Authority: 21 U.S.C. 321, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e.

§ 74.1102 [Amended]

2. Section 74.1102 *FD&C Blue No. 2* is amended by removing paragraphs (b)(1) and (c)(1); and by redesignating paragraphs (b)(2) and (c)(2) as paragraphs (b) and (c) respectively.

3. Section 74.3102 is added to subpart D to read as follows:

§ 74.3102 FD&C Blue No. 2.

(a) *Identity.* The color additive FD&C Blue No. 2 shall conform in identity to the requirements of § 74.102(a)(1).

(b) *Specifications.* (1) The color additive FD&C Blue No. 2 for use in coloring surgical sutures shall conform to the following specifications and shall be free from impurities other than those named to the extent that such impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

Isomeric colors, not more than 18 percent.

Lower sulfonated subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85 percent.

(2) The color additive FD&C Blue No. 2–Aluminum Lake on alumina for use in bone cement shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions.* (1) The color additive FD&C Blue No. 2 may be safely used for coloring nylon (the copolymer of adipic acid and hexamethylene diamine) surgical sutures for use in general surgery subject to the following restrictions:

(i) The quantity of color additive does not exceed 1 percent by weight of the suture;

(ii) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980); and

(iii) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissues.

(2) The color additive FD&C Blue No. 2–Aluminum Lake on alumina may be safely used for coloring bone cement at a level not to exceed 0.1 percent by weight of the bone cement.

(3) Authorization and compliance with these uses shall not be construed as waiving any of the requirements of sections 510(k), 515, and 520(g) of the Federal Food, Drug, and Cosmetic Act with respect to the medical device in which the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2–Aluminum Lake on alumina are used.

(d) *Labeling.* The labels of the color additive FD&C Blue No. 2 and the color additive FD&C Blue No. 2–Aluminum Lake on alumina shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 and its lake shall be certified in accordance with regulations in part 80 of this chapter.

Dated: August 25, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–22994 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 175

[Docket No. 99F–1420]

Indirect Food Additives: Adhesives and Components of Coatings

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 butylated reaction product of *p*-cresol and dicyclopentadiene as an antioxidant in pressure-sensitive adhesives intended for use in contact with food. This action responds to a petition filed by Goodyear Tire and Rubber Co.

DATES: This regulation is effective September 3, 1999. Submit written objections and requests for a hearing by October 4, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** May 26, 1999 (64 FR 28500), FDA announced that a food additive petition (FAP 9B4663) had been filed by Goodyear Tire and Rubber Co., c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 175.125 *Pressure-sensitive adhesives* (21 CFR 175.125) to provide for the safe use of butylated reaction product of *p*-cresol and dicyclopentadiene as an antioxidant in pressure-sensitive adhesives intended for use in contact with food.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 175.125 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 § 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 previously considered the environmental effects of this final rule as announced in the Notice of Filing for FAP 9B4663 (64 FR 28500). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before October 4, 1999, 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 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: 21 U.S.C. 321, 342, 348, 379e.

2. Section 175.125 is amended in paragraph (b)(2) by alphabetically adding an entry to read as follows:

§ 175.125 Pressure-sensitive adhesives.

* * * * *

(b) * * *

(2) * * *

Butylated reaction product of *p*-cresol and dicyclopentadiene produced by reacting *p*-cresol and dicyclopentadiene in an approximate mole ratio of 1.5 to 1.0, respectively, followed by alkylation with isobutylene so that the butyl content of the final product is not less than 18 percent, for use at levels not to exceed 1.0 percent by weight of the adhesive formulation.

* * * * *

Dated: August 26, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–22996 Filed 9–2–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 98F–1122]

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 dimethylolpropionic acid as a pigment dispersant for pigments used as components of food-contact articles. This action is in response to a petition filed by Geo Specialty Chemicals.

DATES: This regulation is effective September 3, 1999. Submit written objections and requests for a hearing October 4, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Vir D. Anand, Center for Food Safety and Applied Nutrition (HFS–215), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3081.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of December, 14, 1998 (63 FR 68777), FDA announced that a food additive petition (FAP 9B4637) had been filed by Geo Specialty Chemicals, c/o Keller and Heckman LLP, 1001 G St. NW., suite 500 West, Washington, DC 20001. The petition proposed to amend the food additive regulations in § 178.3725 *Pigment dispersants* (21 CFR 178.3725) to provide for the safe use of dimethylolpropionic acid as a dispersant for pigments used as components of food-contact articles.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulations in § 178.3725 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 § 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 previously considered the environmental effects of this rule as announced in the notice of filing for FAP 9B4637 (63 FR 68778). No new information or comments have been received that would affect the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the provisions of the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before October 4, 1999, 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 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: