Substances	Limitations
* * *	* * * *
Nylon 6/66 resins complying with § 177.1500(b), item 4.2 of this chapter (CAS Reg. 24993–04–2).	For use only with: 1. Nonalcoholic foods at temperatures not to exceed 82.2 °C (180 °F). Laminate structures with authorized food-contact materials yield no more than 0.15 milligram of *epsilon*-caprolactam per square inch when extracted with water at 82.2 °C (180 °F) for 5 hours. 2. Nonalcoholic foods at temperatures not to exceed 100 °C (212 °F). Laminate films with authorized food-contact materials yield no more than 0.15 milligram of *epsilon*-caprolactam per square inch when extracted with water at 100 °C (212 °F) for 5 hours.
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Dated: September 30, 1997.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–27527 Filed 10–16–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1309

[DEA Number—169N]

Comprehensive Methamphetamine Control Act of 1996; Registration Fees

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of fee wavier.

SUMMARY: DEA is waiving a portion of the registration fee for non-retail distributors of pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products. Under the Comprehensive Methamphetamine Control Act of 1996 (MCA), wholesale distributors of these drug products are subject to the existing List I chemical registration and fee requirements. However, because the drug products are distributed in substantially different channels than other List I chemicals, the existing pre-registration investigation procedures, which were established primarily with respect to the handlers of chemicals, as opposed to drug products, are not necessarily applicable to the new type of applicant. DEA will be reviewing the pre-registration investigation procedures to determine what changes will be necessary to account for the different manner of distribution of the drug products. Recognizing that changes are likely to be made in the pre-registration process, thus causing changes to the fees assessed, DEA is waiving a portion of the fee at this time, rather than requiring that new applicants pay a fee that would not be consistent with the resources actually expended in the issuance of the registration.

EFFECTIVE DATE: October 17, 1997.

FOR FURTHER INFORMATION CONTACT: G. Thomas Gitchel, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Telephone (202) 307–7297.

SUPPLEMENTARY INFORMATION: The MCA's removal of the exemption for pseudoephedrine, phenylpropanolamine, and combination ephedrine drug products (regulated drug products) opens up to chemical registration and regulation a new and different segment of industry from that previously subject to the chemical controls. Prior to the MCA the group subject to chemical registration consisted primarily of specialty chemical handlers distributing products of limited consumer end-use to a largely industrial customer base. By contrast, the principal group subject to registration under the MCA consists of general merchandisers distributing a wide variety of consumer products to retail outlets for sale to the public. Often, one company will operate several distribution centers to serve wholly owned or independent retail outlets. In response to applications submitted by this new group, DEA is re-examining the pre-registration investigation process for issuing registrations. This process will affect the registration application fees.

The procedures for issuing a chemical registration and the associated application fee were developed in 1994 as part of the implementation of the Domestic Chemical Diversion Control Act of 1993 (DCDCA). (For specific details regarding the procedures and fees, see DEA's notice of proposed rulemaking (NPRM) 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)). The procedures were developed based on the type of applicants expected under the DCDCA, e.g., specialty chemical handlers dealing with products of limited consumer end-use. These applicants dealt almost exclusively in chemicals and often distributed from contract operated warehouses/storage depots. Pursuant to the requirements of the Office of Management and Budget (OMB) Circular A–25, the costs and resources required to conduct the pre-registration investigation and issue the registration were assessed to the applicants as the application fee.

The group subject to registration under the MCA is significantly different, consisting principally of general merchandisers distributing hundreds or thousands of different consumer products, often from a large number of applicant-owned warehouse/distribution centers, to retail outlets for sale to the public. The volume of regulated drug products handled is often only a very small portion of the total volume of products distributed by the location. For these applicants,the pre-registration procedures developed for chemical handlers are not entirely suitable. DEA has, therefore, initiated a review of the pre-registration procedures to determine what changes will be necessary to make the process consistent with the different activities of this group of applicants. This review will affect the costs and resources associated with the issuance of registrations to these applicants and, thus, the fee to be charged. DEA will publish notice, with opportunity for comment, in the **Federal Register** regarding any proposed change to the procedures and consequent changes to the fees.

The MCA removed the exemption from regulation for combination ephedrine drug products effective

October 3, 1996, and will remove the exemption from regulation for pseudoephedrine and phenylpropanolamine drug products effective October 3, 1997, making persons who distribute the respective products subject to the registration requirement on those dates. Determination of the appropriate procedures and amendment of the regulations to set the new fees will extend well beyond those deadlines for registration. Therefore, DEA is waiving a portion of the application fee for new registration. It would be inconsistent with the principles of OMB Circular A–25 to charge a fee for a specific service, e.g., completing the processing of the application and the pre-registration investigation, knowing that the costs and resources to be expended in providing that service will change. Persons who have already applied for registration to distribute regulated drug products and paid the existing fee will be refunded the amount of fee that is being waived.

The Acting Deputy Administrator of DEA is, therefore, waiving that portion of the fee for registration as a non-retail distributor of regulated drug products associated with the 12 hours of investigator time allocated for the on-site visit and travel time, which, at $39.92 per hour, amounts to $479.00 (See 59 FR 51892). The remaining administrative costs and time allotted for background checks and reports will continue. Thus the fee for an initial application for registration as a non-retail distributor of regulated drug products is $116.00. That fee will remain in effect until the review of the registration procedures has been completed and a determination has been made regarding how the processing of such applications and the pre-registration investigation will be carried out. At that time, a notice will be published in the **Federal Register** regarding the procedures to be followed and fee that will be required for future applications.

This waiver applies only to applicants for registration as non-retail distributors of regulated drug products. All other applicants remain subject to the full fees, as set forth in Title 21, Code of Federal Regulations, Section 1309.11. As noted earlier, persons who have already submitted an application for registration as a non-retail distributor of regulated drug products and paid the full fee will be provided with a $479.00 refund.

Dated: October 8, 1997.

James S. Milford,

Acting Deputy Administrator.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1309 and 1310

[DEA Number 168I]

RIN 1117–AA46

Temporary Exemption From Chemical Registration for Distributors of Pseudoephedrine and Phenylpropanolamine Products

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim Rule with request for comments.

SUMMARY: DEA is amending its regulations to provide a temporary exemption from registration for persons who distribute pseudoephedrine and phenylpropanolamine drug products. The Comprehensive Methamphetamine Control Act of 1996 (MCA) amends the Controlled Substances Act of 1970 (CSA) to require that, effective October 3, 1997, persons who distribute these drug products shall be subject to the chemical registration requirement. To avoid interruption in the legitimate distribution of the drug products pending promulgation of final regulations and issuance of registrations, DEA is amending its regulations to provide certain temporary exemptions from the registration requirement.

DATES: October 17, 1997. Persons required to register to handle pseudoephedrine or phenylpropanolamine must submit an application on or before December 3, 1997, in order to continue their activities pending final action by DEA on their application. Written comments or objections must be submitted on or before December 16, 1997.

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

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

SUPPLEMENTARY INFORMATION: The Comprehensive Methamphetamine Control Act of 1996 (MCA) requires that, effective October 3, 1997, pseudoephedrine and phenylpropanolamine drug products (regulated drug products) will become subject to regulation as List I chemicals. Under this new requirement, any person who wishes to distribute, import, or export these products must first obtain a DEA chemical registration. Because full implementation of this provision and issuance of the registrations will not be possible prior to the October 3, 1997 deadline, DEA is establishing temporary exemptions from the registration requirement for persons handling regulated drug products to allow for continuation of legitimate commerce in the products. In addition, the existing exemptions from chemical registration for persons registered with DEA to handle controlled substances, which is contained in 21 CFR 1309.25, and for distributors of prescription drug products, which is contained in 21 CFR 1309.28, will also apply to the regulated drug products.

The first exemption applies to retail distributors of regulated drug products. A single transaction limit of 24 grams has been established by the MCA for retail distributions of regulated drug products. Consistent with previous proposals regarding the regulation of retail distributions of drug products that contain List I chemicals, DEA is temporarily exempting retail distributors from the registration requirement. Under this exemption, retail distributors will not be required to obtain a registration if they engage exclusively in distributions of regulated drug products below the 24-gram limit in a single transaction for legitimate medical use, either directly to walk-in customers or in face-to-face transactions by direct sales. This exemption is set out in 21 CFR 1309.29(b).

The second exemption applies to those persons who are required to obtain a registration. Any such person who submits an application for registration for activities involving regulated drug products on or before December 3, 1997 will be exempt from the registration requirement for their lawful activities with regulated drug products until the Administration has taken final action with respect to that application. This exemption is set out in 21 CFR 1310.09.

DEA recognizes that, unlike the second exemption, which provides a general benefit to all affected persons, the first exemption is limited in its application. Therefore, while the regulatory changes in this notice take