

An economic analysis is not necessary, as this proposed rule would not have an economic impact on any entities, large or small. The Office of Management and Budget (OMB) has determined that this proposed rule is not a significant rule under E.O. 12866, and, therefore, OMB has not reviewed this proposed rule.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act: