Any person who will be adversely affected by this regulation may at any time on or before April 30, 1992 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 hearing 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 175

Adhesives, 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 175 is amended as follows:

PART 175—INDIRECT FOOD ADDITIVES: ADHESIVES AND COMPONENTS OF COATINGS

1. The authority citation for 21 CFR part 175 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 175.105 is amended in paragraph (c)(5) by alphabetically adding a new entry to the table to read as follows.

§ 175.105 Adhesives.

* * * * *

(c) * * *

(5) * * *

Substances	Limitations
* * * * *	
Isodecyl benzoate (CAS Reg. No. 131298-44-7)	
* * * * *	

Dated: March 20, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-7324 Filed 3-30-92; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 178

[Docket No. 90F-0350]

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 additional safe uses of hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) as a stabilizer in certain polymers, adhesives, and waxes intended for use in food-contact articles. This action responds to a petition filed by Ciba-Geigy Corp.

DATES: Effective March 31, 1992; written objections and requests for a hearing by April 30, 1992.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Sandra L. Varner, Center for Food Safety and Applied Nutrition (HFF-335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9511.

SUPPLEMENTARY INFORMATION: In a notice published in the Federal Register of November 21, 1990 (55 FR 48693), FDA announced that a food additive petition (FAP OB4227) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532-2188, proposing that § 178.2010 Antioxidants and/or stabilizers for polymers (21 CFR 178.2010) be amended to provide for the additional safe uses of hexamethylene bis(3,5-di-*tert*-butyl-4-hydroxyhydrocinnamate) as a stabilizer in polymers complying with § 175.105 Adhesives (21 CFR 175.105), § 175.125 Pressure-sensitive adhesives (21 CFR 175.125), § 175.300 Resinous and polymeric coatings (21 CFR 175.300), § 175.320 Resinous and polymeric coatings for polyolefin films (21 CFR 175.320), § 176.170 Components of paper and paperboard in contact with aqueous and fatty foods (21 CFR 176.170), § 176.180 Components of paper and paperboard in contact with dry food (21 CFR 176.180), § 177.1210 Closures with sealing gaskets for food containers (21 CFR 177.1210), § 177.2600 Rubber articles intended for repeated use (21 CFR 177.2600), § 178.3800 Preservatives for wood (21 CFR 178.3800), and § 178.3850 Reinforced wax (21 CFR 178.3850).

FDA has evaluated data in the petition and other relevant material. The agency concludes that these data support the requested safe uses of the additive, and that the regulations should be amended in § 178.2010 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 21 CFR 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 April 30, 1992, file with the Dockets Management Branch (address above) written objectives 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 citaton for 21 CFR part 178 continues to read as follows:

Authority: Secs. 201, 402, 409, 706 of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 376).

2. Section 178.2010 is amended in the table in paragraph (b) by revising the "Limitations" column for the entry "Hexamethylenebis (3, 5-di-*tert*-butyl-4-hydroxyhydrocinnamate)" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * * * * * *	
Hexamethylenebis (3, 5-di-*tert*-butyl-4-hydroxyhydrocinnamate) (CAS Reg. No. 35074-77-2).	For use only: 1. As provided in § 177.2470(b)(1) and § 177.2480(b)(1) of this chapter. 2. In adhesives complying with § 175.105 of this chapter. 3. At levels not to exceed 1 percent by weight in pressure-sensitive adhesives complying with § 175.125 of this chapter. 4. At levels not to exceed 1 percent by weight in can end cement formulations complying with § 175.300(b)(3)(xxxi) of this chapter. 5. At levels not to exceed 1 percent by weight in side seam cement formulations complying with § 175.300(b)(3)(xxxii) of this chapter. 6. At levels not to exceed 1 percent by weight in petroleum alicyclic hydrocarbon resins, polyamide resins, and terpene resins complying with § 175.320 of this chapter. 7. At levels not to exceed 1 percent by weight in rosin and rosin derivatives when used in accordance with § 176.170(a)(5) of this chapter. 8. At levels not to exceed 1 percent by weight in petroleum alicyclic hydrocarbon resins or their hydrogenated products complying with § 176.170(b)(2) of this chapter. 9. At levels not to exceed 1 percent by weight in terpene resins complying with § 175.300(b)(3)(xi) of this chapter, when such terpene resins are used in accordance with § 176.170(b)(1) of this chapter. 10. At levels not to exceed 1 percent by weight in resins and polymers authorized for use in accordance with § 176.180 of this chapter. 11. At levels not to exceed 1 percent by weight in closures with sealing gaskets complying with § 177.1210 of this chapter. 12. At levels not to exceed 1 percent by weight in rubber articles intended for repeated use complying with § 177.2600 of this chapter. 13. At levels not to exceed 1 percent by weight in petroleum hydrocarbon resin and rosins and rosin derivatives used in accordance with § 178.3800 of this chapter. 14. At levels not to exceed 1 percent by weight in reinforced wax complying with § 178.3850 of this chapter.
* * * * * * *	

