

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

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

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

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

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

E. Other DCP Operational Issues

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

DEA works diligently to achieve administrative efficiencies in all of its programs, including the Diversion Control Program. Through a scheduled, periodic review process, virtually all aspects of the DCP are inspected to detect any waste, fraud or abuse. All expenditures charged to the DDCFA also

are reviewed and approved by an independent unit charged with this task. Moreover, each of DEA's annual budget requests to Congress, which contains all components of each DEA program, including the DCP, is available for public review. Each budget request is examined and approved by both the Department of Justice and the Office of Management and Budget. DEA will continue to review expenditures through Fiscal Year 2006 and will adjust the fee schedule as necessary again at that time as a result of budget reviews. In February 2003 DEA also established a separate unit, the Diversion Fee Account Validation Unit, to review, approve, and audit fee-funded expenditures.

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

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

effectiveness of programs relative to long-term, measurable outcome goals.

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

VI. Effects on Small Businesses

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