

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

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

Executive Order 12866

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

Executive Order 12988

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

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

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

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. The net effect of

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

List of Subjects in 21 CFR Part 1301

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

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

PART 1301—[AMENDED]

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

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

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

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

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(1)