

**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****21 CFR Parts 1301 and 1309**

[Docket No. DEA-266F]

RIN 1117-AA96

**Controlled Substances and List I Chemical Registration and Reregistration Application Fees**

**AGENCY:** Drug Enforcement Administration (DEA), Department of Justice.

**ACTION:** Final Rule.

**SUMMARY:** This final rule establishes the fee schedule for DEA registration and reregistration fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals to appropriately reflect all costs associated with its Diversion Control Program for the conduct of activities as mandated by 21 U.S.C. 822 and 958. Specifically, this final rule revises the fee schedule for controlled substances and List I chemical handlers so that all manufacturers, distributors, importers, exporters, and dispensers of controlled substances and of List I chemicals pay an annual fee, by registrant category, irrespective of whether they handle controlled substances or List I chemicals. In doing so, this rule implements clarifications to the Diversion Control Program and the Diversion Control Fee Account made by Congress in the Consolidated Appropriations Act of 2005 (Pub. L. 108-447) that amended 21 U.S.C. 886a.

**EFFECTIVE DATE:** This rule is effective November 1, 2006. The new fee schedule will be in effect for all new applications postmarked on or after November 1, 2006 and for all renewal applications postmarked on or after November 1, 2006.

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**SUPPLEMENTARY INFORMATION:****I. Background and Statutory Authority**

The Drug Enforcement Administration published a Notice of Proposed Rulemaking in the **Federal Register** on November 16, 2005 (70 FR 69474) to adjust the registration and reregistration fees for controlled substances and List I chemical handlers.

The Controlled Substances Act (CSA) requires that all manufacturers,

distributors, dispensers, importers and exporters of controlled substances and List I chemicals obtain an annual registration with DEA (21 U.S.C. 822 and 958(f)). In addition, the CSA, as codified in 21 U.S.C. 821, authorizes the Attorney General, who in turn redelegates this authority to the Administrator of DEA, to “promulgate rules and regulations and to charge reasonable fees relating to the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals” (21 U.S.C. 821 as amended by Pub. L. 108-447).

In October 1992, Congress passed the Departments of Commerce, Justice and State, the Judiciary and Related Agencies Appropriations Act of 1993 which changed the source of funding for DEA’s Diversion Control Program (DCP) from being part of DEA’s Congressional appropriation to full funding by registration and reregistration fees through the establishment of the Diversion Control Fee Account (DCFA). The Appropriations Act of 1993 required that “[f]ees charged by the Drug Enforcement Administration under its diversion control program shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program.” The legislation did not, however, provide clarification on what constituted the “Diversion Control Program,” thus leaving open the issue as to what fee-setting criteria should be used to determine which costs could be reimbursed from the DCFA.

In response to the Appropriations Act of 1993, DEA published a Notice of Proposed Rulemaking (NPRM) in December 1992 to adjust the registration and reregistration fees for controlled substance registrants (57 FR 60148, December 18, 1992). In the absence of guidelines from Congress regarding the specific criteria to be followed in identifying costs and setting the fees, DEA relied on the plain language of the Appropriations Act of 1993 and proposed fees necessary to cover the costs of the activities that were identified within the budget decision unit known as the “Diversion Control Program.”

At the time that the Appropriations Act of 1993 was passed, 21 U.S.C. 821 did not extend to chemical control activities; accordingly, there were no registration or fee requirements for handlers of listed chemicals. DEA therefore excluded chemical control costs from its Final Rule implementing the requirements of the Appropriations Act of 1993 (58 FR 15272, March 22, 1993). Congress amended 21 U.S.C. 821

on December 17, 1993 to require reasonable fees relating to “the registration and control of regulated persons and of regulated transactions” (Domestic Chemical Diversion Control Act of 1993, 3(a), Pub. L. 103-200, 107 Stat. 2333); however, despite this amendment, DEA continued to endeavor to maintain separate funding for its controlled substances diversion control and its chemical diversion control activities. That is, DEA has paid for its controlled substance diversion control activities through the Diversion Control Fee Account and registration fees and its chemical diversion control activities through appropriated funds.

Following publication of DEA’s Final Rule, the American Medical Association (AMA) and others filed a lawsuit objecting to the increase in registration and reregistration fees on the grounds that DEA had failed to provide adequate information as to what activities were covered by the fees and how they were justified. Upon appeal, the United States Court of Appeals for the District of Columbia Circuit remanded, without vacating, the rule to DEA, requiring the agency to provide an opportunity for meaningful notice and comment on the fee-funded components of the DCP. In doing so, the court confirmed the boundaries of the DCP that DEA can fund by registration fees, finding that the current statutory scheme (21 U.S.C. 821 and 958) required DEA to set reasonable registration fees to recover the full costs of the DCP. (*AMA v. Reno*, 57 F.3d 1129, 1135 (DC Cir. 1995)).

Thus, in the absence of a simple, objective measure by which DCP costs could be identified and the appropriate fees calculated, both DEA and the courts have looked to 21 U.S.C. 821 and 958 to define the guidelines for determining what costs should be included in the calculation of the fees and from whom the fees might be collected.

On November 20, 2004, Congress passed the Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act of 2005 which provided clarification as to the activities constituting the DCP. This Act was included in the Consolidated Appropriations Act of 2005, which was signed into law by the President on December 8, 2004 (Pub. L. 108-447). The Act amended 21 U.S.C. 886a to define the Diversion Control Program as “the controlled substance and chemical diversion control activities of the Drug Enforcement Administration,” which are further defined as the “activities related to the registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed

chemicals.” It also amended the section to provide that reimbursements from the DCFA “\* \* \* shall be made without distinguishing between expenses related to controlled substances activities and expenses related to chemical activities.” Finally, the Act amended 21 U.S.C. 821 and 958(f) to make the language of those sections consistent with the definition of the DCP (Pub. L. 108–447). The net effect of the amendments is to allow DEA to deposit all registration and reregistration fees (controlled substance and chemical) into the Fee Account and fund all controlled substance and chemical diversion control activities from the account without distinguishing as to the type of activity (controlled substance or chemical) being funded.

