

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 177**

**[Docket No. 1996F-0176]**

**Indirect Food Additives: Polymers; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

*Dmb*

Display Date 3-25-04  
Publication Date 3-26-04  
Certifier *[Signature]*

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**SUMMARY:** The Food and Drug Administration (FDA) is amending its food additive regulations to correctly reflect all materials that are permitted for use as films/layers of laminated articles intended for use with food. The current requirements for polymer films/layers are incomplete due to an inadvertent error. This document is editorial in nature and amends the regulations to correct this error.

**DATES:** This rule is effective [*insert date of publication the Federal Register*]. Submit written or electronic comments by [*insert date 30 days after date of publication in the Federal Register*].

**ADDRESSES:** Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>.

**FOR FURTHER INFORMATION CONTACT:** Joyce A. Strong, Office of Policy and Planning (HF-27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-7010.

**SUPPLEMENTARY INFORMATION:**

## **I. Background**

FDA has discovered that an error has become incorporated into the agency's regulations in part 177 (21 CFR part 177). In the **Federal Register** of August 25, 1999 (64 FR 46271), FDA published a final rule with an inadvertent error. In this final rule, § 177.1390 was amended, and existing paragraph (c)(1)(i)(f) was not redesignated as paragraph (c)(1)(i)(g). Because § 177.1390(c)(1)(i)(g) was not added to the agency's regulations, the regulations are incorrect. Accordingly, § 177.1390 is being amended to correct this error.

To the extent that 5 U.S.C. 553 applies to this action, the agency's implementation of this action without opportunity for public comment comes within the good cause exception in 5 U.S.C. 553(b)(3)(B) in that obtaining public comment is impracticable, unnecessary, and contrary to public interest. This amendment to the food additive regulations corrects an inadvertent omission in the Code of Federal Regulations (CFR). The purpose of this final rule is to update the regulations in part 177 to correctly reflect all materials that are permitted for use as films/layers of laminated articles intended for use with food. In accordance with 21 CFR 10.40(e)(1), FDA is providing an opportunity for comment on whether the regulation should be subsequently modified or revoked.

## **II. Analysis of Impacts**

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental,

public health and safety, and other advantages; distributive impacts; and equity). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation).

The agency concludes that this final rule is consistent with the principles set out in Executive Order 12866 and in these two statutes. FDA has determined that the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order.

The Unfunded Mandates Reform Act of 1995 does not require FDA to prepare a statement of costs and benefits for this final rule, because the final rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation. The current inflation adjusted statutory threshold is \$112.3 million.

The purpose of this final rule is to update the regulations in part 177 to correctly reflect all materials that are permitted for use as films/layers of laminated articles intended for use with food. Because this rule simply adds an additional permitted use that was inadvertently omitted from § 177.1390, this rule does not impose any additional costs on industry. Consequently, the agency certifies that this final rule will not have a significant economic impact

on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

### **III. Paperwork Reduction Act of 1995**

The final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

### **IV. Environmental Impact**

The agency has determined under 21 CFR 25.30(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### **V. Federalism**

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

### **VI. Opportunity for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with

the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management 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, 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 177.1390 is amended by adding paragraph (c)(1)(i)(g) to read as follows:

**§ 177.1390      Laminate structures for use at temperatures of 250 °F and above.**

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(c) \* \* \*

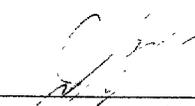
(1) \* \* \*

(i) \* \* \*

(g) Polymeric resins that comply with an applicable regulation in this chapter which permits food type and time/temperature conditions to which the container will be exposed, including sterilization processing.

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Dated: 3/18/04  
March 18, 2004.

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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