

relabelled. The agency believes the actual cost could be lower because some manufacturers may not elect to relabel their products at this time and some of the label changes will be made by private label manufacturers that tend to use simpler and less expensive labeling. In addition, there should be minimal waste of existing labeling for any manufacturer who elects to relabel at this next labeling printing. Manufacturers who wish to enter the marketplace with a new zinc oxide sunscreen combination product will incur the standard costs that all manufacturers have when introducing a new product.

The agency considered but rejected several alternatives: (1) A delayed marketing period, and (2) an exemption from coverage for small entities. The delayed marketing period was rejected because similar products currently exist in the marketplace. The agency does not consider an exemption for small entities appropriate because consumers who use these manufacturers' products would not have appropriate products for safe and effective use.

This analysis shows that this proposed rule is not economically significant under Executive Order 12866 and that the agency has undertaken important steps to reduce the burden to small entities. Nevertheless, some entities could incur some impacts, especially private label manufacturers that provide labeling for a number of affected products. Thus, this economic analysis, together with other relevant sections of this document, serves as the agency's initial regulatory flexibility analysis, as required under the Regulatory Flexibility Act. Finally, this analysis shows that the Unfunded Mandates Reform Act does not apply to the proposed rule because it would not result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million.

## V. Paperwork Reduction Act of 1995

FDA tentatively concludes that the labeling requirements proposed in this document are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Rather, the proposed amendment to the tentative final monograph for OTC sunscreen drug products is a "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

## VI. Environmental Impact

The agency has determined under 21 CFR 25.31(c) 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.

## VII. Public Comment

Interested persons may, on or before January 20, 1999, submit written comments to the Dockets Management Branch (address above). Written comments on the agency's economic impact determination may be submitted on or before January 20, 1999. Three copies of all 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 and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

### List of Subjects in 21 CFR Part 352

Labeling, Over-the-counter drugs. Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 352 (proposed in the **Federal Register** of May 12, 1993 (58 FR 28194) and amended in the **Federal Register** of September 16, 1996 (61 FR 48645)) be amended as follows:

### PART 352—SUNSCREEN DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 352 is revised to read as follows:

**Authority:** 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

2. Section 352.10 is amended by adding paragraph (v) to read as follows:

#### § 352.10 Sunscreen active ingredients.

\* \* \* \* \*

(v) Zinc oxide up to 25 percent.

3. Section 352.20 is amended by revising paragraphs (a)(1) and (a)(3)(xxi) to read as follows:

#### § 352.20 Permitted combinations of active ingredients.

(a) \* \* \*

(1) Two or more sunscreen active ingredients identified in § 352.10(a), and (c) through (v) may be combined when used in the concentrations established for each ingredient in paragraph (a)(3) of this section and the finished product has a minimum sun protection factor

value of not less than 2 as measured by the testing procedures established in subpart D of this part.

\* \* \* \* \*

(3) \* \* \*

(xxi) Zinc oxide 2 to 25 percent.

\* \* \* \* \*

4. Section 352.52 is amended by adding paragraph (b)(2)(vii) to read as follows:

#### § 352.52 Labeling of sunscreen drug products.

\* \* \* \* \*

(b) \* \* \*

(2) \* \* \*

(vii) For products containing the active ingredient identified in § 352.10(v), the following labeling statements may be used—(A) "Broad spectrum sunscreen."

(B) "Provides" (select one of the following: "UVB and UVA" or "broad spectrum") "protection."

(C) "Protects from UVB and UVA" (select one of the following: "rays" or "radiation").

(D) (Select one of the following: "Absorbs," "Protects," "Screens," or "Shields") "within the UVA spectrum."

(E) "Provides protection from the UVA rays that may contribute to skin damage and premature aging of the skin."

Dated: October 10, 1998.

**William K. Hubbard,**

*Associate Commissioner for Policy Coordination.*

[FR Doc. 98-28274 Filed 10-21-98; 8:45 am]

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## PANAMA CANAL COMMISSION

### 35 CFR Part 117

RIN 3207-AA48

### Marine Accidents: Investigations; Control; Responsibility

**AGENCY:** Panama Canal Commission.

**ACTION:** Notice of proposed rulemaking; request for comments.

**SUMMARY:** The Panama Canal Commission (Commission) proposes to amend its regulations to limit its liability in marine accidents. The new regulations will require potential claimants to carry insurance against marine accidents in an amount of \$1 million to cover damages sustained by their vessels at the Canal when transiting the waterway or navigating in waters adjacent thereto.

**DATES:** The agency must receive written comments on or before November 30, 1998.

**ADDRESSES:** Address all comments concerning this proposed rule to Office of the Secretary, Panama Canal Commission, 1825 I Street, N.W., Suite 1050, Washington, D.C. 20006-5402; or Office of General Counsel, Panama Canal Commission, Balboa, Ancon, Republic of Panama.

