Signed at Washington, D.C., this 14th day of October 1997.

Bernard E. Anderson,

Assistant Secretary for Employment Standards.

Shelby Hallmark,

Acting Director, Office of Workers' Compensation Programs.

[FR Doc. 97–27593 Filed 10–16–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 177

[Docket No. 93F–0111]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of Nylon 6/66 copolymers as components of nonfood-contact layers of multilayer food packaging used at temperatures that do not exceed 212 °F. This action is in response to a petition filed by Allied-Signal, Inc.

DATES: The regulation is effective October 17, 1997; written objections and requests for a hearing by November 17, 1997.

ADDRESS: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 3, 1993 (58 FR 26325), FDA announced that a food additive petition (FAP 3B4369) had been filed by Allied-Signal, Inc., c/o 1100 G St. NW., Washington, DC 20001 (presently c/o Keller and Heckman, 1001 G St. NW., suite 500 West, Washington, DC 20001). The petition proposed to amend the food additive regulations in § 177.1395 *Laminate structures for use at temperatures between 120 °F and 250 °F* (21 CFR 177.1395) to provide for the safe use of Nylon 6/66 copolymers complying with 21 CFR 177.1500(b), item 4.2, as components of nonfood-contact layers of multilayer food packaging used at temperatures that do not exceed 100 °C (212 °F).

In reviewing the environmental assessment (EA), the agency found that the petitioner's proposed regulation was much broader than the proposed use covered in the EA. Whereas the analysis in the EA considered only the use of Nylon 6/66 copolymers in laminate films, the petitioner proposed the use of these copolymers in laminate structures, which includes the use in laminate films. In a subsequent communication with the agency, the petitioner agreed that the proposed regulation should be narrowed to state specifically that the intended use of Nylon 6/66 copolymers is in laminate films. Therefore, this regulation limits the use of these copolymers to laminate films, which is consistent with the proposed use covered in the EA.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that the additive will have the intended technical effect, and therefore, that the regulations in § 177.1395 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Any person who will be adversely affected by this regulation may at any time on or before November 17, 1997, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1395 is amended in the table in paragraph (b)(4) by revising the entry for ''Nylon 6/66 resins complying with § 177.1500(b), item 4.2 * * *'' to read as follows:

§ 177.1395 Laminate structures for use at temperatures between 120 °F and 250 °F.

* * * * *

(b) * * *

(4) * * *

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.
* * *	* * * *

Dated: September 30, 1997.

Janice F. Oliver,

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

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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