and TVA accordingly declines to furnish all such material, no fees shall be charged. TVA may waive or reduce fees otherwise chargeable under this section upon its determination that waiver or reduction is in the public interest because furnishing the information can be considered as primarily benefitting the general public.

Dated: June 4, 1981.

W. F. Willis,

General Manager.

[FR Doc. 81-17423 Filed 6-11-81; 8:45 am]

BILLING CODE 8120-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 5

Delegations of Authority and Organization; Medical Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the regulations for delegations of authority regarding medical devices to redelegate certain authorities to additional officials in the Bureau of Medical Devices (BMD) and the Bureau of Radiological Health (BRH). The action will provide greater operating flexibility, more effective and efficient operations, and more expeditious handling of regulated submissions.

EFFECTIVE DATE: June 12, 1981.

FOR FURTHER INFORMATION CONTACT: Robert L. Miller, Office of Management and Operations (HFA-340), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4976.

SUPPLEMENTARY INFORMATION: Section 5.45 (21 CFR 5.45) is amended by adding the Associate Director for Compliance, BMD, and the Director, Division of Compliance, BRH, to the delegates authorized to perform functions relating to the export of medical devices. Section 5.47 (21 CFR 5.47) is amended by adding those same officials to the delegates authorized to perform functions relating to detention of medical devices that may be adulterated or misbranded.

Section 5.50 (21 CFR 5.50) is amended by adding the Deputy Director and the Associate Director for Device Evaluation, BMD, to the delegates authorized to perform functions relating to notification to petitioners of determinations made on petitions for reclassification of medical devices.

Section 5.52 (21 CFR 5.52) is amended by adding the Deputy Director and the Associate Director for Device Evaluation, BMD, and the Director and Deputy Director, BRH, to the delegates authorized to perform functions relating to notification of sponsors of deficiencies in petitions for reclassification of medical devices.

Section 5.53 (21 CFR 5.53) is amended by adding the Deputy Director and the Associate Director for Device Evaluation, BMD, to the delegates authorized to perform functions relating to the approval, disapproval, revocation, or declaration as complete or incomplete product development protocols and the approval, disapproval, or withdrawal of approval of applications for premarket approval for medical devices. Section 5.59 (21 CFR 5.59) is amended by adding those same officials to the delegates authorized to perform functions relating to approval, disapproval, or withdrawal of applications for investigational device exemptions and termination of certain notices of claimed investigational exemptions for a new drug.

Further redelegation of the authority delegated is not authorized. Authority delegated to a position by title may be exercised by a person officially designated to serve in such position in an acting capacity or on a temporary basis.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 5 is amended:

1. By revising § 5.45(e) to read as follows:

§ 5.45 Imports and exports.

* * * * *

(e) The Director, Deputy Director, and the Associate Director for Compliance of the Bureau of Medical Devices and the Director, Deputy Director, and the Director of the Division of Compliance of the Bureau of Radiological Health, for medical devices assigned to their respective Bureaus, Regional Food and Drug Directors, and District Directors are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to exportation of medical devices under section 801(d) of the Federal Food, Drug, and Cosmetic Act.

2. By revising § 5.47 to read as follows:

§ 5.47 Detention of adulterated or misbranded medical devices.

The Director, Deputy Director, and the Associate Director for Compliance of the Bureau of Medical Devices and the Director, Deputy Director, and the Director of the Division of Compliance of the Bureau of Radiological Health, for medical devices assigned to their respective Bureaus, Regional Food and Drug Directors, and District Directors are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention under section 304(g) of the Federal Food, Drug, and Cosmetic Act of medical devices that may be adulterated or misbranded.

3. By revising § 5.50 to read as follows:

§ 5.50 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

The Director, Deputy Director, and the Associate Director for Device Evaluation of the Bureau of Medical Devices are authorized to notify petitioners of:

(a) Determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by section 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act);

(b) Denials of petitions for reclassification of medical devices that are submitted under section 513(e) (except for petitions submitted in response to **Federal Register** notices initiating standard-setting under section 514(b) of the act or premarket approval under section 515(b) of the act).

4. By revising § 5.52 to read as follows:

§ 5.52 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

The Director, Deputy Director, and the Associate Director for Device Evaluation of the Bureau of Medical Devices, and the Director and Deputy Director of the Bureau of Radiological Health, for medical devices assigned to their respective Bureaus, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act.

5. By revising § 5.53 (a) and (b) to read as follows:

§ 5.53 Appproval, disapproval, or withdrawal of approval of applications for premarket approval for medical devices.

(a) The Director, Deputy Director, and Associate Director for Device Evaluation of the Bureau of Medical Devices are authorized to approve, disapprove, revoke, or declare as complete or incomplete product development protocols for medical

devices submitted under section 515(f) of the Federal Food, Drug, and Cosmetic Act.

(b) The Director, Deputy Director, and Associate Director for Device Evaluation of the Bureau of Medical Devices are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under sections 515 and 520(l) of the Federal Food, Drug, and Cosmetic Act.

* * * * *

6. By revising § 5.59 to read as follows:

§ 5.59 Approval, disapproval, or withdrawal of applications for investigational device exemptions.

The Director, Deputy Director, and Associate Director for Device Evaluation of the Bureau of Medical Devices are authorized to approve, disapprove, or withdraw applications for investigational device exemptions submitted under section 520(g) of the Federal Food, Drug, and Cosmetic Act.

Effective date. This regulation shall become effective June 12, 1981.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)))

Dated: June 4, 1981.

Joseph P. Hile,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-17235 Filed 6-11-81; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Parts 74, 101, 135

[Docket No. 79N-0116]

FD&C Yellow No. 5 Labeling of Ice Cream and Frozen Custard; Extension and Confirmation of Effective Date

AGENCY: Food and Drug Administration.

ACTION: Extension and confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is extending from July 1, 1981, to July 1, 1982, the time for complying with the amendment of the standard of identity for ice cream and frozen custard (21 CFR 135.110(f)) and with the label declaration of FD&C Yellow No. 5 required by 21 CFR 74.705(d)(2) and 21 CFR 101.22(c), as the latter two sections apply to ice cream and frozen custard. The purpose of the extension is to allow manufacturers to make the label changes in an orderly, efficient manner. Because no objections were received on the final regulations, other than a petition to extend the effective date by an additional year, FDA confirms that the regulation will be effective on July 1, 1982.

EFFECTIVE DATE: Compliance with 21 CFR 135.110(f) may have begun November 25, 1980. All affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1982, shall fully comply.

FOR FURTHER INFORMATION CONTACT: Eugene T. McGarrahan, Bureau of Foods (HFF-215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-1155.

SUPPLEMENTARY INFORMATION: FDA issued a final regulation in the **Federal Register** of September 26, 1980 (45 FR 63837) amending the standard of identity for ice cream and frozen custard (21 CFR 135.110(f)) to require label declaration of FD&C Yellow No. 5 when it is used in either of these foods (Docket No. 79N-0116). This amendment implements the provisions of 21 CFR 74.705(d)(2) and 21 CFR 101.22(c) that, effective July 1, 1981, will require the declaration of FD&C Yellow No. 5 on the labels of all foods in which the color additive is used, including butter, cheese, and ice cream.

Because food standards are promulgated by formal rulemaking, in the final regulation amending the standard of identity for ice cream and frozen custard FDA gave persons adversely affected an opportunity to submit objections and requests for hearing. Although no objections or requests were received, the International Association of Ice Cream Manufacturers (IAICM) submitted a petition to delay the effective date of the regulation by 1 year. Although IAICM did not object to the labeling requirement itself, the association contended that the label revisions necessary to meet the July 1, 1981 effective date will be costly because the industry recently underwent a major label revision to comply with labeling requirements that became effective July 1, 1979 (42 FR 35152; July 8, 1977). The IAICM stated that the additional costs of another label change following so closely on the previous change will be a burden to manufacturers that ultimately will affect consumers. Therefore, the IAICM requested that the effective date of the FD&C Yellow No. 5 labeling requirement for ice cream and frozen custard be delayed until July 1, 1982, with the provision that any label revisions initiated for the affected product containers before July 1, 1982, shall be in accordance with all applicable provisions of 21 CFR Parts 74 and 101.

FDA concludes that IAICM has presented reasonable grounds in support of the request. Therefore, FDA is extending the effective date of § 135.110(f) to July 1, 1982, from July 1, 1981, and is confirming the July 1, 1982 effective date. Further, to eliminate conflicting effective dates for complying with the new labeling requirements for FD&C Yellow No. 5 in ice cream and frozen custard, FDA advises that, by this notice, it is also extending the effective date for complying with §§ 74.705(d)(2) and 101.22(c), as these two sections apply to ice cream and frozen custard, from July 1, 1981, to July 1, 1982; however, the July 1, 1981 effective date will remain in effect for all other products.

Sections 74.705(d)(2) and 101.22(c) were published under Docket No. 77N-0009 as a final rule in the **Federal Register** of June 26, 1979 (44 FR 37212), and their effective date was confirmed on September 12, 1980 (45 FR 60419).

A copy of the petition is available for public review at the Dockets Management Branch (formerly the Hearing Clerk's office) (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 No. 79N-0116.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701, 52 Stat. 1046 as amended, 1055-1056 as amended (21 U.S.C. 341, 371)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)) there being no objections or requests for a hearing in response to the final regulation, notice is given that 21 CFR 135.110(f), as set forth in the **Federal Register** of September 26, 1980 (45 FR 63837), will be effective July 1, 1982. Voluntary compliance may have begun November 25, 1980. Notice is also given that 21 CFR 74.705(d)(2) and 21 CFR 101.22(c), as set forth in the **Federal Register** of June 26, 1979 (44 FR 37212), as they apply to ice cream and frozen custard only, will also be effective July 1, 1982.

Dated: June 4, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-17301 Filed 6-11-81; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 166

[Docket No. 78P-0254]

Margarine Labeling

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the

margarine labeling regulations by deleting those provisions which set forth the names by which certain ingredients in oleomargarine or margarine should be declared. This will eliminate duplications and inconsistencies in the ingredient labeling requirements for margarine.

EFFECTIVE DATES: July 1, 1983, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date.

Voluntary compliance: August 11, 1981.

Objections by July 13, 1981.

FOR FURTHER INFORMATION CONTACT: Howard N. Pippin, Bureau of Foods (HFF-312), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-245-3092.

SUPPLEMENTARY INFORMATION: In the Federal Register of October 5, 1979 (44 FR 57422), FDA proposed to amend the margarine labeling regulations (21 CFR 166.40) by deleting those provisions, paragraph (b) (1) through (10), which set forth the names by which certain ingredients in oleomargarine or margarine should be declared. This action was taken to eliminate inconsistencies with, or duplications of, the margarine standard of identity labeling requirements and requirements under 21 CFR Part 101. One comment was received from the National Association of Margarine Manufacturers (NAMM) in response to the proposal. The issues raised by NAMM and the agency responses are as follows:

1. NAMM requested that FDA continue to allow the grouping of the fats and/or oils used in margarine and oleomargarine without requiring the identifying phrase before the list of fats and/or oils as established by 21 CFR 101.4(b)(14). NAMM stated that the consumers are already aware that margarine is typically a "vegetable oil blend" and that an identifying phrase will confuse them.

FDA does not agree that the addition of the identifying phrase before a parenthetical listing of the fat and/or oil ingredients will confuse the consumer. On the contrary, the listing of fat and/or oil ingredients as required by § 101.4(b)(14) makes it clear to the consumer that the major portion of the product is a blend of the listed fats and/or oils and that such fats and/or oils are not in the ingredient statement in order of predominance. Thus, the consumer is put on notice that the individual fat or oil ingredients may be present in the amounts less than the amounts of the other ingredients appearing in the ingredient statement. FDA concludes that the labeling requirements as established in 21 CFR Part 101 are in the consumers' best interest and, therefore, if a manufacturer chooses to group the fats and/or oils, the ingredient statement of some labels will have to be changed to include an identifying phrase followed by the parenthetical listing of the fats and/or oils.

2. NAMM stated that butter is listed as an optional ingredient in § 166.40(b)(3) but not in § 166.110 and requested clarification of the use of butter as an optional ingredient.

The question of the use of butter as an optional ingredient included in the term "milk products" was addressed in the Federal Register of September 14, 1973 (38 FR 25671). In that document, FDA stated that "butter may be added without limit as a milk and/or milk product ingredient, providing that some other fat or oil ingredient under § 45.1(a)(1) (currently § 166.110(a)(1)) is also used as part of the 80 percent fat minimum." The deletion of § 166.40(b)(3) does not affect the use of butter as an optional ingredient in margarine.

3. NAMM expressed a concern that manufacturers would no longer be allowed to declare vitamins A and D in conjunction with their sources in the ingredient listing.

FDA advises that, although the phrases, "vitamin A added" or "with added vitamin A" and "vitamin D added" or "with added vitamin D," are no longer required. They are not prohibited and may continue to be placed on the label as long as the required information concerning source and nutrition comply with the applicable sections of Part 101.

FDA recognizes that the proposed effective date of July 1, 1981, has been passed and therefore the effective date for compliance with the amendment is now July 1, 1983, the new uniform effective date for complying with new labeling requirements published after October 31, 1980.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 166 is amended by revising § 166.40(b) to read as follows:

§ 166.40 Labeling of margarine.

* * * * *

(b) The identity standard for oleomargarine or margarine applies to both the uncolored and the colored article.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before July 13, 1981 submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (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 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. Four copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. Except as to any provisions that may be stayed by the filing of proper objections, compliance with this final regulation, including any required labeling changes, may begin August 11, 1981, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply. Notice of the filing of objections or lack thereof will be published in the Federal Register.

Dated: June 5, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-17437 Filed 6-11-81; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 178

[Docket No. 80F-0194]

Indirect Food Additives; Di-n-Alkyl (C_8-C_{10}) Dimethylammonium Chloride, n-Alkyl (C_{12}-C_{16}) Benzyldimethylammonium Chloride and Ethyl Alcohol

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the food additive regulations to provide for the safe use of di-*n*-alkyl(C_8–C_{10})dimethylammonium chloride, *n*-alkyl(C_{12}–C_{18})benzyldimethylammonium chloride and ethyl alcohol as components of sanitizing solutions. The agency is taking this action in response to a petition filed by Lonza, Inc.

DATES: Effective June 12, 1981; objections by July 13, 1981.

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

FOR FURTHER INFORMATION CONTACT: James B. Lamb, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St., SW., Washington, D.C. 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 27, 1980 (45 FR 43473), FDA announced that a food additive petition (FAP OH3502) had been filed by Lonza, Inc., Fair Lawn, NJ 07410, proposing that § 178.1010 (21 CFR 178.1010) of the food additive regulations be amended to provide for the safe use of di-*n*-alkyl(C_8–C_{10})dimethylammonium chloride compounds, *n*-alkyl(C_{12}–C_{18})benzyldimethylammonium chloride compounds and ethyl alcohol as components of a sanitizing solution to be used on food-contact surfaces.

Having evaluated the data in the petition and other relevant material, FDA concludes that the proposed food additive use is safe and that § 178.1010 of the regulations should be amended as set forth below.

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 findings of no significant impact and the evidence supporting that document may be seen in the Dockets Management Branch (formerly the Hearing Clerk's office) (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 5.10 (formerly 21 CFR 5.1; see 46 FR 26052; May 11, 1981)), Part 178 is amended in § 178.1010 by adding new paragraphs (b)(22) and (c)(17) to read as follows:

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(22) An aqueous solution containing (1) di-*n*-alkyl(C_8-C_{10}) dimethylammonium chloride compounds having average molecular weights of 332–361, (2) *n*-alkyl (C_{12}-C_{18}) benzyldimethylammonium chloride compounds having average molecular weights of 351–380 and consisting principally of alkyl groups with 12 to 16 carbon atoms with or without not over 1 percent each of groups with 8 and 10 carbon atoms, and (3) ethyl alcohol. The ratio of compound (1) to compound (2) is 60 to 40.

* * * * *

(c) * * *

(17) Solutions identified in paragraph (b)(22) of this section shall provide, when ready to use, at least 150 parts per million and not more than 400 parts per million of active quaternary compound.

Any person who will be adversely affected by the foregoing regulation may at any time on or before July 13, 1981 submit to the Dockets Management Branch (formerly the Hearing Clerk's office) (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 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. Four copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective June 12, 1981.