While the comingling of controlled substances diversion control and chemical diversion control fees and activities might seem initially to be incongruous, there is, in fact, a significant amount of overlap, both in terms of activities and registrant populations. While it is easy to distinguish between handlers of controlled substances and the handlers of commodity chemicals such as red phosphorous, hydriotic acid, acetic anhydride and nitroethane, the line between handlers of controlled substances and handlers of drug products that contain listed chemicals is blurred considerably. Not only are the drug products that contain List I chemicals often manufactured by controlled substances manufacturers, they are commonly distributed by controlled substances distributors and routinely sold or dispensed by pharmacies, hospitals, and individual practitioners. In calendar year 2004, there were over 30 million prescriptions filled for drug products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine, which is still routinely used in veterinary products. There are undoubtedly many instances in which practitioners also provided their patients with free samples of allergy and cough and cold preparations that contain those chemicals. Within this general environment, the use of a single, unified account to fund the controlled substances and chemical diversion control activities of DEA is consistent with the mandates of the law.

DEA is bound by all of the above-referenced statutory requirements in setting fees that recover the “full cost” of the Diversion Control Program and its activities, as defined in the most recent lawmaking action. Therefore, DEA has developed this rulemaking according to these legislative mandates.

## II. Comments Received

Following publication of the Notice of Proposed Rulemaking on November 16, 2005, DEA received 12 comments to the notice. Three comments were received from practitioners (one physician, one physician assistant, and one dentist); three comments were received from manufacturers or distributors; five comments were received from organizations representing different registrant groups; and one comment was submitted anonymously.

Most commenters raised concern about the increase in fees, particularly for chemical registrants. Two commenters in particular wrote that the increase in fees will have a significant impact on chemical registrants compared to current fee rates and proposed an alternative fee increase. One commenter wrote that programs within DEA should be downsized or eliminated to maintain a “neutral budget” and keep costs lower. Three commenters expressed concern that the fee increase is coming at a time when Congress and other entities are re-evaluating medical reimbursements; one physician commented that he would pay the new fee as soon as his reimbursements increased by the same percentage. Another expressed concern that the cost of the increased fees would discourage physicians from registering with DEA and using controlled substances, thus affecting patient care.

Five commenters objected to the removal of the waiver of the chemical registration requirement for controlled substances registrants that handle drug products that are regulated as List I chemicals. The commenters wrote that they believed removal of this waiver would damage the ability of affected registrants to service their customer base and posed an unreasonable hardship. Two commenters also noted that removal of the waiver could create expensive administrative burdens for both registrants and for DEA.

Two registrants objected to the existing fee exemption for certain entities such as some Federal agencies, certain charitable organizations, law enforcement entities, and military personnel. Commenters noted that exempting these organizations results in larger fees for fee-paying registrants and requested reevaluation of this policy by DEA.

Two commenters raised the issue of performance standards tied to the increase in fees and requested clarification on DEA’s expected outcomes as a result of the increased fees and the performance measures and

metrics DEA has established to assess these outcomes.

One commenter wrote that the required \$15 million annual transfer to the U.S. Treasury out of collected fee funds was a significant percentage of the total fees collected, and the commenter urged DEA to request that Congress resume its annual \$15 million appropriation to offset this transfer. The commenter wrote that it, too, would work to see this appropriation restored.

One anonymous commenter wrote that medical marijuana is “most popular in California especially with grayhaired men and women.” Marijuana is not a licit controlled substance or listed chemical covered by this rulemaking and is not affected by this final rule; accordingly, this comment is not further addressed in this section. Another commenter, a practitioner, submitted a request for reregistration materials through the comment response vehicle. These materials were provided to the commenter, and this matter is not addressed further in this rulemaking.

Three commenters requested that DEA extend implementation of the final rule, noting that the rule comes in the middle of budget cycles for many registrants who had not planned for increased fees as part of their budgets and that it also comes at a time of statutory and other change for the industry. Each of these comments is addressed below.

## III. Objection to Fee Increase

Nine of the twelve comments received by DEA expressed opposition to the increase in fees. As described above, 21 U.S.C. 821 (as amended by Pub. L. 108–447) authorizes DEA to collect reasonable fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals. In addition, the 1993 Departments of Commerce, Justice, and State, the Judiciary, and Related Agencies Appropriations Act that established the Diversion Control Fee Account (DCFA) specifically mandated that fees “shall be set at a level that ensures the recovery of the full costs of operating the various aspects of that program” (21 U.S.C. 886a(3)). Congress, in using the mandatory term “shall” as opposed to the discretionary “may,” unambiguously required DEA to increase its then-existing registration fees resulting in registrants fully funding DCP expenses. DEA, therefore, lacks discretion in this matter and must fund the DCP totally from registration fees (that is, not from fines, Congressional appropriations or other potential sources).

Accordingly, while DEA recognizes the economic pressures facing practitioners, such as declining Medicaid reimbursements and increasing operating, equipment, and insurance costs, the current statutory scheme requires DEA to set registration fees to recover the full costs of the DCP, while limiting DEA to charge "reasonable" fees relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals. DEA does not have the discretion to partially fund the DCP or to find alternative sources of funding for the program. Rather DEA is mandated by law to fund the DCP fully through registration fees. The registration fees outlined below are set at a level to support the full costs of the DCP as mandated by law.

With clarification of the activities constituting the DCP in the Appropriations Act of 2005, DEA is now required to evaluate the "full costs" of the DCP to include all controlled substances and all listed chemical diversion control activities; whereas, previously the only DCP costs supported through registrant fees were controlled substances diversion control costs, and listed chemical diversion control activities were supported through appropriated funds. (See the Notice of Proposed Rulemaking published on November 17, 2005, 70 FR 69474) for additional discussion on this separation of activities.) In fact, operating the DCP as a cohesive whole, that is without distinction in activities between controlled substances and chemical diversion control activities, offers scale efficiencies and ultimately cost savings and improved services for registrants.

The fees set forth in this final rule reflect calculation of the full costs of both the controlled substances and chemical diversion control activities of the DCP. The revised fee structure contained in this final rule includes annual fees (or fee equivalent) ranging from \$184 to \$2,293. DEA recognizes that the increase in fees may represent a budgeting challenge for registrants, particularly registrants with multiple sites requiring separate registrations (e.g., chain drug stores), however, because the fees do not represent a significant financial burden on registrants, DEA has determined that the fees contained in this final rule are reasonable. DEA expects that among all registrants, mid-level practitioners and chemical distributors may feel the greatest impact of the new fees (see discussion in Section XII). However, for most registrants qualifying as small

businesses the revised fee will have a minimal impact, representing from 0.28 percent to as little as 0.01 percent of average annual sales (or income). For registrants that are large businesses with higher annual sales, the impact of the fee is far less.

#### *A. Differences in Fee Increase Among Registrant Categories*

Two commenters expressed concern that the fees for chemical registrants under this final rule reflect a higher percentage increase than the change in fees for controlled substances registrants. Commenters noted that fees for chemical manufacturers will increase by approximately 300 percent and that fees for chemical distributors will increase by about 100 percent compared to the current fee structure for these chemical registrants. Commenters proposed an alternative fee increase for these categories based on the same percentage increase as controlled substances manufacturers and distributors.

Currently, chemical handlers pay a user fee that supports only the costs of registration/reregistration and some administrative oversight—not the operating costs of the DEA's chemical diversion control program. With the transfer of DEA's chemical control program costs to the DCFA, chemical registrants must, together with controlled substances registrants, pay a fee to cover the full costs of the DCP. The same circumstance occurred in 1993 with the establishment of the DCFA; controlled substances registrants were faced with a substantial increase in their fees as they transferred from a similar user fee that supported registration costs only to a fee schedule to cover the full costs of DEA's controlled substances diversion control activities. With the transfer of the chemical control program costs to the DCFA and the amendments to the law that reimbursements shall be made without distinguishing between chemical and controlled substances activities, chemical registrants must now be included in the DCFA population and pay the fees necessary to sustain that account.

DEA does not have the discretion to adjust fees according to percentages, such as was proposed by the commenters, as it is required to fully fund the DCP through fees paid by the registrants while also maintaining reasonable fees.

#### *B. Program Costs*

One commenter suggested that DEA downsize or eliminate programs to maintain a neutral budget and keep fees

low. 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 DCFA also are reviewed and approved by an independent unit within DEA that reviews, approves, and audits fee-funded expenditures.

Moreover, each of DEA's annual budget requests to Congress, which contain 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 has undertaken several initiatives to streamline aspects of the DCP both for DEA and for registrants. For example, DEA is developing a system to permit the electronic transmission of controlled substances prescriptions through electronic creation, signature and record retention, which will significantly increase the efficiency by which prescriptions are transmitted from prescriber to pharmacy; however, it will not reduce the review requirements of DEA employees that monitor the prescription process for controlled substances. DEA has developed a system that permits the electronic transmission of controlled substances orders which provides increased efficiencies for industry. Moreover, in 2005, DEA underwent an internal reorganization to increase operational efficiencies and keep costs as low as possible. This reorganization shifted the focus from business decision units to activities that support the registration and control of the manufacture, distribution, and dispensing of controlled substances and listed chemicals. However, DEA is also subject to costs related to inflation and additional costs of "doing business" that face all organizations despite its best efforts to keep these expenses reasonable.

#### *C. Effect of Fee Increase on Practitioner Registration*

One practitioner commenter noted concern that increases to annual registrant fees could reduce the number of physicians registering with DEA and using controlled substances as part of patient care. The Controlled Substances Act requires that every person who manufactures, distributes or dispenses any controlled substance or who proposes to engage in the manufacture, distribution or dispensing of any controlled substance obtain an annual

registration (21 U.S.C. 822(a)(1) and 822(a)(2)).

DEA notes that the impact of the annual registration fee on practitioners (\$184 annual equivalent) is not significant, ranging from a high of 0.28% to a low of 0.13% based on annual income for this registrant category (see discussion below on small business impacts). The majority of registered practitioners (71 percent) are physicians whose annual income averages more than \$140,000 and for whom the \$184 annual fee equivalent represents approximately 0.13 percent of annual income. Other large practitioner groups in this category include dentists (16 percent of practitioners) for whom the annual fee equivalent represents about 0.14 percent of their average annual income of \$133,000 and veterinarians (5 percent of practitioners) for whom the annual fee equivalent equates to 0.25 percent of their average annual income of \$76,000. The revised fee will have greater impacts on other types of practitioners (less than 5 percent of all registered practitioners) with lower annual incomes, including nurse practitioners, physician assistants, optometrists, and others for whom the annual fee equivalent has an average impact of approximately 0.16–0.28 percent.

#### **IV. Removal of Waiver for Chemical Registrants Holding an Existing Controlled Substances Registration**

Four commenters objected to the removal of the waiver of the registration requirement for persons who distribute, import or export a drug product containing a List I chemical if that person is already registered with DEA to manufacture, distribute or dispense, import or export a controlled substance. Commenters noted that removal of this waiver could dramatically increase the annual registration fees for affected registrants and would damage their ability to service their customers, would pose an “unreasonable hardship,” and could adversely affect the List I chemical supply chain since many affected registrants also hold a controlled substances registration. One commenter also noted that removal of this waiver could require significant changes to internal operations for affected registrants who would have to maintain two DEA registrations, imposing significant paperwork, technological and operational burdens. The commenter also suggested removal of the waiver could result in increased operational burdens for DEA.

After careful review of these comments and consideration of the benefits compared to the drawbacks

associated with removal of this waiver, DEA has decided to retain the current registration waiver for persons who distribute, import, or export a product containing a List I chemical who already hold a valid DEA registration to manufacture, distribute or dispense, import, or export a controlled substance.

Accordingly, the proposed changes to the waiver provision are removed.

DEA will address registration issues created by passage of the Combat Methamphetamine Epidemic Act of 2005, included in the USA PATRIOT Improvement and Reauthorization Act of 2005 (Pub. L. 109–177) as part of the Act’s implementing regulations.

#### **V. Registration Fee Waivers for Certain Organizations and Persons**

Two commenters objected to DEA’s fee exemption for certain entities and persons. Currently, government institutions, law enforcement agencies, and military personnel are exempt from fees. In addition, DEA waives fees for some charitable organizations. The commenters objected to these fee waivers suggesting that the process is inequitable and that the net result is higher fees for fee-paying registrants than if these organizations were also required to pay annual registration and reregistration fees. The commenters also asserted that fee-paying registrants are paying a “hidden contribution” or “forced donation” to charitable organizations, without tax relief, by partially subsidizing their fee requirements.

