

EFFECTIVE DATE: May 8, 1994.

FOR FURTHER INFORMATION CONTACT: Virginia L. Wilkening, Center for Food Safety and Applied Nutrition (HFS-165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5763.

SUPPLEMENTARY INFORMATION: In the Federal Register of August 18, 1993, FDA published a document that amended the regulations that require nutrition labeling on most foods regulated by FDA. The agency intended to revise the introductory text of § 101.9(c)(1)(i) (21 CFR 101.9(c)(1)(i)) to specify that when either specific or general food factors are used in calculating caloric content, the factors should be applied to actual amounts (i.e., before rounding) of food components. The agency inadvertently omitted the words "introductory text" from amendatory statement 2 (58 FR 44076). Consequently, the actual methods for calculating caloric content were removed from the Code of Federal Regulations. Accordingly, this document corrects § 101.9(c)(1)(i) to restore the methods.

List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is corrected by making the following correcting amendments:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6, of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.9 is amended by revising paragraph (c)(1)(i) to read as follows:

§ 101.9 Nutrition labeling of food.

* * * * *

(c) * * *

(1) * * *

(i) Caloric content may be calculated by the following methods. Where either specific or general food factors are used, the factors shall be applied to the actual amount (i.e., before rounding) of food components (e.g., fat, carbohydrate, protein, or ingredients with specific food factors) present per serving.

(A) Using specific Atwater factors (i.e., the Atwater method) given in Table 13, "Energy Value of Foods—Basis and Derivation," by A. L. Merrill and B. K.

Watt, United States Department of Agriculture (USDA) Handbook No. 74 (slightly revised, 1973), which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 and is available from the Office of Food Labeling (HFS-150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, or may be inspected at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(B) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 9-11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section);

(C) Using the general factors of 4, 4, and 9 calories per gram for protein, total carbohydrate less the amount of insoluble dietary fiber, and total fat, respectively, as described in USDA Handbook No. 74 (slightly revised 1973) pp. 9-11, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section);

(D) Using data for specific food factors for particular foods or ingredients approved by the Food and Drug Administration (FDA) and provided in parts 172 or 184 of this chapter, or by other means, as appropriate; or

(E) Using bomb calorimetry data subtracting 1.25 calories per gram protein to correct for incomplete digestibility, as described in USDA Handbook No. 74 (slightly revised 1973) p. 10, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51 (the availability of this incorporation by reference is given in paragraph (c)(1)(i)(A) of this section).

* * * * *

Dated: November 28, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94-29733 Filed 12-2-94; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 177

[Docket No. 91F-0198]

Indirect Food Additives: Polymers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of ethylene/1, 3-phenylene oxyethylene isophthalate/terephthalate copolymer in blends with polyethylene terephthalate polymers in contact with food. This action is in response to a petition filed by Mitsui Petrochemical Industries, Ltd.

DATES: Effective December 5, 1994; written objections and requests for a hearing by January 4, 1995.

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: Richard H. White, Center for Food Safety and Applied Nutrition (HFS-216), 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 July 23, 1991 (56 FR 33761), FDA announced that a food additive petition (FAP 1B4236) had been filed by Mitsui Petrochemical Industries, Ltd., Kasumigaseki Bldg., P.O. Box 90, 2-5 Kasumigaseki 3-chome, Chiyoda-ku, Tokyo 100, Japan. The petition proposed that the food additive regulations in § 177.1345 *Ethylene/1, 3-phenylene oxyethylene isophthalate/terephthalate copolymer* (21 CFR 177.1345) be amended to provide for the safe use of ethylene/1, 3-phenylene oxyethylene isophthalate/terephthalate copolymer in blends with polyethylene terephthalate polymers in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed use of the food additive is safe and that the regulations in § 177.1345 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in 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 January 4, 1995, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

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 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

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

2. Section 177.1345 is amended by revising the introductory text and by adding new paragraph (d) to read as follows:

§ 177.1345 Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer.

Ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer (CAS Reg. No. 87365-98-8) identified in paragraph (a) of this section may be safely used, subject to the provisions of this section, as the non-food-contact layer of laminate structures subject to the provisions of § 177.1395, and in blends with polyethylene terephthalate polymers complying with § 177.1630.

