reported annually until FDA notifies the applicant, in writing, that the agency concurs with the applicant's determination that the study commitment has been fulfilled, or that the study is either no longer feasible or would no longer provide useful information. Each annual progress report shall be accompanied by a completed transmittal Form FDA–2252, which may be obtained from the PHS Forms and Publications Distribution Center, 12100 Parklawn Dr., Rockville, MD 20857, and shall include all the information required under this section that the applicant received or otherwise obtained during the annual reporting interval, which ends on the U.S. anniversary date. The report shall provide the following information for each postmarketing study:

(1) *Applicant's name.*

(2) *Product name.* Include the approved product's proper name and the proprietary name, if applicable.

(3) *Biologics license application (BLA)/reference or supplement number.* The biologics license application number, reference number, or supplement number of the approved product.

(4) *Date of product's U.S. approval.*

(5) *Date of postmarketing study commitment.*

(6) *Description of postmarketing study commitment.* For clinical studies, include the purpose of the postmarketing study, the patient population addressed by the postmarketing study, the number of patients and/or subjects to be included in the study, and the indication and dosage(s) that are to be studied. For nonclinical studies, include the type and purpose of the study.

(7) *Schedule for conduct, completion, and reporting of the postmarketing study commitment.* Include projected dates for initiation of the different phases of the study, for completion of the study, and for submission of the final study report to FDA. Provide a revised schedule, in addition to the original schedule, if the original schedule was revised in the previous report.

(8) *Current status of the postmarketing study commitment.* Categorize the status of each postmarketing study using one of the following terms that describes the study's status on the anniversary date of the U.S. approval of the application or other agreed date:

(i) *Pending.* The study has not been initiated.

(ii) *Ongoing.* The study is proceeding according to or ahead of the original schedule described under paragraph (b)(7) of this section. Include the date the study was completed, if a study has been completed but the final study report has not been submitted to FDA.

(iii) *Delayed.* The study is proceeding but is behind the original schedule described under paragraph (b)(7) of this section.

(iv) *Terminated.* The study was ended before completion.

(v) *Submitted.* The study has been completed or terminated, and a final study report has been submitted to FDA. Include the date the final study report was submitted to FDA.

(9) *Explanation of the study's status.* Provide a brief description of the status of the study, including the number of patients and/or subjects enrolled to date and an explanation of the study's status identified under paragraph (b)(8) of this section. Provide a revised schedule, as well as the reason(s) for the revision, if the schedule under paragraph (b)(7) of this section has changed since the previous report.

(c) *When to report.* Annual progress reports for postmarketing study commitments entered into by applicants shall be reported to FDA within 60 days of the anniversary date of the U.S. approval of the application for the product.

(d) *Where to report.* Submit two copies of the annual progress report of postmarketing studies to the Food and Drug Administration, Center for Biologics Evaluations and Research, Document Control Center (HFM–99), suite 200N, 1401 Rockville Pike, Rockville, MD 20852–1448.

(e) *Public disclosure of information.* Except for the information described in this paragraph, FDA may publicly disclose any information concerning a postmarketing study, within the meaning of this section, if the agency determines that the information is necessary to identify an applicant or to establish the status of the study including the reasons, if any, for failure to conduct, complete, and report the study. Information necessary to establish the status of a postmarketing study includes the study protocol, patient accrual rates, reports of unexpected suspected adverse drug experiences, and study results. Under this section, FDA will not publicly disclose trade secrets, as defined in § 20.61 of this chapter, or information described in § 20.63 of this chapter, the disclosure of which would constitute an unwarranted invasion of personal privacy.

Dated: August 9, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–31123 Filed 11–30–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1309

[DEA NUMBER 185–P]

RIN 1117–AA50

Chemical Registration and Reregistration Fees

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Proposed rule.

SUMMARY: The Drug Enforcement Administration (DEA) proposes to amend its application fees for registration and reregistration of manufacturers, distributors, importers, and exporters of List I chemicals, as authorized by section 3(a) of the Domestic Chemical Diversion Control Act of 1993 (DCDCA), reducing the fees from $595 to $326 for initial registration, and the reregistration fees from $477 to $171. Fees for retail registrants will increase from $255 to $326 for registration, and from $116 to $171 for reregistration. Office of Management and Budget (OMB) Circular A–25 requires a periodic review of user charges for agency programs. This review will bring fees into alignment with current changes in costs or market values.

DATES: Written comments or objections must be submitted on or before January 31, 2000.

ADDRESSES: Comments and objections should be submitted in quintuplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION:

Impact of the Proposed Rule

What Is the Effect of This Proposed Rule, and to Whom Does It Apply?

The Drug Enforcement Administration (DEA) proposes to reduce the registration and

reregistration fees for persons manufacturing, distributing (non-retail), importing and exporting List I chemicals. There are currently 3,685 such registrants. Fees are reduced from $595 to $326 for registration, and from $477 to $171 for reregistration. Registration and reregistration fees for the 47 current retail registrants increase slightly, from $255 to $326 for registration, and from $116 to $171 for reregistration. At this time, DEA is receiving, on average, fewer than the new retail applications per year.

Legislative History

What is the Legal Basis for Registering Persons Manufacturing, Distributing, Importing and Exporting List I Chemicals

The Chemical Diversion and Trafficking Act (CDTA) of 1988 was passed by Congress to control the diversion of certain chemicals that are necessary for the illicit manufacture of controlled substances. The CDTA and its regulations, set forth in Title 21 Code of Federal Regulations (CFR) parts 1310 and 1313, established a system of record keeping and reporting requirements through which DEA and the chemical industry could identify persons seeking to divert listed chemicals for the manufacture of illicit controlled substances.

The Domestic Chemical Diversion Control Act of 1993 (DCDCA), which became effective on April 16, 1994, established a number of new requirements intended to close avenues used by illicit controlled substance manufacturers to circumvent the CDTA. One of the main provisions of the DCDCA was the requirement that manufacturers, distributors, importers and exporters of List I chemicals obtain a registration from DEA.

Concurrent with the establishment of the registration requirement, DEA established, by regulations, the fees to be charged for registration and reregistration of List I chemical handlers, as required under the Independent Offices Appropriations act (IOAA) and the guidelines set forth in the Office of Management and Budget (OMB) Circular A–25.

OMB Circular A–25, Section 6 provides that ''[A] user charge * * * will be assessed against each identifiable recipient for special benefits derived from Federal activities beyond those received by the general public.'' The section further requires that the user charge be sufficient to ''* * * recover the full cost to the Federal Government for providing the special benefit.'' A special benefit is described as a Government service which ''Enables the beneficiary to obtain more immediate or substantial gains or values (which may or may not be measurable in monetary terms) than those that accrue to the general public (*e.g.,* receiving a patient, insurance, or guarantee provision, *or a license to carry on a specific activity or business* [emphasis added] or various kinds of public land use).''

Sections 822 and 957 of Title 21, United States Code, as amended by the DCDCA, require that any person who manufactures, distributes, imports or exports a List I chemical must obtain annually a registration in accordance with DEA rules and regulations. A registration to manufacture, distribute, import or export List I chemicals is a special benefit under Circular A–25, in that it allows the registrant to engage in certain activities while a member of the general public may not. Therefore, the costs associated with DEA's issuance of a registration to manufacture, distribute, import or export a List I chemical; certain costs associated with advising registrants of their responsibilities; and maintenance of the integrity of the registration system must be recovered through assessment of a user fee.

Section 6(d) of Circular A–25 describes the requirements for determining the full cost of a service or benefit. ''Full cost'' is defined as all direct and indirect costs, including, but not limited to: direct and indirect personnel costs, including salaries, fringe benefits (such as life and health insurance and retirement) and travel; physical overhead, including material and supply costs, rent and utilities; management and supervisory costs; and the costs of enforcement, collection, research, establishment of standards, and regulations. Section 6(d)(1)(e) provides that the cost figures shall be established utilizing ''the best available records of the agency, and new cost accounting systems need not be established solely for this purpose.'' The costs of the services provided by DEA were determined by use of proven and accepted budget estimating techniques as outlined in the DOJ budget guidelines and OMB Circular A–11.

Initial Fee Implementation

How did DEA Implement the Initial Fees

DEA established two distinct categories of chemical registrants: retail distributors, such as convenience stores, gas stations, truck stops, liquor stores, etc., whose regulated activities consist of the direct sales to walk-in customers of drug products that are regulated as List I chemicals; and non-retail registrants, such as manufacturers which distribute, distributors, importers, and exporters of List I chemicals. Each category of registrant was addressed independently during the original establishment of the fees.

Establishment of the initial application fee was a simple matter since the costs associated with the processing of each application for registration were direct costs applicable to each individual application; there were minimal general program costs that were required to be averaged across the applicant population. For renewal applications the calculation of the fee required identification of general program maintenance costs which were to be averaged across the registrant population. However, because List I chemical registration was a new requirement, there was no existing registrant population and the fees had to be calculated based on estimates of the potential population. For purposes of calculating the fee DEA estimated 10,000 retail registrants and 1,500 non-retail registrants.

Full details regarding the calculation of the original fees are contained in DEA's proposed rule regarding Implementation of the Domestic Chemical Diversion Control Act of 1993 (Pub. L. 103–200) which was published in the **Federal Register** on October 13, 1994 (59 FR 51887).

New Applications

What Factors Were Involved in Establishing New Application Fees

Due to industry comments regarding the financial impact of the registration fee received at the time the requirements of the MCA were implemented, DEA reviewed the preregistration process and waived a significant portion of the initial registration fee for manufacturers, distributors, importers, and exporters of regulated drug products, requiring that only $116 of the $595 fee be paid. Notice regarding the fee waiver was published in the **Federal Register** on October 17, 1997 (62 FR 53958). Since that time, DEA has continued to assess the situation and has become aware of a number of incidents involving the theft of significant quantities of drug products and raw materials from persons distributing controlled substances and listed chemicals. At least five million dosage units of drug products and 75 kilograms of pseudoephedrine powder have been reported stolen. DEA is concerned that with the emphasis placed on ''knowing the customer'' and ensuring that all sales are legitimate, there may be

insufficient emphasis placed on maintaining security of the listed chemicals that registrants have in their possession. It is clear that a strong DEA presence at the time of initial registration remains necessary to ensure that applicants are fully aware of all requirements, not only in terms of ''knowing the customer'' and ensuring that sales are legitimate, but also ensuring that appropriate safeguards are in place to prevent theft or diversion of listed chemicals from the regulated location. However, while DEA will continue to conduct on-site activities as part of the preregistration investigation, at this time, due to the demand on resources for the pursuit of criminal investigations, DEA will only be able to allocate six hours of investigative time for each preregistrant investigation. However, DEA anticipates that, over time, these demands will lessen and resources currently dedicated to criminal investigations will be reallocated to other chemical regulatory activities, including preregistration investigations. DEA will reexamine chemical registration and reregistration fees when this reallocation of resources occurs.

Reregistration Applications

What Factors Were Involved in Establishing Reregistration Application Fees

Two factors have affected the calculation of the reregistration fees. First, due to the continued demand for resources for the pursuit of investigations, DEA anticipates dedicating a total of six investigator work years to regulatory audits of both retail and non-retail registrants. Second, the actual non-retail registrant population is greater than the originally estimated population of 1,500 registrants, due in part to the expanded registration requirements of the MCA. At the time of drafting of this notice, there are 47 retail registrants and 3,685 non-retail registrants, for a total of 3,732 chemical registrants.

Fees

What Specific Costs Were Included in the Calculation of the Fees?

DEA utilized the standard modular costing method used throughout the federal government to calculate fees. This methodology relates costs to the number of personnel within the program and accounts for inflationary increase. Funding for salaries, benefits, equipment, training, and other position-related expenses is predicted on the modular formula which is reviewed and revised each budget year by the Department of Justice (DOJ) and OMB, the latter having ultimate authority in finalizing the formula for each fiscal year.

As previously stated, the personnel costs listed below include all direct and indirect costs, including salaries, fringe benefits (such as life and health insurance and retirement) and travel; physical overhead, including material and supply costs such as forms, postage, equipment, rent and utilities. Direct costs are those costs which are apportionable to a specific registration or reregistration application, *i.e.,* direct personnel and materials costs, whereas indirect costs are costs not directly apportionable to a specific registration or reregistration application, *i.e.,* managerial, regulatory, and supervisory costs.

In light of the minimal number of retail registrants (47), the fact that direct costs are the same for retail and non-retail registrants, and the indirect costs are averaged across the entire retail/non-retail registrant population, DEA has determined that the initial fee for retail and non-retail registrants can be calculated together rather than separately, and that the renewal fee for retail and non-retail registrants can be calculated together rather than separately.

Based on the costs as laid out in the following tables, the initial registration fee will be $326.00, and the reregistration fee will be $171.00.

Costs for Processing an Application and Issuing an Initial Registration

Direct Costs:		
Clerical Time [1]	.5 hour	$10.34
Material Costs: [2]		
Application Form		.043
Postage		.064
Chemical Handlers Manual		0.30
Registration Certificate		0.10
Investigator Time [3]	6 hours	237.44
Total Direct Costs		249.25
Indirect Costs:		
Management/Supervisory time [4]		23.87
Regulatory/Policy Development [5]		7.82
Applicant/Registrant Support [6]		44.26
Total Indirect Costs		75.95
Total Direct and Indirect Costs		325.20

Notes Regarding the Costs Associated With Issuance of an Initial Registration

1. Clerical time includes the time required for preparing and mailing application packages, time for processing applications received, including computer data entry, encoding the application form, filing, and transmitting a copy of the application to the appropriate DEA field office for the registration review process. Following the registration review, time is required to approve the registration, initiate issuance of the registration certificate, and file copies of the report and application.

2. The printing cost for application forms for chemical registration is $4,500 for 20,000 forms or 22.5 cents per form. The cost for the last printing of the Chemical Handlers Manual was $2,250 for 7,500 copies, or 30 cents per copy.

3. DEA is including an average of six hours of investigator time toward the following: travel, on-site visits, telephonic communications, and paperwork processing.

4. Management/Supervisory time is that time spent by management and supervisory personnel in the overall development and maintenance of the registration program, including establishment of program priorities and policy, resource allocation, and administrative direction. The following positions are involved:

Deputy Assistant Administrator and Deputy Director of the Office of Diversion Control.	.05 work year each	$22,304
Chief, Chemical Control Section	.1 work year	13,067
Chief, Data Processing and Analysis Unit	.25 work year	29,030
Chief, Liaison and Policy Section	.1 work year	13,067
Chief, Policy Unit	.1 work year	11,612
Total Costs		89,080

Because the Management/Supervisory costs are related to the general operation of the registration program, they must be averaged across the entire applicant population. For 3,732 applicants, the average cost would be $23.87.

5. Regulatory and policy development time consists of .5 work year of a program analyst time for drafting new/amended regulations and **Federal Register** notices, issuance of policy statements and directives related to the registration program and responding to registrant queries regarding registration matters. This time is for general chemical registration program purposes and must be spread equally across the applicant population. The cost of that time, $29,192, divided by 3,732 applicants equals $7.82.

6. Applicant/Registrant Support time will consist of 2 work years of Diversion Investigator time, which will be dedicated to providing technical assistance, advice and informational materials to the industry to assist in complying with the registration, record keeping and reporting requirements. The total cost for 2 work years of Diversion Investigator time is $165,178, divided by 3,732 applicants equals $44.26.

Cost for Processing a Reregistration Application

Direct Costs:		
Clerical Time [1]	.25 hours	$5.17
Material Costs [2]		.43
Forms		.64
Postage		.64
Total Direct Costs		6.24
Indirect Costs:		
Management/Supervisory Time [3]		23.87
Regulatory/Policy Development [4]		7.82
Regulatory Audit Time [5]		132.78
Total Indirect Costs		164.47
Total Direct and Indirect Costs		170.71

Notes Regarding the Costs Associated With Reregistration

1. Clerical time includes the time required for preparing and mailing application packages, time for processing applications received, including computer data entry, encoding the application form, filing, and preparing the fee for deposit.

2. The forms cost covers both the reregistration application form and the registration certificate. Postage is for mailing the reregistration application and the registration certificate.

3. Management/Supervisory time is that time spent by management and supervisory personnel in the overall development and maintenance of the registration program, including establishment of program priorities and policy, resource allocation, and administrative direction. The following positions are involved:

Deputy Assistant Administrator and Deputy Director of the Office of Diversion Control.	.05 work year each	$22,304
Chief, Chemical Control Section	.1 work year	13,067
Chief, Data Processing and Analysis Unit	.25 work year	29,030
Chief, Liaison and Policy Section	.1 work year	13,067
Chief, Policy Unit	.1 work year	11,612
Total Costs		89,080

Because the Management/Supervisory costs are related to the general operation of the registration program, they must be averaged across the entire reregistration applicant population. DEA has received 3,732 retail and non-retail reregistration applications. The average cost per applicant would be $23.87.

4. Regulatory and policy development time consists of .5 work year of a program analyst time for drafting new/amended regulations and **Federal Register** notices, issuance of policy statements and directives related to the registration program and responding to registrant queries regarding registration matters. This time is for general chemical registration program purposes and must be spread equally across the reregistration applicant population. The cost of that time, $29,192, divided by 3,732 reregistration applicants, equals $7.82.

5. DEA will conduct regulatory audits to ensure that registrants are complying with the chemical control requirements and that chemicals are not being distributed to persons seeking to divert them. The investigations will consist of a comprehensive review of each registrant's records, reporting systems, and security provisions. Each investigation will require comprehensive on-site review of the registrant's records; verification of transactions and purchasers, including record checks of and visits to purchasers; travel; and report preparation. DEA anticipates that all such investigations combined will require 6 work years of Diversion Investigator time. The total cost for 6 work years of Diversion Investigator time is $495,534, divided by 3,732 reregistration applicants equals $132.78.

Refund of Fees for Certain Registrants

Section 8(e) of OMB Circular A–25 requires periodic review of user fees. DEA's initial review of these fees in 1997 was delayed due to passage of the Comprehensive Methamphetamine Control Act of 1996 (MCA) which significantly expanded the scope of the registration requirement. DEA postponed the review of the fees until all persons affected by the MCA had submitted their applications. Due to this delay, there are registrants who have been required to pay the full reregistration fee of $477.00. DEA will

be making arrangements to refund the difference between the current and proposed reregistration fees. Refunds will be provided to those registrants who have renewed their registration in the year preceding the effective date of the final rule published in conjunction with this notice. Refunds will only be provided to those registrants who renewed their registration on time, not those applicants who, by virtue of renewing late, fell into this payment period.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this proposed rulemaking has been drafted in a manner consistent with the principles of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). It will not have a significant economic impact on a substantial number of small business entities. This notice reduces the registration and reregistration fee substantially for the larger portion of the industry, *i.e.,* those persons required to submit applications for renewal of registration, reducing the registration fee from $595 to $326, and the reregistration fee from $447 to $171, providing economic relief to the small businesses affected. With respect to the one category of fee that increased, for retail distributors, there are currently less than 50 retail distributor registrants and DEA is receiving, on average, less than 10 new applications from retail distributors per year.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles of Executive Order 12866 Section 1(b). DEA has determined that this is not a significant regulatory action. As noted above, this proposed rule reduces the existing fee structure for most registrants, thus providing economic relief to the registrant population . DEA has determined that this rulemaking is not significant. Therefore, it has not been submitted to the Office of Management and Budget for review.

Executive Order 13132

This action has been analyzed with the principles and criteria in Executive Order 13132, and it has been determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism assessment.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local, and tribal governments in the aggregate, or by the private sector, of $100 million or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by Section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or 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.

Plain Language Instructions

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of these regulations, call or write Patricia Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537. Telephone (202) 307–7297.

List of Subjects in 21 CFR Part 1309

Administrative practice and procedure, Drug traffic control, List I and List II chemicals, Security measures For the reasons set out above, 21 CFR Part 1309 is proposed to be amended as follows:

PART 1309—[AMENDED]

1. The authority citation for 21 CFR Part 1309 continues to read as follows:

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

2. Section 1309.11 is revised to read as follows:

§ 1309.11 Fee amounts.

(a) For each initial registration to manufacture for distribution, distribute (either retail distribution or non-retail distribution), import, or export a List I chemical, the applicant shall pay a fee of $326 for an annual registration.

(b) For each reregistration to manufacture for distribution, distribute (either retail distribution or non-retail distribution), import, or export a List I chemical, the registrant shall pay a fee of $171 for an annual registration.

3. 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: October 1, 1999.

John H. King,

Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 99–30960 Filed 11–30–99; 8:45 am]

BILLING CODE 4410–09–M

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 199

RIN 0720–AA54

Civilian Health and Medical Program of the Uniformed Services (CHAMPUS); Expansion of Dependent Eligibility for TRICARE Retiree Dental Program

AGENCY: Office of the Secretary, DoD.

ACTION: Proposed rule.

SUMMARY: This proposed rule implements a change to the TRICARE Retiree Dental Program (TRDP) required by the National Defense Authorization Act for Fiscal Year 1999. This change expands eligibility for enrollment in the program to allow dependents of certain retired members of the Uniformed Services to enroll in the program even if the retired member does not enroll. In addition, this rule clarifies the existing regulatory provisions for election of TRDP coverage and disenrollment.

DATES: Comments must be received on or before January 31, 2000.

ADDRESSES: TRICARE Management Activity, 16401 East Centretech Parkway, Aurora, CO 80011–9043.

FOR FURTHER INFORMATION CONTACT: Linda Winter, TRICARE Management Activity, (303) 676–3682.

SUPPLEMENTARY INFORMATION:

I. Background

Implementation of the TRICARE Retiree Dental Program (TRDP), a