

Any person who will be adversely affected by the foregoing regulation may at any time on or before February 22, 1983, submit to the Dockets Management Branch (address above), 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. Three 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 March 22, 1983, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1985 shall fully comply. Notice of the filing of objections or lack thereof will be published in the *Federal Register*.

(Secs. 401, 701(e), 52 Stat. 1046, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e)))

Dated: January 17, 1983.

William F. Randolph,
Acting Assistant Commissioner for
Regulatory Affairs.

[FR Doc. 83-1642 Filed 1-20-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 145

[Docket No. 79N-0231]

Canned Berries; Standard of Identity; Confirmation of Effective Date and Further Amendment

AGENCY: Food and Drug Administration.

ACTION: Final rule; confirmation of effective date and further amendment.

SUMMARY: The Food and Drug Administration (FDA) confirms the effective date for compliance with the provisions of the amended standard of identity for canned berries and further amends the standard to provide for the use of safe and suitable nutritive carbohydrate sweeteners as optional ingredients.

DATES: Compliance with the provision being revised herein may begin March 22, 1983. Effective July 1, 1985, for all affected products initially introduced or initially delivered for introduction into interstate commerce on or after this date.

Objections to the provision being revised herein by February 22, 1983.

Compliance with the provisions amended in the *Federal Register* of January 9, 1981 (46 FR 2339) may have begun February 10 1981, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: F. Leo Kauffman, Bureau of Foods (HFF-214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204; 202-245-1164.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of January 9, 1981 (46 FR 2339), FDA issued a final rule amending the U.S. standard of identity for canned berries (21 CFR 145.120(a)) in consideration of the identity provisions of the Recommended International Standard for Canned Raspberries and the Recommended International Standard for Canned Strawberries developed by the Codex Alimentarius Commission of the Food and Agriculture Organization of the United Nations and of the World Health Organization (FAO/WHO). The final rule was based on a proposal published in the *Federal Register* of September 25, 1979 (44 FR 55191). Any person who would be adversely affected by the final rule could have, at any time on or before February 9, 1981, filed written objections to the final regulation and requested a hearing on the specific provisions to which there were objections.

The Whey Products Institute (WPI) objected to and requested a hearing on the limitation of the use of optional sweeteners to those named in the final rule (21 CFR 145.120 (a) (4) (iv)) because lactose was not included. WPI said that failure to allow the use of any safe and suitable nutritive carbohydrate

sweetener, such as lactose, as an optional ingredient in canned berries is inconsistent with the generic permission given to the use of optional flavors, organic acids, and fruit juices as found in this rule. It pointed out that lactose, obtained from whey, is considered a safe and suitable optional nutritive carbohydrate sweetener and referred to the standard of identity for lactose in 21 CFR 168.122. WPI also asserted that appropriate sweeteners cannot be excluded solely because FDA is not aware of their use in canned berries.

The September 25, 1979, proposal to amend the standard of identity for canned berries provided for the use of safe and suitable nutritive carbohydrate sweeteners. Subsequent to the proposal, FDA, the United States Department of Agriculture (USDA), and the staff of the Federal Trade Commission's Bureau of Consumer Protection (FTC) announced in the *Federal Register* of December 21, 1979 (44 FR 75990) their tentative positions on a variety of food-related issues. A revision in FDA's policy with regard to safe and suitable ingredients in standardized foods was considered. The January 9, 1981, final rule reflected FDA's December 21, 1979, tentative policy by specifically listing those safe and suitable nutritive carbohydrate sweeteners allowed in canned berries.

Upon review and evaluation of the comments received in response to the December 21, 1979, tentative position, however, FDA has determined that, at this time, it would be in the best interest of the consumers and the regulated industry to retain its established policy for use of safe and suitable optional ingredients in standardized foods. Elsewhere in this issue of the *Federal Register* FDA is announcing this decision. This decision has the effect of acceding to WPI's objection that all safe and suitable nutritive carbohydrate sweeteners should be optional ingredients.