**FOR FURTHER INFORMATION CONTACT:** John A. Mills, Office of the Secretary, Panama Canal Commission, Telephone: (202) 634-6441, Facsimile: (202) 634-6439; Office of General Counsel, Telephone: 011 (507) 272-7511, Facsimile: 011 (507) 272-3748.

**SUPPLEMENTARY INFORMATION:** On October 17, 1998, the President signed into law a measure which allows the Commission to require potential claimants to carry insurance for damages sustained at the Panama Canal to their vessels, or to the cargo, crew and passengers of such vessels, which arise by reason of their passage through the locks or their presence in the Canal or adjacent waters. This proposed regulation would impose that requirement and would limit the liability of the Commission to only such damages as are in excess of \$1 million.

The Commission is taking these measures in an effort to reduce costs of Canal operations.

This proposed rule involves public property, the Panama Canal, and therefore is excluded from coverage of the Administrative Procedures Act, 5 U.S.C. 553(a)(2). Nevertheless, the Commission has elected generally to follow the notice and comment procedures provided for rulemaking under section 553.

The Commission will consider all timely written comments before publishing the final rule in the **Federal Register**.

The final rule, as approved and published by the Commission, will be effective no earlier than 30 days after the date of its publication as final in the **Federal Register**.

The Commission is exempt from Executive Order 12866 and its provisions do not apply to this rule. Even if the Order were applicable, the rule would not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act. The implementation of this rule will have no adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Finally, the Secretary of the Panama Canal Commission certifies these

changes meet the applicable standards set out in sections 3(a) and 3(b)(2) of Executive Order 12998.

#### **List of Subjects in 35 CFR Part 117**

Panama Canal.

For the reasons stated in the preamble, the Panama Canal Commission proposes to amend 35 CFR part 117 as follows:

#### **PART 117—MARINE ACCIDENTS: INVESTIGATIONS; CONTROL; RESPONSIBILITY**

1. The authority citation for part 117 is revised to read as follows:

**Authority:** 22 U.S.C. 3777-3779, 93 Stat. 487; E.O. 12215, 45 FR 36043.

2. Add a new § 117.7 to part 117 to read as follows:

##### **§ 117.7 Insurance; limitation of liability; subrogation.**

(a) A claimant against the Commission under sections 1411 or 1412 of Title 22, United States Code must be covered by insurance in the amount of \$1 million against the types of injuries described in those sections.

(b) The Commission's liability on any claim under sections 1411 or 1412 of Title 22, United States Code shall be limited to amounts in excess of \$1 million.

(c) The Commission may not consider or pay claims presented by or on behalf of an insurer or subrogee of a claimant under section 1411 or 1412 of Title 22, United States Code.

Dated: October 19, 1998.

**John A. Mills,**

*Secretary.*

[FR Doc. 98-28402 Filed 10-21-98; 8:45 am]

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#### **ENVIRONMENTAL PROTECTION AGENCY**

##### **40 CFR Part 52**

[FL-065-9623b; FRL-6167-5]

#### **Approval and Promulgation of Implementation Plans and Designation of Areas for Air Quality Planning Purposes; State of Florida**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The EPA proposes to approve the State Implementation Plan (SIP) revision submitted by the State of Florida which revises the emissions budget for use in determination of Transportation Conformity in the

Florida Southeast counties of Dade, Broward and Palm Beach. In the final rules section of this **Federal Register**, the EPA is approving the State's SIP revision as a direct final rule without a prior proposal because the Agency views this as a noncontroversial revision and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. The EPA will not institute a second comment period on this document. Any parties interested in commenting on this document should do so at this time.

**DATES:** To be considered, comments must be received by November 23, 1998.

**ADDRESSES:** Written comments should be addressed to: Kelly Sheckler at the Region 4, Environmental Protection Agency, Air Planning Branch, 61 Forsyth Street, Atlanta, Georgia 30303.

Copies of the documents relative to this action are available for public inspection during normal business hours at the following locations. The persons wanting to examine these documents should make an appointment with the appropriate office at least 24 hours before the visiting day. Reference file number FL-065-9623. The Region 4 office may have additional background documents not available at the other locations.

Air and Radiation Docket and Information Center (Air Docket 6102), U.S. Environmental Protection Agency, 401 M Street, SW, Washington, D.C. 20460.

Environmental Protection Agency, Region 4 Air Planning Branch, 61 Forsyth Street, Atlanta, Georgia 30303.

Florida Department of Environmental Regulation, Twin Towers Office Building, 2600 Blair Stone Road, Tallahassee, Florida, 32399-2400.

**FOR FURTHER INFORMATION CONTACT:** Kelly Sheckler at (404) 562-9042. Reference file FL-065-9623.

**SUPPLEMENTARY INFORMATION:** For additional information see the direct final rule which is published in the rule's section of this **Federal Register**.

Dated: September 3, 1998.

**A. Stanley Meiburg,**

*Acting Regional Administrator, Region 4.*

[FR Doc. 98-28233 Filed 10-21-98; 8:45 am]

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