DEA appreciates these comments. DEA recognizes that exempting certain entities from paying annual fees provides a benefit to some at the expense of others and is evaluating its current practice of exempting certain organizations and persons from annual registration fees. Any changes to this practice will require a separate regulatory process, including notice and comment.

#### **VI. Performance Standards**

Two commenters objected to the omission of anticipated outcomes or results expected by DEA as a result of the increased fees. The commenters requested detail on how DEA will track such results and correlate them to the higher fees while recommending the development of a system of metrics, accountability and reporting for the DCP.

The Government Performance and Results Act (GPRA) and the President’s Management Agenda (PMA), requires DEA, like all other agencies and components, to provide a budget summary that incorporates performance

information on a quarterly basis. In response to these requirements, 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 PMA, the DCP’s budgetary reporting on outlays from the DCFA includes performance measures that are consistent with DEA’s Strategic Plan and that reflect the effectiveness of programmatic activities funded by registrant fees. Among the objectives included in 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, are intended to provide benefits to the registrant population such as streamlined processing and improved access to information. They are also intended to reduce the paperwork burden on small businesses; reduce forged or stolen prescriptions; improve authentication and 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.

All budget submissions for the Diversion Control Program, like submissions for all programs across DEA, are subject to multiple levels of scrutiny and review within DEA, the Department of Justice, and the Office of Management and Budget before being included in the President’s annual Budget Request to Congress.

#### **VII. \$15 Million Treasury Transfer**

One commenter urged DEA to request that Congress resume the annual \$15 million appropriation to offset the requirement that the first \$15 million in fee collections be transferred to the Treasury, so that all fee funds may be used for DCP activities. The commenter noted that the annual \$15 million transfer represents a “significant component” of the amounts to be collected each year.

The Appropriations Act of 1993 requires that DEA transfer the first \$15 million of fee revenue to the General Fund of the Treasury each year (21 U.S.C. 886a(1)). For each fiscal year from Fiscal Year 1993 through Fiscal Year 1998, Congress appropriated an additional \$15 million to offset this requirement (a total infusion to the DCFA of \$90 million). However, beginning in Fiscal Year 1999, Congress

discontinued this additional appropriation. Accordingly, since Fiscal Year 1999, DEA has to include the annual \$15 million transfer for fee calculations; that is, DEA must pay for all operational costs of the DCP plus the \$15 million transfer out of fee funds collected from registrants.

### VIII. Extension of Implementation of the Final Rule

Three commenters requested delay of implementation of the final rule to Fiscal Year 2007 or later. Two commenters requested the delay because of the potential effects of removal of the registration waiver for chemical handlers holding a current controlled substance registration. Following careful review of comments, DEA has decided to keep this waiver intact (see discussion above).

Three commenters requested the delay because of ongoing changes in the industry, including pending state and Federal legislation affecting over-the-counter products containing listed chemicals (such as products containing pseudoephedrine and ephedrine). One commenter noted that such pending legislation could affect distributors carrying these products and therefore DEA registrations and revenue projections. The commenters also noted that the fee modifications are coming at a time when Congress, Federal agencies, and private party payers are exploring methods for reducing reimbursement for prescription drugs. Two commenters wrote that implementation of the final rule would come in the middle of budget cycles for affected registrants and would, therefore, impose financial challenges because of the unanticipated additional expenses in the annual fees, particularly for chain drug stores with many separately registered sites. DEA notes that very few chain registrants have registrations expiring during the current calendar year, thus limiting the potential impact of the fee increase in the current budget cycle. With respect to pending legislation and its possible effect on DEA registrations, DEA takes into account the potential ebb and flow of the registrant population through the retirement of old registrations and new applications for registration when calculating the fees. DEA cannot delay implementation of the new fee schedule as the agency is required, by statute, to recover the full costs of the diversion control program through registration fees.

### IX. Overview of Diversion Control Program Responsibilities

The mission of DEA's Diversion Control Program (DCP) is to enforce the

provisions of the Controlled Substances Act as they pertain to ensuring the availability of controlled substances and listed chemicals for legitimate uses in the United States while exercising controls to prevent the diversion of these substances and chemicals for illegal uses.

DCP activities include: Program priorities and field management oversight; coordination of major investigations; drafting and promulgating of regulations relating to the enforcement of the CSA and other legislation; establishment of national policy on diversion; fulfillment of U.S. obligations under drug control treaties; advice and leadership on state legislation/regulation; legal control of drugs and chemicals not previously under Federal control; control of imports and exports of licit controlled substances and chemicals; and program resource planning and allocation, among other activities.

As was outlined in the Notice of Proposed Rulemaking, DCP activities funded to date out of the DCFA have been limited to controlled substances diversion control activities, including controlled substances scheduling, registration, investigation, inspection, data collection and analysis, training, establishing production quotas, cooperative efforts with state, local and other Federal agencies, cooperative efforts with the regulated industry, international activities relating to the registration and control of the manufacture, distribution and dispensing of controlled substances, and attendant management, personnel, administrative and clerical oversight for the DCP. Fee-fundable activities also have included travel, rent, utilities, supplies, equipment, and services associated with the above-listed activities and activities related to the control of licit controlled substances in the U.S. in which the initial source is foreign. One commenter wrote that administrative expenses should not be paid for out of the DCFA and fee funds; however, the courts have found that all activities and expenses that are directly related to diversion control may be funded with registration and reregistration fees (*AMA v. Reno*, 57 F.3d 1129, 1135 (DC Cir. 1995)). Administrative and other operational costs are directly related to the ongoing diversion control efforts of the DCP.

With the inclusion of the chemical diversion control activities in the DCFA and registrant fees by the Appropriations Act, activities related to the overall control of listed chemicals, registration, investigation, inspection, data collection and analysis, cooperative

efforts with the regulated industry, related management and administrative positions devoted to diversion control activities, other personnel, and administrative and clerical oversight have been included in the budget calculations that are used to determine the registration fees.

For detail on the specific DCP components to be funded through the DCFA and their associated costs for the Fiscal Year 2006–2008 period covered by this rulemaking, please see DEA's Notice of Proposed Rulemaking, published in the **Federal Register** on November 16, 2005 (70 FR 69474).