(d) *Limitations.* Copolymer blends described above shall not exceed 30 percent by weight of ethylene/1,3-phenylene oxyethylene isophthalate/terephthalate copolymer. The finished blend may be used in contact with food only under conditions of use C through G, as described in Table 2 of § 176.170(c) of this chapter, except that with food identified as Type III, IV-A, V, VIII-A, and IX in § 176.170(c), Table 1, the copolymer may be used under condition of use C at temperatures not to exceed 160 °F (71 °C).

Dated: November 18, 1994.

Raymond E. Newberry,
Acting Director, Center for Food Safety and Applied Nutrition.
[FR Doc. 94-29854 Filed 12-2-94; 8:45 am]
BILLING CODE 4160-01-F

21 CFR Part 178

[Docket No. 91F-0430]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of 2-methyl-4,6-bis[(octylthio)methyl]phenol as a stabilizer in can-end and side seam cements and in various polymers intended for use in contact with food. This action is in response to a petition filed by Ciba-Geigy Corp.

DATES: Effective December 5, 1994; written objections and requests for a hearing by January 4, 1995.

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: Richard H. White, Center for Food

Safety and Applied Nutrition (HFS-216), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3094.

SUPPLEMENTARY INFORMATION: In a notice published in the *Federal Register* of December 2, 1991 (56 FR 61253), FDA announced that a food additive petition (FAP 1B4283) had been filed by Ciba-Geigy Corp., Seven Skyline Dr., Hawthorne, NY 10532-2188. The petition proposed that § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) be amended to provide for the safe use of 2-methyl-4,6-bis[(octylthio)methyl]phenol as a stabilizer in can-end and side seam cements and in various polymers intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. The agency concludes that the proposed food additive use is safe, and that this use should be listed in § 178.2010, as set forth below. In addition, FDA is correcting the entry for this additive in § 178.2010(b), in the table under the heading "Substances" to capitalize the letter "m" in "methyl." Thus, it will read "2-Methyl-4,6-bis[(octylthio)methyl]phenol."

A review of the petition indicates that the additive may contain trace amounts of formaldehyde as an impurity. The potential carcinogenicity of formaldehyde was reviewed by the Cancer Assessment Committee (the committee) that has been formed by FDA's Center for Food Safety and Applied Nutrition. The committee noted that for many years formaldehyde has been known to be a carcinogen by the inhalation route, but it concluded that these inhalation studies are not appropriate for assessing the potential carcinogenicity of formaldehyde in food. The committee reached its conclusion because the route of administration was not relevant to food safety, and the fact that tumors were observed only locally at the portal of entry (nasal turbinates). The agency has received literature reports of two drinking water studies on formaldehyde: (1) A preliminary report of a carcinogenicity study purported to be positive by Soffritti et al. (1989), conducted in Bologna, Italy (Ref. 1) and (2) a negative study by Til, et al. (1989), conducted in The Netherlands (Ref. 2). The committee reviewed both studies and concluded in a "Memorandum of Conference," dated April 24, 1991, and March 4, 1993, " * * * that data concerning the Soffritti study reported were unreliable and could not be used in the assessment of the oral

carcinogenicity of formaldehyde" (Ref. 3). This conclusion is based on a lack of critical details in the study, questionable histopathologic conclusions, and the use of unusual nomenclature to describe the tumors. Thus, the committee concluded that there is no basis to find that formaldehyde is a carcinogen when ingested.

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 January 4, 1995, file with the Dockets Management Branch (address above) written objections

thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Soffritti, M., C. Maltoni, F. Maffei, and R. Biagi, "Formaldehyde: An Experimental Multipotential Carcinogen," *Toxicology and Industrial Health*, Vol. 5, No. 5:699-730, 1989.

2. Til, H. P., R. A. Woutersen, V. J. Feron, V. H. M. Hollanders, H. E. Falke, and J. J. Clary, "Two-Year Drinking-Water Study of Formaldehyde in Rats," *Food Chemical Toxicology*, Vol. 27, No. 2, pp. 77-87, 1989.

3. Memorandum of Conference concerning "Formaldehyde," Meeting of the Cancer Assessment Committee, FDA, April 24, 1991, and March 4, 1993.

