Dated: October 15, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28410 Filed 10–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 96F–0164]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations for the use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food. When the regulation was last amended, the agency inadvertently omitted the limitation on the use level for the additive. This document corrects that inadvertent omission.

EFFECTIVE DATE: October 23, 1998.

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 the **Federal Register** of December 16, 1996 (61 FR 65942), FDA published a document amending the food additive regulations to provide for the expanded safe use of sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate as a clarifying agent in high density polyethylene intended for use in contact with food. The limitation added by this document was inadvertently omitted from the December 16, 1996, final rule due to an administrative error. Limiting the use level of the additive to no more than 0.30 percent by weight of the olefin polymers is supported by the administrative record of the final rule. Accordingly, FDA is amending the regulation to accord with the record.

List of Subjects in 21 CFR Part 178

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 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

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

2. Section 178.3295 is amended in the table in the entry for ''Sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate'' by revising entry ''3.'' under the heading ''Limitations'' to read as follows:

§ 178.3295 Clarifying agents for polymers.

* * * * *

Substances	Limitations
* * *	* * * *
Sodium 2,2′-methylenebis(4,6-di-*tert*-butylphenyl)phosphate (CAS Reg. No. 85209–91–2)	For use only: * * * * * 3. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.2, where the finished polymer contacts food only of types I, II, IV–B, VI–A, VI–B, and VII–B as identified in Table 1 of § 176.170(c) of this chapter, and limited to conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, or foods of types III, IV–A, V, VI–C, and VII–A as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.

Dated: October 16, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–28409 Filed 10–22–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 201

[Docket No. 77N–094W]

Over-the-Counter Drug Products Containing Analgesic/Antipyretic Active Ingredients for Internal Use; Required Alcohol Warning

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to require an alcohol warning for all over-the-counter (OTC) drug products, labeled for adult use, containing internal analgesic/antipyretic active ingredients. The required warning statements advise consumers with a history of heavy alcohol use to consult a physician for advice about the use of OTC internal analgesic/antipyretic drug products. FDA is issuing this final rule after considering comments on the agency's proposed regulation for OTC internal analgesic, antipyretic, and antirheumatic drug products; a proposed regulation to establish an alcohol warning; recommendations of its Nonprescription Drugs Advisory Committee (NDAC) and Arthritis Drugs Advisory Committee (ADAC); and new data and information that have come to the agency's attention. This final rule is part of the ongoing