### X. Budget Changes

In calculating the registration and reregistration fees contained in this Final Rule, DEA has included all DCP activities associated with the "registration and control of the manufacture, distribution and dispensing, importation and exportation of controlled substances and listed chemicals" (Pub. L. 108–447).

As discussed in detail in the Notice of Proposed Rulemaking (70 FR 69474), beginning in Fiscal Year 2006, both controlled substance and chemical diversion control costs must be included in the calculation of DCFA registration and reregistration fees. Among the chemical diversion control costs to be included among the "full costs" of operating the DCP are a portion of the Office of Training (TR) that specifically supports the activities of the DCP by providing training, guidance and instruction for Diversion Investigators, Diversion Task Force Officers, regulatory agencies, state and local law enforcement, and DCP personnel on controlled substances and chemical diversion control, advanced skills and technical knowledge, and systems applications. Also included are 188 chemical diversion control positions; 12 overseas diversion investigators dedicated to the DCP; and costs associated with the chemical transaction system (CTRANS).

The chemical diversion control costs that will be supported through the DCFA total \$24,499,000 for Fiscal Year 2006, \$24,880,000 for Fiscal Year 2007, and \$25,235,000 for Fiscal Year 2008, accounting for salary growth and inflation.

In addition to the chemical control costs, DEA is including among fee-fundable activities certain other internal resources that support the DEA's diversion control activities, but that, as was discussed more fully in previous rulemakings regarding the DCFA, had previously been supported through appropriated funds despite their direct

relationship to and support of the DCP. These activities include portions of the Office of Chief Counsel, the Office of Forensic Sciences Special Testing Laboratory, and the Special Operations Division; and additional special agent and intelligence analyst costs not previously supported through the DCFA. These components and associated costs are described below. A portion of DEA's internal computer system, Firebird, which already is supported through the DCFA, is included in the fee-fundable cost. The total cost of these non-chemical additions for Fiscal Year 2006 is \$26,996,000; for Fiscal Year 2007 is \$31,198,000; and for Fiscal Year 2008 is \$34,736,000.

In calculating the revised fee schedule, DEA used the Fiscal Year 2006 enacted Appropriation, the President's Budget Request for Fiscal Year 2007, the expected Budget Request for Fiscal Year 2008, and the annual \$15 million transfer to the U.S. Treasury as mandated by the CSA (21 U.S.C. 886a). In addition to fee funding all program elements and activities related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals, DEA must transfer the first \$15 million of fee revenue to the General Fund of the Treasury each year as described above (21 U.S.C. 886a(1)).

The Fiscal Year 2006 cost of the DCP is \$201,673,000, including a base of \$150,178,000 for controlled substances diversion control activities, \$24,499,000 in chemical diversion control activities, and \$26,996,000 for the additional non-chemical DCP support activities outlined above and described in detail in the November 16, 2005 Notice of Proposed Rulemaking (70 FR 69474), including 52 additional special agent positions; a portion of the Forensic Sciences Special Testing Laboratory; a portion of the Office of Chief Counsel that directly supports diversion control activities; 34 of the 67 field intelligence analysts to be phased in between Fiscal Year 2006–2007 and 6 Headquarters intelligence analysts to support domestic and international diversion control investigations (the remaining 33 field intelligence analysts will be phased in during Fiscal Year 2007); a portion of the Special Operations Division directly related to diversion

control efforts; and Firebird operations costs to support communication and infrastructure of the diversion control program.

With the addition of the required \$15 million transfer to the U.S. Treasury, the total amount necessary to collect through registrant fees in Fiscal Year 2006 is \$216,673,000.

The DCP cost for Fiscal Year 2007, including all activities relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals, is \$212,078,000, as reflected in the President's Budget Request to Congress. Including the required \$15 million transfer to the U.S. Treasury, the total amount necessary to collect through registrant fees in Fiscal Year 2007 is \$227,078,000. The anticipated costs of the DCP for Fiscal Year 2008, including all activities relating to the registration and control of the manufacture, distribution and dispensing of controlled substances and listed chemicals, is \$218,669,000. Including the required \$15 million transfer to the U.S. Treasury, the total amount necessary to collect through registrant fees in Fiscal Year 2008 is \$233,669,000.

The total amount that must be collected through fee funds for the Fiscal Year 2006–2008 period to fully fund the DCP as mandated by statute is \$677,420,000. Without an increase in fees, DEA would fall short by \$185,475,536 in funds to support the operations of the DCP. The new fee structure contained in this final rule, therefore, provides the necessary additional funds to ensure that the operational costs of the DCP are fully funded through registrant fees as mandated by statute. As explained above, DEA is required by statute to collect the "full costs" associated with operating the DCP.

**XI. Calculation of Fees**

Based on the total amount necessary to collect for Fiscal Years 2006–2008, DEA developed the specific fee levels for each registrant category according to its current fee structure and the fee-paying ratios that have been in existence since the inception of registrant fees. New fees are shown in the table below. For discussion on DEA's analysis of alternative fee schedules and approaches to calculating registrant fees, please see DEA's 2002 Final Rule (67 FR

51988, August 9, 2002) and its 1996 Final Rule (61 FR 68624, December 30, 1996).

In developing the fee schedule, DEA opted to set the fee level for a three-year period (FY 2006–2008) for two reasons. First, the vast majority of registrants are practitioners who pay a three-year registration fee. These registrants are divided into roughly three separate groups who pay their three-year registration fees on alternate year cycles. Accordingly, the fees below reflect the *total amount* necessary to be collected for the full three-year period (FY 2006–2008), 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. In calculating the final fee schedule reflected below, DEA relied on the latest and current registrant population figures, which have fluctuated since the proposed fees contained in the Notice of Proposed Rulemaking. Because the fees reflect the total amount necessary for collection over a three-year period (Fiscal Years 2006–2008) and because the type and number of registrants varies from year to year, the total amount of fees collected may not equal the requested budget level for any given year. Surplus fees collected in one year are used to offset fee collection shortfalls in another year. In no case are fees spent in excess of the levels enacted by Congress.

In evaluating options to structure the fee schedule, DEA opted to remain with the current fee structure to reduce reporting burdens on registrants and operational costs associated with the DCP which would then be passed on to registrants through annual fees.

