All volumes of natural gas purchased by an eligible user and transported by an interstate pipeline pursuant to this subpart shall not be considered as either a natural gas supply or market in a determination of an interstate pipeline's customer's requirements for present or future allocations of natural gas during periods of natural gas curtailment.

Con Ed intends to file a petition for rehearing alleging that this amendment to § 284.206 is in error. Con Ed alleges that certain of its gas purchase contracts are contingent upon receiving the assurances provided in § 284.206. In order to prevent the possible loss of these supplies to Con Ed while the Commission consideration of its petition for rehearing is pending, a stay of the amendment to § 284.206 will be granted.

The Commission Orders:

The amendment to § 284.206 specified in Ordering Paragraph (6) of Order No. 30–D shall be stayed until after the Commission issues its order on rehearing of Order No. 30–D.

By the Commission. Commissioner Holden voted present.

Kenneth F. Plumb,

Secretary.

[FR Doc. 80–27576 Filed 9–11–80; 8:45 am]

BILLING CODE 6450–85–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 74 and 201

[Docket No. 77N–0009]

Color Additives Subject To Certification; FD&C Yellow No. 5; Labeling In Food and Drugs For Human Use; Confirmation of Effective Date and Amendments

AGENCY: Food and Drug Administration.

ACTION: Final Rule.

SUMMARY: This document confirms the effective dates of July 1, 1981 for food and of June 26, 1980 for drugs of regulations requiring the label declaration of FD&C Yellow No. 5. The regulations have been revised in response to objections to those portions that pertain to the use of FD&C Yellow No. 5 in drugs for human use that are administered orally, nasally, vaginally, or rectally. Specifically, sections are revised to state that the labels of drug products that are also cosmetics do not have to include the name "tartrazine" in the declaration of FD&C Yellow No. 5, and a section is revised to state that it applies only to drugs for human use.

EFFECTIVE DATE: The effective dates are confirmed: For foods, July 1, 1981; for drugs, June 26, 1980. Foods and drugs initially introduced or initially delivered for introduction into interstate commerce shall be labeled as set forth in the regulations below on or after these dates.

FOR FURTHER INFORMATION CONTACT:

Foods—Gerad L. McCowin, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–472–5690.

Drugs—Paul O. Fehnel, Bureau of Drugs (HFD–30), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6490.

SUPPLEMENTARY INFORMATION: A regulation published in the **Federal Register** of June 26, 1979 (44 FR 37212) added § 201.20 (21 CFR 201.20) to Subpart A of Part 201 (21 CFR Part 201) to require the declaration of the presence of FD&C Yellow No. 5 in certain drugs and amended §§ 74.705, 74.1705, and 101.22 (21 CFR 74.705, 74.1705, and 101.22) to require label declaration of the presence of FD&C Yellow No. 5 in foods and/or drugs.

In response to the order, 15 objections were filed. They came from food, drug, and cosmetic manufacturers, industry associations, and a consumer group. Most of the objections relate to drug labeling. One of the fifteen objections also requested a hearing and is discussed below under objection 5. Because the agency agrees with this objection and has revised the regulation accordingly, the issue of a hearing is moot.

A summary of the objections and FDA's responses follow:

Food-Related Objections

1. One objection, in the form of a citizen petition from the Grocery Manufacturers of America, Inc., (GMA) requested that the abbreviated term "Yellow 5" be permitted on foods. This petition was assigned a color additive petition number, 9CP0147. The petition claimed that manufacturers would conserve 50 percent of the total space required by the label declaration of "FD&C Yellow No. 5."

The agency denied this petition on February 11, 1980, for the following three reasons:

a. The denial was based primarily on the safety considerations involved. Because of the serious, sometimes life-threatening nature of the reaction in those people who are sensitive to the dye, it is extremely important that labeling information enable both the physician responsible for the diagnosis and management of the allergic-type reaction and the consumer with the condition to immediately recognize products containing FD&C Yellow No. 5. The agency considers the need for both physicians and consumers to determine easily that FD&C Yellow No. 5 is synonymous with tartrazine so important that, for drug products, both names are required on the label to ensure easy identification. The simple terminology "Yellow 5" on the label suggested in the petition prevents, or at least impedes, such persons from making this link between tartrazine and FD&C Yellow No. 5 because no compendia list "Yellow 5." Instead, all compendia list the common or usual name "FD&C Yellow No. 5" (e.g., Merck Index, Handbook of Food Additives, Food Chemicals Codex, Colour Index). The two names also have different Chemical Abstract numbers. FD&C Yellow No. 5 is CAS #1934–21–0, while Yellow 5 is CAS #1342–47–8. Further, it is not possible to find a structure, molecular formula, or systematic name under the term "Yellow 5." Although the common or usual name could be changed for FD&C Yellow No. 5, it would take at least a decade for all compendia, registries, and computerized literature files to incorporate this change. Meanwhile, the potential safety hazard would exist.

b. The consumer confusion that would result from foods, drugs, and cosmetics each being labeled differently could further compound this safety problem. The petition would amend the food labels to read "Yellow 5." Drugs will be labeled "FD&C Yellow No. 5 (tartrazine)," and cosmetics are already labeled "FD&C Yellow No. 5." Consumers could easily fail to recognize that, indeed, all three labels represented the same compound.

c. "Yellow 5" is not a unique name. Many other Yellow 5's exist, including Ext. D&C Yellow No. 5, C.I. Acid Yellow 5, C.I. Mordant Yellow 5, C.I. Basic Yellow 5, C.I. Disperse Yellow 5, C.I. Natural Yellow 5, and C.I. Food Yellow 5 (permitted in the United Kingdom).

The common or usual name of the color is "FD&C Yellow No. 5" and, therefore, it should be stated as such on the labels of all food products by the effective date of July 1, 1981.

On March 12, 1980, GMA filed a petition for reconsideration of the denial. This petition was treated as part of the earlier petition (9CP0147). FDA is considering its response. The common or usual name issue will in any case continue to be handled separate from the disclosure regulations under discussion.

2. One objection from an alcoholic beverage manufacturer requested a 3-year transition period to make the label changes on its products. This 3-year period would be the same as that mandated by the Bureau of Alcohol, Tobacco and Firearms for conversion of alcoholic beverage labels to the metric

system. However, an objection from a consumer group argued that the July 1, 1981 effective date was much too long because manufacturers have been aware of the impending change since the proposal of February 4, 1977.

The effective date of July 1, 1981 for food labeling provides a reasonable and sufficient period of time for businesses to use up current stocks of labels and acquire new stocks of labels which include a declaration of the presence of FD&C Yellow No. 5. As discussed in the preamble to the final rule (44 FR 37215; June 26, 1979), the agency is applying the same effective date to a number of regulations requiring labeling changes to avoid the undue economic hardship that a series of label changes might entail. However, the agency cannot further extend this date to 1982 because of the serious health problem involved. Two years' notice (4 years since the proposed rule) is reasonable and adequate for a relatively simple labeling change.

3. One objection requested a ban on the use of FD&C Yellow No. 5 because of the safety problems involved and the data submitted by the Health Research Group in its petition of January 1, 1977, which sought the revocation of the color additive regulations providing for the use of six color additives, including FD&C Yellow No. 5.

The agency rejects this suggestion for the following two reasons:

a. As discussed in the preamble to the final rule (44 FR 37214), there is insufficient data to suggest that a ban of the color is necessary to protect those persons sensitive to FD&C Yellow No. 5. On the contrary, the preponderance of data suggests that a simple label declaration that FD&C Yellow No. 5 is present in a product will be sufficient to protect these individuals.

b. In the **Federal Register** of November 24, 1978 (43 FR 54990) the agency denied the petition submitted by the Health Research Group because the claims concerning safety problems were not supported by adequate scientific evidence.

4. One objection requested the dual declaration of FD&C Yellow No. 5 (tartrazine) on foods containing the color. It also requested the label declaration of FD&C Yellow No. 5 when packaging material in contact with cheese contains the color.

The agency rejects these suggestions because of the reasons discussed in the preamble to the final rule (44 FR 37214–37215). This objection offered no new data to change the agency's previous conclusions.

