

# Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 34

[Docket No. PRM-34-5]

#### Amersham Corporation, Receipt of a Petition for Rulemaking: Extension of Comment Period

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Petition for rulemaking: extension of comment period.

**SUMMARY:** On June 18, 1996 (61 FR30837), the Nuclear Regulatory Commission (NRC) published for public comment a petition for rulemaking filed by Amersham Corporation. The petitioner requested that the NRC amend its regulations by removing the reference to "associated equipment" from the radiography equipment regulations. The petitioner believes that this amendment would clarify the licensing reviews of sealed sources and radiographic exposure devices to meet the applicable requirements. The comment period for this petition for rulemaking was to have expired on September 3, 1996.

A public workshop was held by NRC on August 29, 1996, concerning the issues raised in the petition, and many of the attendees were planning to follow up their public comments with letters on the petition. The petitioner believes that the issues raised in the petition require significant input from the affected licensees in order that the most effective regulations can be put in place. Therefore, Amersham Corporation has requested that the comment period be extended until September 30, 1996.

**DATES:** The comment period has been extended and now expires on September 30, 1996. Comments received after this date will be considered if it is practical to do so, but assurance of consideration cannot be given except for comments received on or before this date.

**ADDRESSES:** Send written comments to: Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Docketing and Service Branch.

Deliver comments to 11555 Rockville Pike, Rockville, Maryland, between 7:45 am and 4:15 pm on Federal workdays.

For a copy of the petition, write: Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

**FOR FURTHER INFORMATION CONTACT:** Michael T. Lesar, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001. Telephone 301-415-7163 or Toll Free: 800-368-5642.

Dated at Rockville, Maryland, this 10th day of September 1996.

For the Nuclear Regulatory Commission,  
John C. Hoyle,  
*Secretary of the Commission.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 352

[Docket No. 78N-0038]

RIN 0910-AA01

#### Sunscreen Drug Products for Over-the-Counter Human Use; Amendment to the Tentative Final Monograph

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that amends the tentative final monograph (proposed rule) for over-the-counter (OTC) sunscreen drug products. This amendment would establish conditions under which products containing avobenzone (Parsol® 1789) are generally recognized as safe and effective and not misbranded at concentrations of up to 3 percent alone and 2 to 3 percent avobenzone in combination with the sunscreen ingredients cinoxate,

diethanolamine methoxycinnamate, dioxybenzone, homosalate, octocrylene, octyl methoxycinnamate, octyl salicylate, oxybenzone, sulisobenzone, and/or trolamine salicylate. OTC marketing pursuant to this amendment may not begin until FDA publishes a subsequent notice in a future issue of the Federal Register. This proposal is in response to a citizen petition and is part of the ongoing review of OTC drug products conducted by FDA.

**DATES:** Written comments by October 16, 1996; written comments on the agency's economic impact determination by October 16, 1996. The agency is requesting comments within a 30-day period, instead of the normal 90 days, so that the marketing status of OTC avobenzone-containing sunscreen drug products can be determined in an expeditious manner (see section II.E. of this document). FDA is proposing that any final rule based on this proposal become effective 12 months after its date of publication in the Federal Register.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857. Desk copies of these written comments to Debra L. Bowen, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** William E. Gilbertson, Center for Drug Evaluation and Research (HFD-105), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2304.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In the Federal Register of August 25, 1978 (43 FR 38206), FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), an advance notice of proposed rulemaking to establish a monograph for OTC sunscreen drug products. Proposed § 352.10 listed the active ingredients to be generally recognized as safe and effective for use in these products. Avobenzone was not included in § 352.10 at that time. Subsequently, a manufacturer petitioned the agency to reopen the administrative record for OTC sunscreen drug products and to include avobenzone, an ultraviolet A (UVA)