To recover the full costs of the DCP as required by statute and as outlined in the preceding sections, DEA is adjusting the fees in accordance with its existing fee structure as shown in the following table. Under this fee schedule, controlled substances registrants and chemical registrants in the same registrant category (e.g., manufacturers) pay the same fee regardless of the substance or chemical being handled. The table also includes the current fees paid by each category.

| Registrant class                            | New annual fee | Current annual fee |
|---|----------------|--------------------|
| Manufacturers (controlled substances) ..... | \$2,293        | \$1,625            |

| Registrant class  | New annual fee | Current annual fee    |
|---|----------------|-----------------------|
| Manufacturers (chemical) .....  | 2,293          | 595<br>(registration) |
| Distributors, Importers/Exporters (controlled substances), including reverse distributors ..... | 1,147          | 813                   |
| Distributors, Importers/Exporters (chemical) .....  | 1,147          | 595<br>(registration) |
| Chemical Retail Distributors .....  | 1,147          | 255<br>(registration) |
| Dispensers/Practitioners* .....   | 184            | 130                   |
| Researchers, Narcotic Treatment Programs .....  | 184            | 130                   |

\* Practitioners, mid-level practitioners, pharmacies, hospitals/clinics, and teaching institutions will pay a fee of \$551 for a three-year registration period.

The fee structure above supplants the current fee structure for controlled substances and for chemical registrants. These fees go into effect November 1, 2006.

### XI. Related Issues and Waivers

Also by this Notice, DEA is removing differentiation between retail and non-retail distributors of List I chemicals. As of the effective date of this final rule, both retail and non-retail distributors must pay the same fee as described above.

DEA also is withdrawing, by this notice, its Notice of Proposed Rulemaking issued on December 1, 1999, which proposed changes in registration and reregistration fees for manufacturers, distributors, importers, exporters and retail distributors of List I chemicals (64 FR 67216, December 1, 1999).

DEA also is rescinding the 1997 Notice of Fee Waiver published on October 17, 1997 (62 FR 53958) which had waived a portion of the registration fee for non-retail distributors of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products.

### XII. Effects on Small Businesses

The new registrant fees range from \$184 to \$2,293 annually per location and per registered business activity. To assess whether the fees could impose a significant economic impact on a small entity, DEA considered whether the fees represent more than one percent of annual revenues for the registrant groups that qualify as small entities under the Small Business Administration (SBA) standards. As discussed below, DEA does not anticipate that the increase in fees will have a significant impact on a substantial number of small entities.

Most DEA registrants qualify as small entities under the SBA standards. Almost all practitioners, who compose 85 percent of all registrants affected by this rulemaking, would be considered small. For practitioners and dispensers,

the annual revenues would have to be below \$18,400 to have the annual registration fee or equivalent represent more than one percent of revenues.

Medical practitioners who are granted authority to handle controlled substances have annual incomes well above that level. Eighty-six percent of all practitioners have annual incomes in excess of \$133,000 (Bureau of Labor Statistics salary information). For these practitioners, the new annual fee equivalent of \$184 represents less than 0.14 percent of annual income. Physician assistants, the mid-level practitioner with the lowest average salary, have annual salaries of about \$65,000 (*ibid.*). For this practitioner group, which represents about 2 percent of registered practitioners, the annual fee equivalent equates to 0.28 percent of annual income.

The higher fees also will not impose a significant burden on dispensers. The average independent pharmacy has sales of almost \$2 million according to the National Association of Chain Drug Stores. The smallest clinics have revenue streams higher than \$18,400. Among dispensers, the greatest impact of this regulatory fee change will be on chain pharmacies which must hold a registration for each of their locations. The largest chain holds retail pharmacy registrations for more than 5,000 locations as well as almost 40 registrations for its distribution centers. However, these businesses do not qualify as small entities; moreover, for the annual fee to have a significant economic impact, annual revenues would have to be less than \$18,400.

DEA acknowledges the concerns of one commenter that fee increases going into effect in the middle of a budget cycle represent a non-controllable and, perhaps, unanticipated, expense for large chain drug stores and chain pharmacy distribution centers; however, as discussed above, only a small fraction of registered chain drug stores must renew their DEA registration in the second half of Calendar Year 2006 and

are thus affected by the budgetary implications of the fee increase.

For manufacturers, the 2002 Census data indicate that the value of shipments for the smallest chemical manufacturers (including drugs) ranged from \$477,000 to \$1.1 million per location (establishment). For this registrant group, therefore, the fee of \$2,293 does not represent more than one percent of revenues and will not impose a significant burden.

The one registrant group for which the fees could exceed one percent of revenues and have a significant economic impact is chemical distributors. According to 2004 Duns data, between one percent and 11 percent of the wholesale sectors handling listed chemicals have revenues below \$100,000. DEA does not collect financial data on its registrants, but it is possible that some chemical distributor registrants have revenues below \$100,000. The increase in the annual reregistration fee for chemical distributors (from \$477 to \$1,147) may impose a significant burden on these registrants. The increase in the initial registration fee (from a subsidized \$116 for certain entities to \$1,147 annually) also could be a barrier to entrance for these very small firms. Based on its experience, however, DEA considers it unlikely that any firm that lacked the resources to pay the initial registration fee would be granted a registration because it would be unlikely to have the resources necessary to prevent diversion of the products. Moreover, the new registration fees for all wholesale level activities are far less than the estimated annual fee of \$6,400 that chemical registrants would be charged if they were required to independently fund the chemical portion of the diversion control program, as previously discussed in the Notice of Proposed Rulemaking (70 FR 69474, November 16, 2005).

In short, combining all diversion control activities into a single Diversion Control Program, as mandated by the Consolidated Appropriations Act of

2005, results in scale efficiencies and overall reduced costs to all registrants.

**XIII. Regulatory Analysis**

*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)) and has provided above detailed regulatory analysis on the effects of this rulemaking on small entities. The rule will not have a significant economic impact on a substantial number of small entities as discussed in Section XII. While DEA recognizes that this regulation will have a financial effect on registrants, the change in fees is necessary to fully comply with 21 U.S.C. 886a and related statutes, which mandate that DEA establish the fees at a level necessary to recover the full costs of the Diversion Control Program.