Drug Related Objections

5. Several objections requested the agency to exempt drug products which are also cosmetics, particularly antibacterial mouthwashes and fluoride toothpastes, from the requirement that both "FD&C Yellow No. 5" and "tartrazine" appear on the labels of drugs. The objections argued that, as cosmetics, these products already bear labels setting forth their active and inactive ingredients including "FD&C Yellow No. 5." Thus, it was argued, the labeling on these products should be comparable to the labeling of cosmetic products and manufacturers of these drug products that are also cosmetics should not be required to incur the expense of a labeling change when FDA has determined that the current ingredient labeling is adequate for other cosmetic products.

The agency agrees with these objections and has revised the final regulations to exempt mouthwashes and toothpastes that are both drugs and cosmetics from the dual labeling requirement. Section 701.3 (21 CFR 701.3) requires cosmetic products, including drug products that are also cosmetics, to declare the presence of FD&C Yellow No. 5 on their labels by a simple declaration without reference to tartrazine. Different labeling requirements under § 201.20 for the same ingredient in competing products might become a source of confusion for consumers and would impose an inequitable burden on affected products.

6. One objection requested that the final rule be revised by adding the words "for use by man" after the words "drug products" in § 201.20(a) and after the word "drugs" in § 201.20(b). The objection stated that this request would be consistent with statements made in the preamble that the declaration of FD&C Yellow No. 5 is not required on animal drugs, and would eliminate any confusion as to whether the requirements imposed by § 201.20 are intended to apply to drugs for animal use.

As stated in the last paragraph of the preamble to the final rule, the agency is not requiring the label declaration of FD&C Yellow No. 5 in animal feeds and pet foods. The agency, therefore, agrees with this recommendation. Therefore, §§ 74.1705 and 201.20, which deal with the requirements for certification of FD&C Yellow No. 5, are revised accordingly.

7. Several objections requested a change in the effective date requirement for drug products containing FD&C Yellow No. 5. As published, the regulation was effective for drugs initially introduced or initially delivered for introduction into interstate commerce on or after June 26, 1980 or at the next printing of the labeling, whichever occurs first. The objections requested that the requirement for revision "at the next printing" be deleted.

The agency deleted the requirement for labeling revision "at the next printing" in a notice published in the **Federal Register** of August 3, 1979 (44 FR 45614). This action, requested in a petition from the Pharmaceutical Manufacturers Association, was taken because of unforeseen difficulties in implementing this requirement.

8. One objection requested modification of the words "initially introduced or initially delivered for introduction into interstate commerce" in the effective date for drugs. The objection argued that this wording would require the relabeling of inventories of drugs containing FD&C Yellow No. 5 whose label did not declare its presence after June 26, 1980. The objection stated that this relabeling was unreasonable, costly, and unnecessary, particularly in view of the fact that the effective date for goods is not until July 1, 1981. The objection recommended that the effective date be revised so as to apply to drugs labeled after 1 year from the date of publication of the regulation. Another objection requested that the effective date for drugs be revised to conform to the effective date for foods.

The agency rejects the suggested changes to the effective date. First, the term "labeled" is not sufficiently precise to serve as the basis for an effective date. For example, it may apply when labels are placed on containers, or when containers are placed into another carton or package which itself bears a label. Second, the language "initially introduced or initially delivered for introduction into interstate commerce" is from the Federal Food, Drug, and Cosmetic Act, and is the traditional test applied to violative conduct under the act. Finally, the requirement is reasonable; it has provided manufacturers sufficient time (1 year) to use existing supplies of labeling and to plan for new labeling. The reasonableness of the date is supported by the fact that other firms stated they would have sufficient time to implement the necessary labeling changes if the phrase "at the next printing" was removed from the effective date requirement. The July 1, 1981 effective date for foods was chosen because that date was published in the **Federal Register** of September 29, 1978 (43 FR

44830) as the uniform effective date for compliance with all food labeling regulations, not just FD&C Yellow No. 5. A mandatory uniform effective date has not been established for drugs, and for reasons detailed in the preamble to the final rule (44 FR 37219), the agency concluded that the requirements for drug products should become effective earlier than those for foods.