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, 21 CFR part 178 is amended as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

1. The authority citation for 21 CFR part 178 continues to read as follows:

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

2. Section 178.2010 is amended in the table in paragraph (b) by revising the entry for "2-Methyl-4,6-bis[(octylthio)methyl]phenol" under the heading "Substances," and by revising entry "2," and by numerically adding new entries "5" and "6" under the heading "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances

Limitations

2-Methyl-4,6-bis[(octylthio)methyl]phenol (CAS Reg. No. 110553-27-0). For use only:

* * *

2. At levels not to exceed 0.5 percent by weight of can-end cements and side-seam cements complying with § 175.300(b)(3)(xxxi) and (xxxii) of this chapter.
5. At levels not to exceed 0.1 percent by weight of petroleum alicyclic hydrocarbon resins complying with § 175.320 of this chapter; rubber-modified polystyrene complying with § 177.1640 of this chapter that contact food only under conditions of use B through H described in Table 2, § 176.170(c) of this chapter; and petroleum hydrocarbon resins and rosins and rosin derivatives complying with § 178.3800 of this chapter.
6. At levels not to exceed 0.2 percent by weight of styrene block polymers complying with § 177.1810 of this chapter that contact food of Types I, II, IV-B, VI, VII-B, and VIII described in Table 1, § 176.170(c) of this chapter, only under conditions of use C through H described in Table 2, § 176.170(c) of this chapter.

Dated: November 22, 1994.

William K. Hubbard,

Interim Deputy Commissioner for Policy.

[FR Doc. 94-29732 Filed 12-2-94; 8:45 am]

BILLING CODE 4180-01-F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin and Bacitracin Methylene Disalicylate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Elanco Animal Health, Division of Eli Lilly and Co. The NADA provides for use of two separately approved Type A medicated articles, one containing monensin sodium and the other containing bacitracin methylene disalicylate, to make combination Type C medicated feeds for the prevention of coccidiosis, for increased rate of weight gain and for improved feed efficiency in growing turkeys.

EFFECTIVE DATE: December 5, 1994.

FOR FURTHER INFORMATION CONTACT:

James F. McCormack, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1602.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, has filed NADA 140-937. The NADA provides for use of separately approved 45 and 60 grams per pound (g/lb) monensin and 10, 25, 30, 40, 50, and 60 g/lb bacitracin methylene disalicylate Type A medicated articles to make Type C medicated feeds containing 54 to 90 g per ton (g/t) monensin and 4 to 50 g/t bacitracin methylene disalicylate. The feed is used for the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagridis*, and *E. gallopavonis*, for increased rate of weight gain, and for improved feed efficiency in growing turkeys. The NADA is approved as of November 8, 1994, and the regulations are amended in 21 CFR 558.355(f)(2) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Certain limitations currently required on the monensin turkey feed labeling are not in the regulations. At this time,

FDA is adding these limitations to the regulations.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning November 8, 1994, because the application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) or human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(ii) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.355 is amended by redesignating paragraphs (f)(2)(ii) and (f)(2)(iii) as paragraphs (f)(2)(i)(a) and (f)(2)(i)(b), respectively, by revising newly redesignated paragraph (f)(2)(i)(b), and by adding new paragraph (f)(2)(ii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not

allow horses, other equines, mature turkeys, or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis.

(ii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 4 to 50 grams.

(a) *Indications for use.* For prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagridis*, and *E. gallopavonis*, for increased rate of weight gain, and for improved feed efficiency.

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.

* * * * *

Dated: November 18, 1994.

Richard H. Teske,

Deputy Director, Pre-market Review, Center for Veterinary Medicine.

[FR Doc. 94-29855 Filed 12-2-94; 8:45 am]

BILLING CODE 4180-01-F

POSTAL SERVICE

39 CFR Part 111

Special Bulk Third-Class Rates—State or Local Voting Registration Official

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: On May 20, 1993, the President signed into law Public Law 103-31, the National Voter Registration Act of 1993, which amends title 39, United States Code, by adding section 3629. The amendment authorizes voting registration officials to mail, effective January 1, 1995, certain third-class matter at the special bulk third-class rates. This notice contains regulations implementing the legislative changes.

EFFECTIVE DATE: January 1, 1995.

FOR FURTHER INFORMATION CONTACT:

Ernest J. Collins, (202) 268-5316.

SUPPLEMENTARY INFORMATION: The Postal Service published in the *Federal Register* (59 FR 45652-45653) on