Substances	Limitations
* * *	* * * *
4-Chloro-2-[[5-hydroxy-3-methyl-1-(3-sulfophenyl)-1H-pyrazol-4-yl]azo]-5-methylbenzenesulfonic acid, diammonium salt (1:2): (C.I. Pigment Yellow 191:1, CAS Reg. No. 154946–66–4).	For use at levels not to exceed 0.5 percent by weight of polymers. The finished articles are to contact food under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: July 30, 1998.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 98–22091 Filed 8–14–98; 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–0055]

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 expanded safe use of 2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol as a light stabilizer/ultraviolet (UV) absorber for polyethylene phthalate polymers intended for use in contact with food. This action is in response to a petition filed by Ciba Specialty Chemicals Corp.

DATES: The regulation is effective August 17, 1998; written objections and requests for a hearing by September 16, 1998.

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 February 4, 1998 (63 FR 5809), FDA announced that a food additive petition (FAP 8B4573) had been filed by Ciba Specialty Chemicals Corp., 540 White Plains Rd., Tarrytown, NY 10591–9005. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of 2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol as a light stabilizer/UV absorber for polyethylene phthalate polymers complying with 21 CFR 177.1630 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 the proposed use of the additive is safe, that the additive will achieve its intended technical effect, and therefore, that the regulations in § 178.2010 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 carefully considered the potential environmental effects of this rule as announced in the notice of filing for FAP 8B4573 (63 FR 5809). 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 September 16, 1998, 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 objection 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 citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) in the entry for ''2-(4,6-diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol'' by adding entry ''3.'' under the heading ''Limitations'' to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers.

* * * * *

(b) * * *

Substances	Limitations
* * *	* * * *
2-(4,6-Diphenyl-1,3,5-triazin-2-yl)-5-(hexyloxy)phenol (CAS Reg. No. 147315–50–2).	For use only: * * * 3. At levels not to exceed 0.5 percent by weight of polyethylene phthalate polymers complying with § 177.1630 of this chapter, in contact with food under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: August 3, 1998.

L. Robert Lake,

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

[FR Doc. 98–22090 Filed 8–14–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 179

[Dockte No. 98N–0392]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations on labeling requirements for foods treated with irradiation. This action is intended to clarify the agency's regulations following enactment of the FDA Modernization Act of 1997 (FDAMA). FDAMA adds a new section to the Federal Food, Drug, and Cosmetic Act (the act); this new section addresses the prominence of radiation disclosure statements on the labeling of food.

DATES: The regulation is effective August 17, 1998. Submit written comments on or before September 16, 1998.

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

FOR FURTHER INFORMATION CONTACT: Nega Beru, Center for Food Safety and Applied Nutrition (HFS–206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–418–3097.

SUPPLEMENTARY INFORMATION:

I. Background

Through a series of proceedings under section 409 of the act (21 U.S.C. 348), FDA has approved the use of ionizing radiation for various food uses (see § 179.26 (21 CFR 179.26)). The agency's regulations require that the label and labeling of retail packages of foods treated with ionizing radiation include both the radura logo, which is the international symbol that indicates radiation treatment, and a disclosure statement (either ''Treated with radiation'' or ''Treated by irradiation'') in addition to information required by other regulations (§ 179.26(c)(1)). The regulations require that the logo be placed prominently and conspicuously in conjunction with the required statement. The regulation does not specify the prominence of the disclosure statement, either generally or relative to other information required in the label and labeling.

On November 21, 1997, President Clinton signed into law FDAMA (Pub. L. 105–115). Section 306 of FDAMA amends the act by adding section 403C (21 U.S.C. 341 *et seq.*). Section 403C of the act addresses the disclosure of irradiation on the labeling of food as follows:

(a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

(b) In this section, the term 'radiation disclosure statement' means a written statement that discloses that a food has been intentionally subject to irradiation.

As noted, FDA's current regulations do not specify how prominent a radiation disclosure statement must be, and thus, the current regulation could simply be read to include the requirement imposed by new section 403C of the act. However, the agency believes that there is merit to having the regulation in § 179.26 include the prominence specification of the new statutory provision. Accordingly, FDA is amending the labeling requirement for irradiated foods to include a statement that a radiation disclosure statement is not required to be any more prominent than the declaration of ingredients required under the applicable regulations issued under section 403(i)(2) of the act (21 U.S.C. 343(i)(2)).

The agency has determined under 21 CFR 25.30(k) 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.

II. Analysis of Economic Impacts

A. Benefit-Cost Analysis

FDA has examined the impacts of the final rule under Executive Order 12866. Executive Order 12866 directs Federal agencies to assess the cost and benefits of available regulatory alternatives and when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). According to Executive Order 12866, a regulatory action is ''significant'' if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million, adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that this final rule is not a significant regulatory action as defined by Executive Order 12866. In addition, it has been determined that this final rule is not a major rule for the purpose of congressional review.

The final rule is offered to clarify the existing labeling requirements for irradiated foods. The rule will not require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than