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

Dated: June 1, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR. 81–17433 Filed 6–11–81; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 178

[Docket No. 80F–0160]

Indirect Food Additives, Antioxidants and Stabilizers; Octadecyl 3,5-di-tert-butyl-4-hydroxy-hydrocinnamate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the food additive regulations to provide for the expansion of the safe use of octadecyl 3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate as an antioxidant and/or stabilizer as a component of polycarbonate resins in articles intended for food-contact use. This action responds to a food additive petition filed by Ciba-Geigy Corp.

DATES: Effective June 12, 1981; objections by July 13, 1981.

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

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

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 30, 1980 (45 FR 36523), FDA announced that a food additive petition (FAP 0B3504) had been filed by Ciba-Geigy Corp., Ardsley, NY 10502, proposing to amend § 177.1580 *Polycarbonate resins* (21 CFR 177.1580) to provide for the safe use of octadecyl 3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate as an antioxidant and thermal stabilizer for polycarbonate resins used in articles intended for food-contact use. This document corrects that notice to read that the food additive petition (FAP 0B3504) had been filed by Ciba-Geigy Corp., Ardsley, NY 10502, proposing to amend § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the safe use of octadecyl 3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate as an antioxidant and/or stabilizer for polycarbonate resins complying with

§ 177.1580 used in articles intended for food-contact use.

FDA has evaluated data in the petition and other relevant information and has concluded that the proposed use of octadecyl 3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate as an antioxidant and thermal stabilizer for polycarbonate resins used in articles intended for food-contact use is safe, and that § 178.2010 should be amended as set forth below.

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 5.10 (formerly 21 CFR 5.1; see 46 FR 26052; May 11, 1981)), Part 178 is amended in § 178.2010(b) by adding a new limitation for "Octadecyl 3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* *
Octadecyl 3,5-di-*tert*-butyl-4-hydroxy-hydrocinnamate (CAS Reg. No. 2082-79-3).	For use only: * * * 8. At levels not to exceed 0.3 percent by weight of polycarbonate resins that comply with § 177.1580 and that contact food only under conditions of use E, F, and G described in table 2, § 176.170(c) of this chapter.
* * *	* *

Any person who will be adversely affected by the foregoing regulation may at any time on or before July 13, 1981 submit to the Dockets Management Branch (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 presented in support of the objection in the event of the right to a hearing on the objection. Four copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation becomes effective June 12, 1981.

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

Dated: June 2, 1981.

William F. Randolph,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 81-17435 Filed 6-11-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 178

[Docket No. 80F–0219]

Indirect Food Additives; Tris(2,4-di-Tert-Butylphenyl)-Phosphite

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the food additive regulations to provide for the safe use of tris(2,4-di-*tert*-butylphenyl)-phosphite as an antioxidant and thermal stabilizer for ethylene-vinyl acetate copolymers intended for use in contact with food and complying with § 177.1350 (21 CFR 177.1350), as requested in a petition filed by Ciba-Geigy Corp.

DATES: Effective June 12, 1981; objections by July 13, 1981.

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

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

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of July 15, 1980 (45 FR 47473), FDA announced that a food additive petition (FAP 0B3511) 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(2,4-di-*tert*-butylphenyl)-phosphite as an antioxidant and thermal stabilizer for ethylene-vinyl acetate copolymers intended for use in contact with food and complying with § 177.1350.

Having evaluated data in the petition and other relevant materials, FDA concludes that tris(2,4-di-*tert*-butylphenyl)-phosphite is safe for its intended use and that § 178.2010 should be amended as set forth below.

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 5.10 (formerly 5.1; see 46 FR 26052; May 11, 1981)), Part 178 is amended in § 178.2010(b) by inserting alphabetically a new item in the list of substances to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitation
* * *	* *
Tris (2,4-di-*tert*-butylphenyl)-phosphite (CAS Reg. No. 31570-04-4).	For use only: At levels not to exceed 0.2 percent by weight of ethylene-vinyl-acetate copolymers complying with § 177.1350 of this chapter, provided that the finished polymer contacts food only under conditions of use E, F, and G described in Table 2 of § 176.170(c) of this chapter; and further provided that the average thickness of such polymers in the form in which they contact fatty food shall not exceed 0.1 millimeter (0.004 inch).
* * *	* *

Any person who will be adversely affected by the foregoing regulation may at any time on or before July 13, 1981 submit to the Dockets Management Branch (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 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. Four copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this