Therefore, FDA is removing § 145.120(a)(4)(iv) that would have listed permitted nutritive carbohydrate sweeteners as optional ingredients and is revising § 145.120(a)(3)(i) to allow the use of safe and suitable nutritive carbohydrate sweeteners in canned berries as proposed.

List of Subjects in 21 CFR Part 145

Canned fruit, Food standards, Fruits.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 401, 701(e), 52 Stat. 1046 as amended, 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), notice is given that the

standard of identity for canned berries (21 CFR 145.120(a)) as amended in the Federal Register of January 9, 1981 (46 FR 2339) will become effective July 1, 1983, except § 145.120(a)(4)(iv) which is removed, and § 145.120(a)(3)(i) which is revised to read as follows:

PART 145—CANNED FRUITS

§ 145.120 Canned berries.

(a) * * *

(3) *Packing media.* (i) the optional packing media referred to in paragraph (a)(1) of this section as defined in § 145.3 are:

- (a) Water.
- (b) Fruit juice(s) and water.
- (c) Fruit juice(s).

Such packing media may be used as such or any one or any combination of two or more safe and suitable nutritive carbohydrate sweeteners may be added. Sweeteners listed in § 145.3 shall be as defined therein, except that a nutritive carbohydrate sweetener for which a standard of identity has been established in Part 168 of this chapter shall comply with such standard in lieu of any definition that may appear in § 145.3.

Any person who will be adversely affected by the foregoing amendment to the final regulation to provide for the use of safe and suitable nutritive carbohydrate sweeteners as optional ingredients may at any time on or before February 22, 1983, submit to the Dockets Management Branch (HFA-305) (address above), 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. Three 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 the amendment that may be stayed by the filing of proper objections, compliance with this amendment to the final regulation may begin March 22, 1983. The mandatory compliance date for this amendment shall be July 1, 1985. Notice of the filing of objections or lack thereof will be published in the Federal Register. Accordingly, except as to the provisions herein amended, the effective date of § 145.120(a) as published in the Federal Register of January 9, 1981 (46 FR 2339) is confirmed as follows: Compliance with this regulation, including any required labeling changes, may have begun on February 10, 1981, and all affected products initially introduced or initially delivered for introduction into interstate commerce on or after July 1, 1983, shall fully comply.

[Secs. 401, 701(e), 52 Stat. 1046 as amended, 70 Stat. 919 as amended (21 U.S.C. 341, 371(e))]

Dated: January 17, 1983.
William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-1082 Filed 1-20-83; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 173

[Docket No. 76G-0117]

Secondary Direct Food Additives Permitted in Food for Human Consumption; Esterase-Lipase Enzyme Derived From *Mucor Miehei*; Correction

AGENCY: Food and Drug Administration.
ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the regulation that provides for the use of esterase-lipase enzyme derived from *Mucor miehei* as a food additive.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Bureau of Foods (HFF-355), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-5487.

SUPPLEMENTARY INFORMATION: In FR Doc. 82-17501 at page 28089 in the issue for Tuesday, June 29, 1982, FDA added new § 173.140 *Esterase-lipase derived from Mucor miehei* (21 CFR 173.140).

In the introductory paragraph of the added section, FDA inadvertently omitted two words, "maltodextrin or", although the agency stated in the preamble of the document that maltodextrin could be used as a carrier.

The agency is now correcting this omission.

Therefore, the introductory paragraph of § 173.140 is corrected to read as follows:

§ 173.140 Esterase-lipase derived from *Mucor miehei*.

