pancaking should be a condition for all mergers.[76]

APPA and TDU Systems urge the Commission to codify or apply as a general condition its current requirement of single system transmission pricing for all merged systems, unless the applicants show a public interest basis for different treatment. TDU Systems also suggests that all merging parties be prevented from reducing the transmission capacity presently available for use by transmission customers. Environmental Action *et al.* would prohibit market pricing for power transactions among affiliates of merged companies in regions lacking regional transmission pricing.

(d) Eliminate transmission constraints. Some commenters state that transmission constraints should be addressed by conditioning the approval of the merger on the applicants' building facilities to alleviate the constraints or taking other measures to eliminate local market power.[77]

Competitive Coalition and TDU Systems suggest that where two constrained systems are merging, divestiture of transmission assets should always be considered.

Southern Company cautions against becoming overly concerned with remedying transmission constraints by imposing conditions or by market definition, since other potential remedies or alternatives exist.

(e) Have retail access. Competitive Coalition realizes that the Commission's authority does not extend to ordering direct access at the retail level, but suggests that the concerns over monopsony would be eliminated if merging parties offered open-access distribution. Industrial Consumers, supported by Otter Tail, recommend that, where necessary to avoid anticompetitive effects, we condition approval of mergers by adjacent suppliers on their agreement to provide nondiscriminatory direct access or a finding that a state's adoption of a direct access initiative avoids anticompetitive concerns.

(f) Forego stranded cost recovery. Several commenters see a need to require all merging parties to forego stranded cost recovery in order to mitigate market power.[78]

(g) Reform contracts. Commenters argue that all merging utilities should be required to offer an open season for all of their wholesale requirements contracts and transmission contracts. UtiliCorp argues that many utilities and wholesale customers remain bound to requirements contracts that impede their ability to take advantage of the benefits of the recent competitive influences in the market.[79]

To achieve unrestricted wholesale competition, Competitive Coalition calls for the complete unbundling of transmission services to be required of all merger applicants, including the transmission services contained in existing requirements contracts. It would also extend the 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.[80] 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 Montaup 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 restrictions on its pricing other than the market by the year 2000. It prefers a market structure that ensures that customers have access to many suppliers, none of which will be able to exercise significant market power over the long term.

CINergy, with support from OK Com, argues that rather than debating claims of net benefits, the Commission should protect customers by requiring all merging companies to commit not to recover merger-related costs from ratepayers. Low-Income Representatives would condition all mergers to: (1) continue existing rates, payment programs, protections regarding customer service, and shut-offs for low-income consumers; and (2) assure no impact on attaining or maintaining universal service.

(k) *Retain generation reserve sharing and other coordination arrangements.* TAPS and TDU Systems believe that the Commission should consider imposing a requirement that all merged utilities engage in joint planning and joint ownership of future facilities, continue to offer basic reserve sharing and coordination services, and continue to offer cost-based firm full requirements and partial requirements service.

(l) Maintain reliability and the quality of service. International Brotherhood would require every merger application to contain a plan to maintain or improve reliability and the quality of service.

(m) Eliminate economic impacts. International Brotherhood would require every merger application to demonstrate a lack of adverse economic impact on the economy of the communities served.

(n) Eliminate environmental impacts. Project would condition mergers to mitigate significant adverse environmental impacts identified in an environmental assessment. It would require applicants to bring existing generation units up to standards comparable to the environmental restrictions on their competitors, in effect, to hold the environment harmless from merger-related impacts.

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[76] For example, OK Com, NV Com, CCEM, and TDU Systems.

[77] For example, Florida and Montaup and Wisconsin PS.

[78] Industrial Consumers, Otter Tail, TAPS, and Wisconsin Customers.

[79] For example, UtiliCorp, CCEM, Wisconsin Customers, and Southwestern Electric.

[80] Joint Consumer Advoc., Industrial Consumers, Otter Tail, CINergy, Illinois Industrials, and Texas Industrials.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 96F–0101]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

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 triisopropanolamine as a component of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, as a stabilizer for olefin polymers intended for use in contact with food. This action is in response to a petition filed by General Electric Co.

DATES: Effective December 30, 1996; written objections and requests for a hearing by January 29, 1997.

ADDRESSES: 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–216), 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 June 19, 1996 (61 FR 31141), FDA announced that a food additive petition (FAP 6B4507) had been filed by General Electric Co., 1 Lexan Lane, Mt. Vernon, IN 47620–9364. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of triisopropanolamine as a component of phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester, as a stabilizer for olefin polymers intended for use in contact with food. The additive, triisopropanolamine, was identified in the filing notice (61 FR

31141) as being a component of the stabilizer, phosphorous acid, cyclic butylphenyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester. The correct identity of the stabilizer is phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl 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 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 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. 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 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:

Authority: Secs. 201, 402, 409, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 379e).

§ 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 butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester (CAS Reg. No. 161717–32–4'' by adding the phrase '', which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122–20–3)'' before the period.

Dated: December 19, 1996.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 96–33099 Filed 12–27–96; 8:45 am]

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21 CFR Part 201

[Docket No. 92N–0165]

Specific Requirements on Content and Format of Labeling for Human Prescription Drugs; Revision of ''Pediatric Use'' Subsection in the Labeling; Extension of Compliance Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; extension of compliance date.

SUMMARY: The Food and Drug Administration (FDA) is extending the compliance date of a final rule, that published in the Federal Register of December 13, 1994. The document revised 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 with large numbers of products had encountered 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