9. One objection requested that labels with insufficient space be exempt from the required label statements.

The agency did not include such an exemption in the final rule because the provisions of § 201.10(i) (21 CFR 201.10(i)) already provide such an exemption for all drugs. Section 201.10(i) states that if the label has insufficient space to contain all required information, the information may appear on the carton or other outer container or wrapper provided certain prescribed information, i.e., proprietary name of the drug, established name of the drug, if any, a lot or control number, and name of manufacturer, packer, or distributor of the drug, appear on the container label. If a firm believes it has a product with a label too small to bear all the required information and the label cannot be made larger to accommodate the required information, it is recommended that the firm discuss the need for the exemption with the agency.

10. One objection said it was repetitive and unnecessary to have the FD&C Yellow No. 5 warning statement appear on the label of prescription drugs because it is required to appear on the package insert.

Both prescription drugs and OTC drugs are required to declare on their labels presence of FD&C Yellow No. 5. The package inserts used with prescription drugs are also required to contain a statement warning about the possible allergic-type reactions that FD&C Yellow No. 5 causes in certain susceptible persons. The presence of the warning in a package insert does not abrogate the need for the required label declaration on the drug's container. The primary purpose of requiring a label declaration on prescription drugs is to enable health professionals to readily identify those drug products containing FD&C Yellow No. 5 without opening the package to read the package insert. This purpose can only be met by the required label declaration. The warning appearing in the package insert is intended to inform prescribers and other health professionals of the basis for the label declaration. It is not intended to be a substitute for the label declaration.

11. The agency received an objection from one firm requesting that the warning statement, required in the "Precautions" section of the package insert, be amended to read "This product contains FD&C Yellow No. 5 (tartrazine) which may cause hypersensitivity reaction, including bronchial asthma in patients with a history of aspirin sensitivity." The petition asserted that the statement required by the regulation strongly implies, by the use of the phrase "frequently seen in patients who also have aspirin hypersensitivity" that many people who are aspirin sensitive also show hypersensitivity to tartrazine. Further, the petition stated that because only a small percentage of persons sensitive to aspirin are also sensitized to tartrazine, the statement required by the June 26, 1979 regulation overstates the facts and is misleading.

The agency rejects this requested change in the warning statement. The revision requested is not acceptable because it implies that only patients with known aspirin sensitivity are susceptible to hypersensitivity reactions to tartrazine. Such an implication is incorrect. Reactions to tartrazine have been reported in allergic patients who can take aspirin without incident. Also incorrect is the petitioner's supporting rationale, that "only a relatively small percentage of aspirin-sensitive individuals are also sensitive to tartrazine." Data placed on file with FDA's Hearing Clerk in support of the FD&C Yellow No. 5 proposal show the reported incidence of tartrazine intolerance among patients with known aspirin sensitivity has varied from 5 to 80 percent, depending upon the particular allergic population, the dose of tartrazine, and the criteria used in assessing the effects. Despite imprecise data on incidence, however, the majority of reports indicate that patients who are intolerant of aspirin are likely to have intolerance to certain other chemical substances including azo dyes such as tartrazine. The frequency of cross sensitivity between tartrazine and aspirin has led some experts to advocate routine testing for both substances in asthmatic patients. (Stenius, B. S. M. and M. Lemola, "Hypersensitivity to Acetylsalicylic Acid (ASA) and Tartrazine in Patients with Asthma," *Clinical Allergy*, 6:119–129, 1976.)

12. The agency received two petitions to change the supplemental new drug application requirements providing for the deletion of FD&C Yellow No. 5 and the reformulation of the product with another color additive.

One petition requested that all such changes be permitted to be placed into effect before the agency has approved the supplement. The petition alleged that the ultimate objective of the final rule was to encourage manufacturers to eliminate FD&C Yellow No. 5 from their products, and that the 1 year provided would not be sufficient time for reformulation work, generation of minimal stability data, submission of a supplemental NDA, and approval of the supplement by the FDA. The petition stated that manufacturers should be encouraged to reformulate their products to remove FD&C Yellow No. 5 if regulatory requirements were modified to facilitate the process as requested in the petition.

