

veterinarian-client relationship. One commenter also alleged that Internet pharmacies are selling pharmaceuticals without prescriptions from authorized practitioners. Three commenters from the same institution suggested that the DEA tax the Internet drug companies to fund the DCP and leave the current controlled substance handlers fees at the same level.

DEA assures the commenters that any violations of the Controlled Substances Act, including the unauthorized dispensing of controlled substances, are subject to prosecution to the fullest extent of the law. Over the past several years, DEA has undertaken a number of concerted initiatives to control and prevent the diversion of licit controlled substances over the Internet, with the number of diversion arrests more than doubling between Fiscal Year 1995 and Fiscal Year 2000. DEA's diversion control actions do not cover legal commerce transactions such as the legal dispensing of controlled substances through Internet sites or the sale of non-controlled substances (such as other veterinary products) which is outside the purview of the DEA. DEA also notes that Internet pharmaceutical companies, like other dispensers of controlled substances, must register with the DEA in order to handle controlled substances and as such already pay a registration fee like other registered dispensers.

IX. Miscellaneous Issues

A. Mandatory \$15 Million Transfer to U.S. Treasury

One commenter objected to registrant fees supporting the mandatory transfer of \$15 million to the U.S. Treasury, noting that this burden should not be placed on registrants and requesting that DEA petition Congress to appropriate the required \$15 million, so that all fee funds are used to support DCP activities.

DEA is required by the Appropriations Act of 1993 to transfer the first \$15 million of fee revenue to the General Fund of the Treasury each year (21 U.S.C. 886a(1)). Calculation of the fees, therefore, must account for this mandated transfer. That is, DEA has no discretion in that matter, and the fees collected by DEA must represent the total amount necessary to "fully fund" the DCP by law *plus* an additional \$15 million. For the period of Fiscal Year 1993 through Fiscal Year 1998, Congress appropriated an additional \$15 million to offset the transfer requirement (a total infusion to the DDCFA of \$90 million). However, beginning in Fiscal Year 1999, Congress discontinued this additional appropriation, and the additional \$15

million became an additional net expense to the DCP at that time. Congress has not agreed to appropriate the additional \$15 million towards the mandatory transfer since that time.

B. Alternative Funding Sources for DCP

Seven commenters raised the issue of finding alternative sources of funding for the DCP to replace the registration fees, including congressional funding and collecting fees from other non-registrant entities (e.g., health insurance companies). As has been detailed above, DEA's authority to charge registration fees to support the DCP derives from three statutory provisions. Of these provisions, the Appropriations Act of 1993 specifically mandates that DEA collect through fees an amount sufficient to ensure the recovery of the "full costs" (emphasis added) of the DCP (21 U.S.C. 886(a)(3)). That is, DEA is required by statute to fully fund DCP expenses *through registration fees*. For the period of Fiscal Year 1993 through Fiscal Year 1998, Congress appropriated an additional \$15 million to the DDCFA to offset the annual mandatory \$15 million transfer to the U.S. Treasury described in the previous section. Such appropriations were discontinued beginning in Fiscal Year 1999, and the DCP remains entirely funded through registration fees.

C. Clarification of Fee Amount

Certain registrants pay a single fee for a three-year registration period. Such registrants include dispensers (including practitioners, hospitals/clinics, and retail pharmacies) and teaching institutions. Since publication of the February 18, 2003 notice of proposed rulemaking, DEA has finalized a number of other regulatory actions which affect the CFR sections amended by this final rule. On June 24, 2003, DEA finalized regulations regarding the use of central fill pharmacies to fill controlled substances prescriptions on behalf of retail pharmacies (68 FR 37405). This final rule amended 21 CFR 1301.13(e)(1)(iii) to add "central fill pharmacy" as a business activity under dispensing (effective July 24, 2003). Consequently, central fill pharmacies are subject to the same fee as all other dispensers, including pharmacies and teaching institutions. Effective with this rulemaking, the registration/reregistration fee for dispensers, including central fill pharmacies, and teaching institutions is \$390 for a three-year period.

Because other categories of registrants secure a registration on an annual basis, much of the discussion in this rulemaking addressed the value of

annual registration. In such discussions, DEA often referred to an annual value of \$130 which is one-third of \$390.

The annual registration and reregistration fee for researchers, narcotic treatment programs (including compounders), effective with this rulemaking, is \$130. These categories of registrants obtain a registration and pay the associated fee on an annual basis.

This rulemaking also establishes new annual registration/reregistration fee amounts for manufacturers of \$1,625, for distributors of \$813, for importers of \$813, and for exporters of \$813. Reverse distributors are subject to the same annual fee of \$813 as distributors as a result of an interim rule published by DEA on July 11, 2003 defining "reverse distributor" and establishing reverse distributor as a new category of registration. (68 FR 41222). This interim rule amended 21 CFR 1301.13 by redesignating paragraph (e)(1)(iii) which contained dispensing activities as paragraph (e)(1)(iv) and adding a new paragraph (e)(1)(iii) "reverse distributors". In its February 18, 2003 **Federal Register** notice proposing new registration and reregistration application fees, DEA inadvertently included language in the regulatory text regarding fees to be assessed to reverse distributors (referred to as "disposers" in the proposed rulemaking), although regulations establishing reverse distributor as a new registration category had not yet been established. As regulations establishing reverse distributors as a new category of registration have now been established, the fees included in this final rule are now accurate and apply as delineated above to this category of registrants. In its February 18, 2003 proposed rule DEA also inadvertently assigned an incorrect annual fee of \$131 to disposers. As described above, reverse distributors or disposers, like other distributors, are subject to an annual fee of \$813.

Regulatory Analyses

Regulatory Flexibility Act

The Deputy Assistant 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. DEA recognizes that this regulation will have a financial effect on a substantial number of registrants with the increase in fees; however, DEA believes that, based on the length of time between fee