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Dated: March 20, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92-7325 Filed 3-30-92; 8:45 am]

BILLING CODE 4160-01-M

FOOD AND DRUG ADMINISTRATION

21 CFR Parts 182 and 184

[Docket No. 78N-0335]

Glycerophosphates; Affirmation of GRAS Status as Direct Human Food Ingredients

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is: (1) Affirming that calcium glycerophosphate is generally recognized as safe (GRAS) as a direct human food ingredient in conventional food; (2) removing calcium, manganese, and potassium glycerophosphates from 21 CFR Part 182, subpart I, for use as nutrients used in food; and (3) taking no action with respect to the listing of calcium, manganese, and potassium glycerophosphates in 21 CFR part 182, subpart F, for use in dietary supplements. The safety of these ingredients as nutrients in food has been evaluated under the comprehensive safety review conducted by the agency.

DATES: Effective April 30, 1992. The Director of the Office of the Federal Register approves the incorporation by reference in accordance with 5 U.S.C.

552(a) and 1 CFR part 51 of a certain publication in 21 CFR 184.1201, effective on April 30, 1992.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–254–9500.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of May 15, 1979 (44 FR 28336), FDA published a proposal to affirm that calcium glycerophosphate is GRAS for use as a direct human food ingredient in conventional food. (FDA is using the term "conventional food" to refer to food that would fall within any of the 43 categories listed in § 170.3(n) (21 CFR 170.3(n)). The agency also proposed to remove potassium glycerophosphate and manganese glycerophosphate from the list of GRAS ingredients because there were no reported uses for these substances. The proposal was published in accordance with the announced FDA review of the safety of GRAS and prior-sanctioned food ingredients.

In accordance with § 170.35 (21 CFR 170.35), copies of the scientific literature review on glycerophosphates and the report of the Select Committee on GRAS Substances on glycerophosphates are available for public review in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Copies of these documents also are available for public purchase from the National Technical Information Service, as announced in the proposal.

In addition to proposing to affirm the GRAS status of calcium glycerophosphate and to remove manganese and potassium glycerophosphate from the GRAS list, FDA gave public notice that it was unaware of any prior-sanctioned food ingredient uses for these substances other than the uses listed in part 181—Prior-Sanctioned Food Ingredients (21 CFR part 181). Persons asserting additional or extended uses in accordance with approvals granted by the U.S. Department of Agriculture or FDA before September 7, 1958, were given notice to submit proof of those sanctions, so that the safety of any prior-sanctioned uses could be determined. That notice was also an opportunity to have additional prior-sanctioned uses of the glycerophosphates recognized by issuance of an appropriate regulation under part 181, or affirmed as GRAS under part 184 or 186 (21 CFR part 184 or 186), as appropriate. FDA also gave notice that failure to submit proof of any applicable prior sanction in response to the proposal would constitute a waiver of the right to assert that sanction at any future time.

