U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

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Dear Registrant:

On April 16, 2012, the Drug Enforcement Administration (DEA) will begin collecting adjusted fees for registrations. These fees fund DEA's Diversion Control Program (DCP), which enforces the Controlled Substances Act and its regulations to prevent, detect and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring a sufficient supply for legitimate medical, scientific, research, and industrial purposes. The DCP is responsible for registering and regulating more than 1.4 million registrants who handle, dispense or prescribe controlled substances or listed chemicals. The program also maintains information technology infrastructures used by registrants to submit new or renewal applications, order controlled substance pharmaceuticals, and submit required reports to DEA in electronic format. The DCP employs more than 1,400 personnel who, in addition to registration activities, conduct administrative, civil and criminal investigations that expose and obstruct unlawful diversion activities. The DCP is also responsible for managing and issuing quotas, and conducting rulemaking and scheduling actions.

This fee adjustment is the first since 2006. Although fee adjustments are generally considered every three years, DEA was able to maintain fees at the 2006 level for several additional years as a result of cost savings efforts and efficiencies. However, without an adjustment to the current fee structure, DEA cannot sustain appropriate and necessary staffing levels and operational effectiveness, and will be unable to continue current operations. DEA is required by law to set fees at a level that will allow it to recover the full costs of operating the various aspects of the DCP, and as a result, DEA must now adjust the fee schedule to meet that statutory mandate. For the vast majority of registrants (healthcare practitioners), the increase will be $5 per month over a three-year registration period.

The mission of the DCP is more important now than ever. Several national studies demonstrate that prescription drug abuse is on the rise, and a rise in abuse imposes significant costs throughout the system and on society. According to the 2010 National Survey on Drug Use and Health (NSDUH), seven million Americans were current (past month) non-medical users of psychotherapeutic drugs. This statistic is significantly higher than what was reported in 2008 (6.2 million more persons, or an increase of 12 percent). Over three-quarters of that number, 5.1 million Americans, reported non-medical use of pain relievers. The consequences of prescription drug abuse are seen in the data collected by the Substance Abuse and Mental Health Services Administration

(SAMHSA) on emergency room visits. According to the latest data, SAMHSA estimates that of the 4.6 million emergency department visits in 2009 associated with drug use, about 1.2 million visits involved the non-medical use of pharmaceuticals. Emergency department visits involving non-medical use of pharmaceuticals (misuse or abuse) almost doubled between 2004 and 2009, representing a 98.4 percent increase. About half of the 2009 emergency department visits related to abuse or misuse of pharmaceuticals involved painkillers and more than one-third involved drugs to treat insomnia and anxiety.

In response to the rise in abuse, over the past several years Congress has expanded the scope of the DCP through legislative actions aimed at controlling the diversion of controlled substances and listed chemicals. Some of these actions include the Combat Methamphetamine Epidemic Act, the Ryan Haight Online Consumer Protection Act, and the Secure and Responsible Drug Disposal Act. DEA has also responded to emerging trends by enhancing certain programs and operations. For example, the DCP has increased scheduled investigations and drug scheduling initiatives, and made other modifications in its diversion control efforts. Congress has supported these enhancements in budgets passed during the FY 2009 – FY 2012 timeframe. Additionally, operational expenses have also increased; DEA must fund inflationary increases in areas such as rent and payroll. Total obligations for the DCP have increased from FY 2007 to FY 2010 by approximately 49 percent, primarily due to payroll, operating, and capital expenditures. DEA has been and continues to be fiscally responsible and has made every effort to project collections and expendituresto minimize costs to registrants.

The process of developing the new fee schedule began with the July 2011 Notice of Proposed Rulemaking (NPRM) published in the Federal Register. This NPRM announced DEA's intention to adjust the registration fees that support the DCP, proposed a methodology for doing so, and solicited public comment. DEA received numerous comments in response to the NPRM. DEA carefully reviewed and thoroughly considered the concerns reflected in the comments.

DEA's Final Rule regarding Controlled Substances and List I Chemical Registration and Reregistration Fees is now available for public inspection with the Federal Register Electronic Public Inspection Desk (www.federalregister.gov/public-inspection). On March 15, 2012, this Final Rule will be published in the Federal Register (https://federalregister.gov/a/2012-06253). The Final Rule and supporting documents (New Registrant Fee Schedule Calculations and Economic Impact Analysis) describe in detail the need for the adjustment in fees, and the DEA's consideration of the various methodologies for the allocation of fees.

In determining the new fee structure, DEA considered four methodologies in light of the amount of the fee, the change in fee as a percentage of registrant revenue in recent years, and the relative increase across registrant groups. The four options included the Past-Based option, the Future-Based option, the Flat-Fee option and the Weighted-Ratio option.

For reasons described in the Final Rule, DEA selected aWeighted-Ratio option. The different fees are expressed in ratios: 1 for researchers, canine handlers, analytical labs, and narcotic treatment programs; 3 for registrants on three year registration cycles such as pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners; 6.25 for distributors and importers/exporters; and 12.5 for manufacturers. Accordingly, the new fees are as follows:

Registration and Reregistration Fees

Registrants on Three Year Registration Cycle

Registrant Class/Business	Current Three YearFee*	New Three Year Fee*	Difference Per Year
Pharmacy	$551	$731	$60
Hospital/Clinic	$551	$731	$60
Practitioner	$551	$731	$60
Teaching Institution	$551	$731	$60
Mid-Level Practitioner	$551	$731	$60

*Pharmacies, hospitals/clinics, practitioners, teaching institutions, and mid-level practitioners currently pay a fee for a three-year period. This current three-year fee is $551. The new fee for the threeyear registration period would be $731. The three year difference is $180, or an annual difference of $60.

Registrants on Annual Registration Cycle

Registrant Class/Business	Current Annual Fee	New Annual Fee	Difference
Researcher/Canine Handler	$184	$244	$60
Analytical Lab	$184	$244	$60
Maintenance	$184	$244	$60
Detoxification	$184	$244	$60
Maintenance and Detoxification	$184	$244	$60
Compounder/Maintenance	$184	$244	$60
Compounder/Detoxification	$184	$244	$60
Compounder/Maintenance/ Detoxification	$184	$244	$60
Distributor (chemical and controlled substances)	$1,147	$1,523	$376
Reverse distributor	$1,147	$1,523	$376
Importer (chemical and controlled substances)	$1,147	$1,523	$376
Exporter (chemical and controlled substances)	$1,147	$1,523	$376
Manufacturer (chemical and controlled substances)	$2,293	$3,047	$754

As explained in the Economic Impact Analysis supporting the Final Rule, DEA concluded that theFinal Rule does not result in a materially adverse effect on the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities. DEA recognizes that any increase to the fee structure impacts the registrant community and has worked diligently to avoid any increase over the last several years

and, now that an increase is required, minimize the economic impact on registrants. DEA believes that it has achieved these objectives, while aligning the DCP's funding to accommodate activities that areessential to protect the public health and safety.

More detailed information, including the NPRM, the Final Rule, and the supporting documents, may be found on DEA's website: www.deadiversion.usdoj.gov. DEA appreciates the support it receives from the regulated community, and looks forward to continuing to work in partnership to maintain the integrity of the closed system of distribution for controlled substances.

Sincerely,

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control