

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.

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(e) * * *

(1)