No reports of prior-sanctioned uses for these ingredients were submitted in response to the proposal. Therefore, in accordance with the proposal, any right to assert a prior sanction for uses of these ingredients under conditions different from those set forth in part 181 has been waived.

After publication of the May 5, 1979, proposal to affirm the GRAS status of calcium glycerophosphate and to remove manganese and potassium glycerophosphates from the GRAS list, the agency issued, in the **Federal Register** of September 5, 1980 (45 FR 58837), a document outlining the reorganization of 21 CFR part 182 to provide separate listings for the use of GRAS ingredients in dietary supplements and for the use of the same ingredients as nutrients in conventional food. The reorganization document stated that creation of these separate lists was intended to facilitate the separate GRAS reviews of these substances as nutrients and as dietary substances. The reorganization thus resulted in the listings of calcium, manganese, and potassium glycerophosphates on both the GRAS "Dietary Supplements" list (21 CFR 182, subpart F), and the GRAS "Nutrients" list (21 CFR 182, subpart I).

One comment was received in response to the agency's proposal on glycerophosphates. The comment submitted information on the use of manganese glycerophosphate in enteral dietary formulas which are used under medical supervision. The company, a pharmaceutical manufacturer, stated that this use was not included in FDA's survey of food manufacturers for the purpose of determining the specific foods in which various glycerophosphates are used and the levels of usage. The company, therefore, requested that the agency retain manganese glycerophosphate on the GRAS list to permit its continued use in enteral dietary supplement formulas.

FDA's May 15, 1979 (44 FR 28336), proposal to affirm the GRAS status of calcium glycerophosphate and to remove manganese and potassium glycerophosphates from the GRAS list addressed the use of these ingredients in conventional foods (those described in the food categories listed in the 21 CFR 170.3(n)). The proposal did not address the use of these ingredients in dietary supplements or in enteral formulas designed for use under medical supervision in the nutritional management of patients. Although use in enteral formulas was reported in the comments to this proposal, FDA did not take any action on the use of the subject glycerophosphates in dietary supplements or enteral formulas because it had only limited information on such uses. Therefore, calcium, manganese, and potassium glycerophosphates will continue to be listed as GRAS for use in dietary supplements in part 182, subpart F. Likewise, even though enteral formulas are not dietary supplements, use of vitamins and minerals in enteral formulas will be considered to be covered under the GRAS listing for dietary supplements in part 182, subpart F.

Therefore, in the **Federal Register** of March 14, 1991 (56 FR 10843), a tentative final rule was published: (1) Affirming that calcium glycerophosphate is GRAS as a direct human food ingredient in conventional food; (2) removing calcium, manganese and potassium glycerophosphates from 21 CFR part 182, subpart I, for use an nutrients used in food; and (3) taking no action with respect to the listing of calcium, manganese, and potassium glycerophosphates in 21 CFR part 182, subpart F, for use in dietary supplements. This action was published as a tentative final rule because the proposal to affirm glycerophosphate was published 12 years earlier in the **Federal Register** of May 15, 1979 (44 FR 28336). The agency believed that because of the length of time that has passed, it would be prudent to allow an opportunity for additional comments on the proposed action.

No comments were received in response to the tentative final rule. Therefore, the agency is issuing this final rule to affirm calcium glycerophosphate for use in conventional foods and to remove calcium, manganese, and potassium glycerophosphates from subpart I, of part 182 for use as nutrients. FDA is retaining the listing of calcium, manganese, and potassium glycerophosphates in part 182, subpart F, pending further action on the dietary supplement use of these ingredients.

As explained in the tentative final rule, the format of the final regulation for calcium glycerophosphate differs from the format of the proposed regulation. FDA has modified § 184.1201(c) to make clear the agency's determination that its GRAS affirmation is based upon current good manufacturing practice (CGMP) conditions of use, including both the technical effects and the food categories listed. This change removes the

maximum CGMP level of use that was included in the proposal. FDA concludes, that it is unnecessary to include this level of use in the regulation to assure the safe use of this ingredient.

FDA is also modifying this final rule to adopt specifications for calcium glycerophosphate that have been published in the "Food Chemicals Codex," 3d Ed. (1981), pp. 51–52. No differences exist between these specifications and the specifications that were proposed for adoption from the "Food Chemicals Codex," 2d Ed. (1972), pp. 130–131. This change, therefore, has no substantive effect. Therefore, the agency is adding new § 184.1201 to 21 CFR subpart B.

In the tentative final rule, the agency determined under 21 CFR 25.24(b)(7) that the GRAS affirmation of calcium glycerophosphate as a direct human food ingredient for use in conventional food under 21 CFR 184.1201 is an action of a type that does not individually or cumulatively have a significant effect on the human environment. No comments were submitted on this aspect of the tentative final rule. Therefore, FDA continues to conclude that neither an environmental assessment nor an environmental impact statement is required.

As explained in the tentative final rule, the agency has carefully considered the potential environmental effects of removing manganese glycerophosphate and potassium glycerophosphate from the GRAS list for use as nutrients in food (21 CFR part 182, subpart I). FDA has concluded that this 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 at the Dockets Management Branch, (address above) between 9 a.m. and 4 p.m., Monday through Friday.

In accordance with the Regulatory Flexibility Act, the agency has considered the potential effects that this rule would have on small entities, including small businesses. In accordance with section 605(b) of the Regulatory Flexibility Act, the agency has determined, that no significant economic impact on a substantial number of small entities would derive from this action.

In accordance with Executive Order 12291, FDA has analyzed the potential economic effects of this final rule and has determined that the final rule is not a major rule as determined by that Order.

The agency's finding of no major economic impact and no significant impact on a substantial number of small entities, and the evidence supporting these findings, are contained in a threshold assessment which may be seen in the Dockets Management Branch (address above).

List of Subjects

21 CFR Part 182

Food ingredients, Food packaging, Spices and flavorings.

21 CFR Part 184

Food ingredients, Incorporation by reference.

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 parts 182 and 184 are amended as follows:

PART 182—SUBSTANCES GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 182 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

§§ 182.8201, 182.8455, and 182.8628 [Removed]

2. Section 182.8201 *Calcium glycerophosphate*, § 182.8455 *Manganese glycerophosphate*, and § 182.8628 *Potassium glycerophosphate* are removed from subpart I.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

3. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

4. New § 184.1201 is added to subpart B to read as follows:

§ 184.1201 Calcium glycerophosphate.

(a) Calcium glycerophosphate ($C_3H_7CaO_6P$, CAS Reg. No. 27214–00–2) is a fine, white, odorless, almost tasteless, slightly hygroscopic powder. It is prepared by neutralizing glycerophosphoric acid with calcium hydroxide or calcium carbonate. The commercial product is a mixture of calcium β-, and *D*-, and *L*-α-glycerophosphate.

(b) The ingredient meets the specifications of the "Food Chemicals Codex," 3d Ed. (1981), pp. 51–52, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 1100 L St. NW., Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a nutrient supplement as defined in § 170.3(o)(20) of this chapter.

(2) The ingredient is used in gelatins, puddings, and fillings as defined in § 170.3(n)(22) of this chapter.

(d) Prior sanctions for this ingredient different from the uses established in this section or different from that as set forth in part 181 of this chapter, do not exist or have been waived.

Dated: March 20, 1992.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 92–7327 Filed 3–30–92; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 312, 606, 610, 630, and 640

Drugs and Biologics; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the drugs and biologics regulations to correct certain typographical and other inadvertent errors. This action is being taken to clarify and improve the accuracy of the regulations.

EFFECTIVE DATE: March 31, 1992.

FOR FURTHER INFORMATION CONTACT: Joanne Binkley, Center for Biologics Evaluation and Research (HFB–132), Food and Drug Administration, 3800 Rockville Pike, Bethesda, MD 20892, 301–295–8188.

SUPPLEMENTARY INFORMATION: FDA has discovered certain nonsubstantive errors that have been incorporated into the agency's codified regulations on drugs and biologics. FDA is correcting