*Executive Order 12866*

The Deputy Administrator certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 § 1(b). DEA has determined that, because the increased fees will result in a total increase of less than \$70 million annually to be collected through fees (that is the difference between the amount collected annually under the previous fee structure and the amount to be collected under the new fee structure), this is not a significant regulatory action; however, it was reviewed by the Office of Management and Budget. The fees to be collected represent an increase of less than \$70 million each year for the Fiscal Year 2006–2008 period (based on estimated fee collection figures and compared to the previous fee schedule) and are required to fully support the President’s budget for the DCP, as approved by Congress through the appropriations process. Therefore, DEA has no discretion in the establishment of the new fees and is required by law to collect registration and reregistration fees of sufficient amount to fully support the DCP.

*Executive Order 12988*

This regulation meets the applicable standards set forth in §§ 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 \$118,000,000 or more in any one year, and will not significantly or uniquely affect small governments. The increase in fees for private sector entities and individuals will result in a total increase of less than \$70 million annually to be collected through fees (that is the difference between the amount collected annually under the prior fee structure and the amount to be collected under the new fee structure). Moreover, the effect on individual entities and practitioners is minimal. The majority of the affected entities will pay a fee of \$551 for a three year registration period (the equivalent of \$184 per year) which equates to about 0.13 percent of annual income for most practitioners (the vast majority of all registrants). This rule is promulgated in compliance with 21 U.S.C. 886a that the full cost of operating the DCP be collected through registrant fees.

*Small Business Regulatory Enforcement Fairness Act of 1996*

This rule is not a major rule as defined by § 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, in that it will result in the collection of approximately \$216–\$234 million annually, the increase in fees (that is, the difference between the amount collected annually under the previous fee structure compared to the new fee structure) will result in a total increase of less than \$70 million annually. Moreover, 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 U.S.-based companies to compete with foreign-based

companies in domestic and export markets. This rule is not a discretionary action but rather responds to statutory clarification as to the activities constituting the DCP which, by law, must be fully funded through registrant fees (21 U.S.C. 821 and 958 and 21 U.S.C. 886a, respectively). Moreover, the individual effect on small business registrants is minimal. The majority of registrants considered to be small businesses are practitioners who will pay a three-year registration fee of \$551 or the equivalent of \$184 per year. For the majority of these practitioners, who compose the vast majority of registrants and registrants qualifying as small businesses, this annual fee equivalent represents about 0.13 percent of their annual mean salary. The impact on other small business entities is described in greater detail in the preceding regulatory analysis.

**List of Subjects**

*21 CFR Part 1301*

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

*21 CFR Part 1309*

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

■ For the reasons set out above, 21 CFR parts 1301 and 1309 are amended as follows:

**PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS AND DISPENSERS OF CONTROLLED SUBSTANCES**

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

**Authority:** 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877, 886a, 951, 952, 953, 956, 957.

■ 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.**

\* \* \* \* \*  
(e) \* \* \*  
(1)



| Business activity  | Controlled substances | DEA application forms               | Application fee (dollars) | Registration period (years) | Coincident activities allowed  |
|--|-----------------------|-------------------------------------|---------------------------|-----------------------------|--|
| (i) Manufacturing .....  | Schedules I-V ....    | New—225 .....<br>Renewal—225a ..... | 2,293<br>2,293            | 1                           | Schedules I-V: May distribute that substance or class for which registration was issued; may not distribute or dispose any substance or class for which not registered. Schedules II-V: except a person registered to dispose of any controlled substance may conduct chemical analysis and preclinical research (including quality control analysis) with substances listed in those schedules for which authorization as a mfg. was issued.  |
| (ii) Distributing .....  | Schedules I-V ....    | New—225 .....<br>Renewal—225a ..... | 1,147<br>1,147            | 1                           |  |
| (iii) Reverse distributing .....   | Schedules I-V ....    | New—225 .....<br>Renewal—225a ..... | 1,147<br>1,147            | 1                           |  |
| (iv) Dispensing or instructing (includes Practitioner, Hospital/Clinic, Retail Pharmacy, Central fill pharmacy, Teaching Institution). | Schedules II-V ...    | New—224 .....<br>Renewal—224a ..... | 551<br>551                | 3                           | May conduct research and instructional activities with those substances for which registration was granted, except that a mid-level practitioner may conduct such research only to the extent expressly authorized under state statute. A pharmacist may manufacture an aqueous or oleaginous solution or solid dosage form containing a narcotic controlled substance in Schedule II-V in a proportion not exceeding 20% of the complete solution, compound or mixture. A retail pharmacy may perform central fill pharmacy activities. |
| (v) Research .....   | Schedule I .....      | New—225 .....<br>Renewal—225a ..... | 184<br>184                | 1                           | A researcher may manufacture or import the basic class of substance or substances for which registration was issued, provided that such manufacture or import is set forth in the protocol required in § 1301.18 and to distribute such class to persons registered or authorized to conduct research with such class of substance or registered or authorized to conduct chemical analysis with controlled substances.  |

| Business activity  | Controlled substances             | DEA application forms               | Application fee (\$) | Registration period (years) | Coincident activities allowed   |
|--|-----------------------------------|-------------------------------------|----------------------|-----------------------------|---|
| (vi) Research .....                                      | Schedules II-V ...                | New—225 .....<br>Renewal—225a ..... | 184<br>184           | 1                           | May conduct chemical analysis with controlled substances in those schedules for which registration was issued; manufacture such substances if and to the extent that such manufacture is set forth in a statement filed with the application for registration or reregistration and provided that the manufacture is not for the purposes of dosage form development; import such substances for research purposes; distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities or research with such substances, and to persons exempted from registration pursuant to § 1301.24; and conduct instructional activities with controlled substances. |
| (vii) Narcotic Treatment Program (including compounder). | Narcotic Drugs in Schedules II-V. | New—363 .....<br>Renewal—363a ..... | 184<br>184           | 1                           | May distribute that substance or class for which registration was issued; may not distribute any substance or class for which not registered.   |
| (viii) Importing .....                                   | Schedules I-V ...                 | New—225 .....<br>Renewal—225a ..... | 1,147<br>1,147       | 1                           |   |
| (ix) Exporting .....                                     | Schedules I-V ...                 | New—225 .....<br>Renewal—225a ..... | 1,147<br>1,147       | 1                           | May manufacture and import controlled substances for analytical or instructional activities; may distribute such substances to persons registered or authorized to conduct chemical analysis, instructional activities, or research with such substances and to persons exempted from registration pursuant to § 1301.24; may export such substances to persons in other countries performing chemical analysis or enforcing laws related to controlled substances or drugs in those countries; and may conduct instructional activities with controlled substances.  |
| (x) Chemical Analysis .....                              | Schedules I-V ...                 | New—225 .....<br>Renewal—225a ..... | 184<br>184           | 1                           |   |