Esterase-lipase enzyme, consisting of enzyme derived from *Mucor miehei* var. *Cooney et Emerson* by a pure culture fermentation process, with maltodextrin or sweet whey as a carrier, may be safely used in food in accordance with the following conditions:

* * * * *

Dated: January 14, 1983.
William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-1518 Filed 1-20-83; 8:45 am]
BILLING CODE 4160-01-M

21 CFR Part 176

[Docket No. 81F-0403]

Indirect Food Additives; Paper and Paperboard Components

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 soluble anthraquinones, 1,4,4a,9a-tetrahydro-9,10-anthracenedione and the disodium salt of 1,4-dihydro-9,10-dihydroxyanthracene, as catalysts in the production of paper and paperboard for contact with aqueous and fatty foods. This action is in response to a petition filed by Kawasaki Kasei Chemicals, Ltd.

DATES: Effective January 21, 1983; objections by February 22, 1983.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Geraldine E. Harris, 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 January 15, 1982 (47 FR 2407), FDA announced that a petition (FAP 1B3585) had been filed by Kawasaki Kasei Chemicals, Ltd., Tokyo, Japan, proposing that § 176.170 (21 CFR 176.170) be amended to provide for the safe use of soluble anthraquinones, 1,4,4a,9a-tetrahydro-9,10-anthracenedione and the

disodium salt of 1,4-dihydro-9,10-dihydroxyanthracene, as components of paper and paperboard in contact with aqueous and fatty foods.

FDA has evaluated data in the petition and other relevant material, and concludes that the proposed food additive use is safe and that § 176.170 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 Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 171.1(h)(2), 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 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 evidence supporting that finding may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 176

Food additives, Food packaging, Paper and paperboard.

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), Part 176 is amended in § 176.170(a)(5) by alphabetically inserting two new items in the list of substances to read as follows:

PART 176—INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

- (a) * * *
- (5) * * *

List of substances	Limitations
Disodium salt of 1,4-dihydro-9,10-dihydroxyanthracene (CAS Reg. No. 73347-80-5).	For use only as a catalyst in the alkaline pulping of lignocellulosic materials at levels not to exceed 0.1 percent by weight of the raw lignocellulosic materials.

List of substances	Limitations
1,4,4a,9a-Tetrahydro-9,10-anthracenedione (CAS Reg. No. 56136-14-2)	For use only as a catalyst in the alkaline pulping of lignocellulosic materials at levels not to exceed 0.1 percent by weight of the raw lignocellulosic materials.

Any person who will be adversely affected by the foregoing regulation may at any time on or before February 22, 1983 submit to the Dockets Management Branch (address above), 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. Three 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 January 21, 1983.

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

Dated: January 13, 1983.

William F. Randolph,
Acting Associate Commissioner for
Regulatory Affairs.

[FR Doc. 83-1520 Filed 1-20-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 176

[Docket No. 82F-0215]

Indirect Food Additives; Paper and Paperboard Components; Styrene-Butadiene-Vinylidene Chloride and Styrene-Vinylidene Chloride Copolymers

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 styrene-butadiene-vinylidene chloride copolymers and styrene-vinylidene chloride copolymers, with minor monomers, as components of paper and paperboard in contact with aqueous and fatty foods. This action responds to a petition filed by Dow Chemical Co.

DATES: Effective January 21, 1983; objections by February 22, 1983.

ADDRESS: Written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Patricia J. McLaughlin, Bureau of Foods (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of September 3, 1982 (47 FR 38988), FDA announced that a petition (FAP 2B3630) had been filed by Dow Chemical Co., 1803 Building, Midland, MI 48640, proposing that Part 176 (21 CFR Part 176) of the food additive regulations be amended to provide for the safe use of styrene-butadiene-vinylidene chloride copolymers, with one or more of the minor monomers acrylic acid, fumaric acid, 2-hydroxyethyl acrylate, itaconic acid, and methacrylic acid, and styrene-vinylidene chloride copolymers, with one or more of the minor monomers acrylic acid, fumaric acid, itaconic acid, and methacrylic acid, as components of paper and paperboard in contact with food.

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed food additive use is safe and that § 176.170(b)(2) of the food additive regulations should be amended as set forth below. The agency believes, however, that the regulated substance can be more precisely identified by the description set forth in the regulation 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 Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.