(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]

BILLING CODE 4160–01–F

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

the declaration of ingredients. Therefore, it will not result in regulatory changes for firms and thus, will not result in any costs to firms. Firms will still be able to communicate the same information in the same manner to consumers.

B. Small Entity Analysis

FDA has examined the impacts of the final rule under the Regulatory Flexibility Act. The Regulatory Flexibility Act (5 U.S.C. 601–612) requires Federal agencies to consider alternatives that would minimize the economic impact of their regulations on small businesses and other small entities. In compliance with the Regulatory Flexibility Act, FDA finds that this final rule will not have a significant impact on a substantial number of small entities.

The final rule is offered to clarify the existing label requirements. The rule to not require a separate disclosure statement that is more prominent than the declaration of ingredients will not result in any costs to firm. Therefore, this rule will not have a significant impact on a substantial number of small entities. Accordingly, under the Regulatory Flexibility Act, the agency certifies that this final rule will not have a significant economic impact on a substantial number of entities.

C. Unfunded Mandates Act of 1995

FDA has examined the impacts of this final rule under the Unfunded Mandates Reform Act of 1995 (UMRA) (Pub. L. 104–4). This rule does not trigger the requirement for a written statement under section 201(a) of the UMRA because it does not impose a mandate that results in an expenditure of $100 million or more by State, local, and tribal governments in the aggregate, or by the private sector, in any 1 year.

III. Paperwork Reduction Act of 1995

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

IV. Comments

Because the amendments set forth in this document incorporate the language of section 306 of FDAMA into § 179.26, FDA finds, for good cause, that notice and public procedure are unnecessary and, therefore, are not required under 5 U.S.C. 553. Nonetheless, under 21 CFR 10.40(e), FDA is providing an opportunity for comment on whether the regulations set forth in this document should be modified or revoked.

Interested persons may, on or before September 16, 1998, submit to the Dockets Management Branch (address above) written comments regarding this final rule. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday though Friday.

List of Subjects in 21 CFR Part 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

2. Section 179.26 is amended by adding a sentence at the end of paragraph (c)(1) to read as follows:

§ 179.26 Ionizing radiation for the treatment of food.

* * * * *

(c) * * * (1) * * * The radiation disclosure statement is not required to be more prominent than the declaration of ingredients required under § 101.4 of this chapter. As used in this provision, the term ''radiation disclosure statement'' means the written statement that discloses that a food has been intentionally subject to irradiation.

* * * * *

Dated: August 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–21998 Filed 8–14–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 250

RIN 1010–AC39

Oil and Gas and Sulphur Operations in the Outer Continental Shelf; Pipelines and Pipeline Rights-of-Way

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Final rule.

SUMMARY: This rule implements a Memorandum of Understanding (MOU) between the Department of the Interior (DOI) and the Department of Transportation (DOT) regarding joint regulation of Outer Continental Shelf (OCS) pipelines. MMS regulations will apply to all OCS oil or gas pipelines located upstream of the points at which operating responsibility for the pipelines transfers from a producing operator to a transporting operator. This rule requires OCS producers and transporters to designate the transfer point.

DATES: Effective October 16, 1998.

FOR FURTHER INFORMATION CONTACT: Carl W. Anderson, Operations Analysis Branch, at (703) 787–1608; e-mail Carl.Anderson@mms.gov.

SUPPLEMENTARY INFORMATION: MMS, through delegations from the Secretary of the Interior, has authority to promulgate and enforce regulations that promote safe operations, environmental protection, and conservation of the natural resources of the OCS, as that area is defined in the OCS Lands Act (43 U.S.C. 1331 *et seq.*). This authority includes the pipeline transportation of mineral production and the approval and granting of rights-of-way for the construction of pipelines and associated facilities on the OCS. Thus, whether a pipeline is built and operated under DOI or DOT regulatory requirements, MMS, as the Federal land management agency, reviews and approves all OCS pipeline right-of-way applications. MMS also administers the following laws as they relate to OCS pipelines: (1) The Federal Oil and Gas Royalty Management Act of 1982 (FOGRMA) for oil and gas production measurement, and (2) the Federal Water Pollution Control Act, as amended by the Oil Pollution Act of 1990 (OPA) and implemented under Executive Order 12777. (Under a February 3, 1994, MOU to implement OPA, DOI, DOT, and the U.S. Environmental Protection Agency divided their respective responsibilities for oil spill prevention and response