\* \* \* \* \*

**PART 1309—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, IMPORTERS, AND EXPORTERS OF LIST I CHEMICALS**

■ 3. The authority citation for part 1309 is amended to read as follows:

**Authority:** 21 U.S.C. 821, 822, 823, 824, 830, 871(b), 875, 877, 886a, 958.

■ 4. Section 1309.11 is revised to read as follows:

**§ 1309.11 Fee amounts.**

(a) For each application for registration or reregistration to manufacture for distribution the applicant shall pay an annual fee of \$2,293.

(b) For each application for registration or reregistration to distribute (either retail distribution or non-retail distribution), import, or export a List I chemical, the applicant shall pay an annual fee of \$1,147.

■ 5. Section 1309.12 is revised to read as follows:

**§ 1309.12 Time and method of payment; refund.**

(a) For each application for registration or reregistration to manufacture for distribution, distribute (either retail distribution or non-retail distribution), import, or export a List I chemical, the applicant shall pay the fee when the application for registration or reregistration is submitted for filing.

(b) Payment should be made in the form of a personal, certified, or cashier's check or money order made payable to "Drug Enforcement Administration." Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

Dated: August 22, 2006.

**Michele M. Leonhart,**

*Deputy Administrator.*

[FR Doc. E6-14286 Filed 8-28-06; 8:45 am]

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## DEPARTMENT OF JUSTICE

### Drug Enforcement Administration

[Docket No. DEA-269F]

#### 21 CFR Part 1308

#### Schedules of Controlled Substances: Placement of Embutramide Into Schedule III

**AGENCY:** Drug Enforcement Administration, Department of Justice.

**ACTION:** Final rule.

**SUMMARY:** With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance embutramide, including its salts, into Schedule III of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule III will be applicable to the manufacture, distribution, dispensing, importation and exportation of embutramide and products containing embutramide.

**DATES:** *Effective Date:* September 28, 2006.

**FOR FURTHER INFORMATION CONTACT:** Christine A. Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, (202) 307-7183.

**SUPPLEMENTARY INFORMATION:** Embutramide has the chemical name of N-[2-(m-methoxyphenyl)-2-ethyl-butyl]-gamma-hydroxybutyramide (CAS number 15687-14-6). On May 20, 2005, the Food and Drug Administration (FDA) approved a New Animal Drug Application (NADA) for embutramide for marketing under the trade name Tributame™ Euthanasia Solution (70 FR 36336). This product is a combination of embutramide, chloroquine phosphate, and lidocaine for prescription use by intravenous injection for euthanasia of dogs.

On January 26, 2005, the Acting Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that embutramide be placed into Schedule III of the CSA. Enclosed with the January 26, 2005, letter was a document prepared by the FDA entitled, "Basis for the Recommendation to Control Embutramide in Schedule III of the Controlled Substances Act (CSA)." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b))

Similar to barbiturates, embutramide has a central nervous system (CNS) depressant effect. It produces a reversible stupor-like state (narcosis) in experimental animals. The effects of embutramide on locomotor activity, rearing, forelimb grip strength, hind-limb splay, and the performance of inverted screen tests on rodents were similar to those of pentobarbital, a classical barbiturate. Embutramide mimics discriminative stimulus effects of pentobarbital in mice. Methohexital-trained rhesus monkeys self-administer embutramide, suggesting that embutramide produces positive reinforcing effects.

The pharmacological data suggest that the abuse potential of embutramide may be similar to that of CNS depressants such as barbiturates and their products (Schedule III through IV) that are controlled under the CSA. Embutramide as one of the ingredients in the veterinary euthanasia drug product T-61, was previously marketed in the United States. T-16 was withdrawn from the market in 1991. Embutramide is not currently marketed in the United States. During the period of marketing of T-61, a limited number of case reports of suicides, attempted suicides, and accidental exposures involving this and similar embutramide containing products were published in the scientific literature. DEA searched, but has not found, any evidence of abuse or trafficking of either T-61 or embutramide.

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation received from DHHS, the Deputy Administrator of the DEA, in a July 29, 2005, **Federal Register** Notice of Proposed Rulemaking (70 FR 43809), proposed placement of embutramide into Schedule III of the CSA. The proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for

hearing to be received by the DEA on or before August 29, 2005.

On August 2, 2005, DEA received a request for an extension of the period in which to comment and request a hearing. The requestor indicated that the additional time was necessary to review the scientific articles and other information cited by DEA in support of its scheduling proposal. DEA granted a 30 day extension of the time to comment and request a hearing, until September 28, 2005 (70 FR 50996).

#### Comments Received

DEA received two comments in response to the notice of proposed rulemaking. One commenter supported the current proposal to control embutramide as a Schedule III drug. Another commenter supported the proposal to schedule embutramide, the substance, but not its finished pharmaceutical product, Tributame™. This commenter stated that the abuse potential of Tributame™ is non-existent because the negative characteristics such as the presence of a cardiotoxin and the high cost of this formulation outweigh its desirable effects.

DEA does not agree. Careful consideration of all the available data suggests that the amounts of cardiotoxin present in the Tributame™ formulation are insufficient to eliminate the abuse potential of this product. DEA field experience suggests that the cost of a given product is not a consistent predictor of its actual abuse.

DEA also received a request for a hearing on the scheduling of embutramide and a request for an exemption of the product, Tributame™, from scheduling; however, the requestor subsequently withdrew these requests and asked that the scheduling of embutramide be expedited.

#### Scheduling of Embutramide

Relying on the scientific and medical evaluation and the recommendation of the Acting Assistant Secretary for Health, received in accordance with Section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in response to the notice of proposed rulemaking, the Deputy Administrator of DEA, pursuant to Sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Based on information now available, embutramide has a potential for abuse less than the drugs or other substances in Schedules I and II;

(2) Embutramide has a currently accepted medical use in treatment in the United States; and