The second petition requested that the agency stay the effective date of the final rule for any new drug which is the subject of a supplemental new drug application submitted before June 26, 1980 and which provides for the substitution of FD&C Yellow No. 5 with another color additive. This petition pointed out that if a supplemental new drug application providing for the removal of FD&C Yellow No. 5 and its replacement with another color additive were not approved in sufficient time, firms would be faced with the prospect of multiple labeling changes, first to show the presence of FD&C Yellow No. 5 and then, when the supplement is approved, to reflect the new formulation which does without FD&C Yellow No. 5.

The first petition is granted. The objective of the final rule was not to encourage manufacturers to eliminate FD&C Yellow No. 5 from their products, but rather to require its identification, through labeling, where it is used. Nonetheless, the agency does agree with the petitioner that supplements providing for the substitution of FD&C Yellow No. 5 with another approved color additive, or simply the removal of FD&C Yellow No. 5 as an ingredient, should be permitted to be placed into effect at the earliest possible time. Therefore, the agency is advising that no action will be taken against a drug or applicant solely because either of these changes is placed into effect prior to approval of the supplemental new drug application, if the supplement complies with the requirements of § 314.8(e) (21 CFR 314.8(e)). Section 314.8(d) (21 CFR 314.8(d)) provides that certain kinds of changes can be placed into effect by an applicant prior to receipt of a written notice of approval of a supplemental NDA. The agency believes that, if an applicant is going to replace FD&C Yellow No. 5 with another color additive approved for such use, it is a type of change that need not be delayed pending approval of an NDA supplement.

The second petition is denied. The requested stay of effective date would allow some drug products to be marketed for an unspecified time after the present effective date without declaring the color's presence. The agency believes this result would be contrary to the public interest. Nonetheless, insofar as the petition was based upon the agency's requirement that an NDA supplement be approved prior to the initiation of any formulation changes, the petitioner has a positive response because of the agency's decision to permit changes to be made with respect to replacements for FD&C Yellow No. 5 prior to approval of the supplement.

Copies of all objections received and other documents referenced are available for public review at the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., under docket number 77N–0009.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 501, 502, 701, 706 (b), (c), and (d), 52 Stat. 1049–1051 as amended, 1055–1056 as amended, 74 Stat. 399–403 (21 U.S.C. 351, 352, 371, 376 (b), (c), and (d))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), there being no other objections or requests for a hearing in response to the order of June 26, 1979, the amendments to Parts 74, 101, and 201 promulgated thereby become effective on July 1, 1981 for foods and June 26, 1980 for drugs. Sections 74.705 and 101.22 remain as originally published in the regulation of June 26, 1979. Sections 74.1705 and 201.20 are amended in response to objections received to read as follows:

1. In Part 74, in § 74.1705 by revising paragraph (c) to read as follows:

§ 74.1705 FD&C Yellow No. 5.

* * * * *

(c) *Labeling requirements.* (1) The label of the color additive and any mixtures intended solely or in part for coloring purposes prepared therefrom shall conform to the requirements of § 70.25 of this chapter.

(2) The label of OTC and prescription drug products intended for human use administered orally, nasally, rectally, or vaginally containing FD&C Yellow No. 5 shall specifically declare the presence of FD&C Yellow No. 5 by listing the color additive using the names FD&C Yellow No. 5 and tartrazine. The label shall bear a statement such as "Contains FD&C Yellow No. 5 (tartrazine) as a color additive" or "Contains color additives including FD&C Yellow No. 5 (tartrazine)." The labels of certain drug products subject to this labeling requirement that are also cosmetics, such as: antibacterial mouthwashes and fluoride toothpastes, need not comply with this requirement provided they comply with the requirements of § 701.3 of this chapter.

(3) The labeling required by § 201.100(d) of this chapter for prescription drugs for human use containing FD&C Yellow No. 5 that are administered orally, nasally, vaginally, or rectally shall, in addition to the label statement required under paragraph (c)(2) of this section, bear the warning statement "This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity." This warning statement shall appear in the "Precautions" section of the labeling.

* * * * *

2. In Part 201, by revising § 201.20 to read as follows:

§ 201.20 Declaration of presence of FD&C Yellow No. 5 in certain drugs for human use.

