unbundling requirement to the transmission services embodied in pooling or bilateral coordination and joint transmission agreements to which merger applicants are parties.

(h) Eliminate affiliate advantage. APPA urges the Commission to adopt standard conditions for utility mergers to govern affiliate transactions.

(i) Monitor achievement of claimed benefits. Joint Consumer Advoc. argues that there should be a mechanism to monitor whether claimed benefits are actually achieved, but does not offer any specific proposals.

(j) Freeze or reduce rates. Several commenters advocate guaranteed cost reductions to be passed on to consumers or rate freezes by the merger applicants. This would be a condition to overcome the potentially anticompetitive effects of the merger and to ensure that claimed benefits of the merger are received.

Environmental Action et al. believes that a better approach than rate freezes is to simply set rates appropriately.

Florida and Montauk argues that the Commission should not require rate freezes as a condition of approving a merger or a condition to avoiding a hearing on a rate freeze. WI Com discounts the value of a four-year rate freeze if a utility will no longer have an annual rate freeze. This would be a condition to overcome the potentially anticompetitive effects of the merger and to ensure that claimed benefits of the merger are received.

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31141) as being a component of the stabilizer, phosphorous acid, cyclic butylphenyl propanediol, 2,4,6-tri-tert-butylnyl phenyl ester. The correct identity of the stabilizer is phosphorous acid, cyclic butyl ethyl propanediol, 2,4,6-tri-tert-butylenyl ester and is used throughout this final rule.

FDA has evaluated the data in the petition and other relevant material. The agency concludes that the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.2010 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 all personal information 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 January 29, 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. 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 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 and redelegated to the Director, Center for Food Safety and Applied Nutrition, 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:


§ 178.2010 [Amended]

2. Section 178.2010 Antioxidants and/or stabilizers for polymers is amended in the table in paragraph (b) in the entry for "Phosphorous acid, cyclic butyl phenyl propanediol, 2,4,6-tri-tert-butylenyl ester (CAS Reg. No. 161717–32–4") by adding the phrase "the level of response to the December 13, 1996, final rule extends the "Pediatric use" subsection of the professional labeling requirements for prescription drugs. This final rule extends to April 7, 1997, the date for submission of supplemental applications to comply with the new regulation for those manufacturers who notify FDA in writing by January 29, 1997, of their intent to submit a supplement. The agency is taking this action in response to a request for an extension of the compliance date.

Effective Date: December 30, 1996

For further information contact: Erica L. Keys, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1046.

Supplementary Information: In the Federal Register of December 13, 1994 (59 FR 64240), FDA published a final rule that amended its regulations governing the content and format of labeling for human prescription drug products. The regulation revised the "Pediatric use" subsection of the professional labeling requirements for prescription drugs (21 CFR 201.57(f)(9)) to provide for the inclusion of more complete information about the use of a drug in the pediatric population (ages birth to 16 years). The regulation requires sponsors to reexamine existing data to determine whether the "Pediatric use" subsection of the labeling can be modified based on adequate and well-controlled studies in adults and other information supporting pediatric use, and, if appropriate, submit a supplemental application to comply with the new requirements by December 13, 1996. The final regulation gave manufacturers 2 years in which to submit supplements, in response to comments requesting that FDA extend the 1-year implementation period originally proposed.

On November 6, 1996, FDA sent a letter to 250 manufacturers asking them to notify the agency whether and when they intended to file supplements. FDA has received responses from only 40 manufacturers. On November 20, 1996, the Pharmaceutical Research and Manufacturers of America (PhRMA) requested that FDA extend the compliance date of the final rule because some of their members had experienced unexpected problems in gathering the required information.

The absence of adequate pediatric labeling continues to present a significant public health issue and the level of response to the December 13, 1994, final rule is cause for concern. To