(a) The label of OTC and prescription drug products intended for human use administered orally, nasally, rectally, or vaginally containing FD&C Yellow No. 5 shall specifically declare the presence of FD&C Yellow No. 5 as a color additive using the names FD&C Yellow No. 5 and tartrazine. The labeling shall bear a statement such as "Contains FD&C Yellow No. 5 (tartrazine) as a color additive" or "Contains color additives including FD&C Yellow No. 5 (tartrazine)." The labels of certain drug products subject to this labeling requirement that are also cosmetics, such as: antibacterial mouthwashes and fluoride toothpastes, need not comply with this requirement provided they comply with the requirements of § 701.3 of this chapter.

(b) The labeling required by § 201.100(d) of this part for prescription drugs for human use containing FD&C Yellow No. 5 that are administered orally, nasally, vaginally, or rectally shall bear the warning statement "This product contains FD&C Yellow No. 5 (tartrazine) which may cause allergic-type reactions (including bronchial asthma) in certain susceptible persons. Although the overall incidence of FD&C Yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity." This warning statement shall appear in the "Precautions" section of the labeling.

Effective dates. The amendments promulgated by the regulation of June 26, 1979, and the amendments set forth above shall be effective as to foods and drugs initially introduced or initially delivered for introduction into interstate commerce on or after the following dates: For foods, July 1, 1981; for drugs, June 26, 1980.

(Secs. 501, 502, 701, 706(b), (c), and (d), 52 Stat. 1049–1051 as amended, 1055–1056 as amended, 74 Stat. 399–403 (21 U.S.C. 351, 352, 371, 376(b), (c), and (d)))

Dated: September 5, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–27870 Filed 9–11–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 178

[Docket No. 80F–0033]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers; Tris(2,4-Di-Tert-Butylphenyl)Phosphite

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of tris(2,4-di-*tert*-butylphenyl)phosphite as an antioxidant and/or stabilizer for polybutadiene used in rubber articles intended for repeated use. Ciba-Geigy Corp. petitioned for this use.

DATES: Effective September 12, 1980. Objections by October 14, 1980.

ADDRESS: Written objections to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Mary W. Lipien, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St., SW., Washington, DC 20204, 202–472–5740.

SUPPLEMENTARY INFORMATION: FDA published a notice in the **Federal Register** of March 11, 1980 (45 FR 15672) announcing that a food additive petition (FAP OB3492) had been filed by Ciba-Geigy Corp., Ardsley, NY 10502, proposing that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of tris(2-di-*tert*-

butylphenyl)phosphite as an antioxidant and/or stabilizer for polybutadiene used in rubber articles complying with § 177.2600. FDA has evaluated data in the petition and other relevant material and concluded that § 178.2010 should be amended as set forth below to include the petitioned additive.

The agency has carefully considered the potential environmental effects of this action and 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 environmental assessment may be seen in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1), Part 178 is amended in § 178.2010(b) by inserting a new entry alphabetically in the table, to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	*Limitations*
* * *	* * * *
Tris(2,4-di-*tert*-butylphenyl) phosphite. (CAS Reg. No. 31570–04–4).	For use only at levels not to exceed 0.5 percent by weight of polybutadiene used in rubber articles complying with § 177.2600 of this chapter, provided that the rubber end product contacts foods only of the types identified in categories I, II, IV–B, VI, VII–B, and VIII in table 1, § 176.170(c) of this chapter and only at temperatures not to exceed 150° F.
* * *	* * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before October 14, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. 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 present 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. Four copies of all documents shall be submitted and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this regulation. Received objections may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective September 12, 1980.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: September 3, 1980.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 80–27868 Filed 9–11–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Parts 436 and 442

CFR Correction

The following are corrections to errors made in Title 21, Parts 300 to 499, revised as of April 1, 1980.

§ 436.105 [Amended]

1. In § 436.105(a) table located on page 249, the item Cefamandole is corrected to read as follows:

Cefamandole	2	1	21	5	A	0.06	37

2. In § 436.105(b) table located on page 251, the item Cefamandole is corrected to read as follows:

Cefamandole	Not dried		3	1 mg[5]	1 day	1	1.28, 1.60, 2.00, 2.50, 3.12 μg

§ 442.40 [Amended]

3. In § 442.40 the illustration located on page 413 should read as follows:

BILLING CODE 1505–01–M