

involves a proposed regulation which is not major under Executive Order 12291 and (2) is not a significant rule pursuant to the Department of Transportation Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this proposed rule, if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities because few, if any, Model 747 series airplanes are operated by small entities. A copy of a draft regulatory evaluation prepared for this action is contained in the regulatory docket.

List of Subjects in 14 CFR Part 39

Aviation Safety, Aircraft.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes to amend § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

PART 39—[AMENDED]

1. The authority citation for Part 39 continues to read as follows:

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.1 [AMENDED]

2. By adding the following new airworthiness directive:

Boeing: Applies to Model 747 series airplanes, production line numbers 1 through 200, certified in any category. Compliance required as indicated, unless previously accomplished.

To prevent depressurization resulting from cracks and/or corrosion in the fuselage skins, accomplish the following:

A. Within 1,000 landings after the effective date of this AD, and thereafter at intervals not to exceed 1,000 landings, conduct a detailed external visual inspection of the upper row of fasteners of all skin lap joints at and above stringer S-23 from body station (BS) 140 to BS 2360 for cracks and evidence of corrosion (bulging skin between fasteners, blistered paint, dished or popped rivet heads, or loose fasteners).

B. If cracking or corrosion is detected during the inspection required by paragraph A., above, prior to further flight, conduct High Frequency Eddy Current (HFEC) inspection for cracks at the upper row of fasteners of the affected skin panel lap joint. The HFEC method used must be approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

1. Any cracks or corrosion detected during the HFEC inspection must be repaired prior to further flight, in accordance with the Boeing Model 747 Structural Repair Manual.

2. Within 7 days after the completion of the HFEC inspection, submit a written report of findings to the Manager, Seattle Aircraft Certification Office, ANM-100S, FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168. The report must contain the following information:

- a. Serial number of the airplane inspected;
- b. Total number of landings on the airplane inspected;
- c. Number of landings since last inspected;
- d. The location and dimensions of cracks and/or corrosion detected.

C. To conduct the inspections required by this AD, remove the paint, using an approved chemical stripper, or ensure that the fastener head is clearly visible and that no more than two coats of paint are on the airplane skin.

D. Special flight permits may be issued in accordance with FAR 21.197 and 21.199 to operate airplanes to a base in order to comply with the requirements of this AD.

E. An alternate means of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, Seattle Aircraft Certification Office, FAA, Northwest Mountain Region.

Note.—The request should be forwarded through an FAA Principal Maintenance Inspector (PMI), who may add any comments and then send it to the Manager, Seattle Aircraft Certification Office.

All persons affected by this directive who have not already received the appropriate service documents from the manufacturer may obtain copies upon request to Boeing Commercial Airplanes, P.O. Box 3707, Seattle, Washington 98124. These documents may be examined at the FAA, Northwest Mountain Region, 17900 Pacific Highway South, Seattle, Washington, or Seattle Aircraft Certification Office, FAA, Northwest Mountain Region, 9010 East Marginal Way South, Seattle, Washington.

Issued in Seattle, Washington, on February 9, 1989.

Leroy A. Keith,

*Manager, Transport Airplane Directorate,
Aircraft Certification Service.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 355

[Docket No. 80N-0042]

Anticaries Drug Products for Over-the-Counter Human Use; Tentative Final Monograph; Reopening of Record for Receipt of Comments

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking; reopening of record for receipt of comments.

SUMMARY: The Food and Drug Administration (FDA) is reopening the record of the amendment to the tentative final monograph for over-the-counter (OTC) anticaries drug products for the receipt of comments. This action responds to a request to extend the comment period.

DATE: Comments by March 13, 1989.

ADDRESS. Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the Federal Register of June 15, 1988 (53 FR 22430), FDA issued a notice of proposed rulemaking that amended the tentative final monograph for OTC anticaries drug products. That notice contained the agency's proposals regarding final formulation testing, i.e., "Laboratory Testing Profiles" (LTPs), for Category I active ingredients in dentifrice formulations, and issues relating to this testing. This notice of proposed rulemaking is part of the ongoing review of OTC drug products conducted by the agency. Interested persons were given until October 13, 1988, to submit comments.

One comment from the American Dental Association (ADA) (Ref. 1) stated that all fluoride-containing dentifrice products should either be clinically tested or be equivalent to clinically-tested products. The ADA indicated that, in order to qualify as an equivalent product, a dentifrice should have a fluoride/abrasive system similar to a clinically tested effective product. The ADA expressed concern that the agency's proposed monograph would permit the marketing of any dentifrice containing an established fluoride agent, regardless of what abrasive system (either tested or untested) is used. The ADA argued that "due to the very limited nature of laboratory tests required by the monograph, there is no guarantee that the fluoride agent will be biochemically available during the very limited exposure periods associated with brushing." The ADA also expressed concern that the agency would allow marketing of products with new fluoride/abrasive systems that

have no history of clinical testing. Stating that its own product review has shown that abrasives can play a critical role in the rate of release/availability of the fluoride ion, the ADA contended that only clinically tested fluoride/abrasive systems should be eligible for review under the OTC anticaries monograph and that untested systems should be required to provide clinical data to support efficacy.

The ADA further noted that some dentifrice products contain agents that inhibit calculus formation and thus influence the calcification/decalcification process associated with caries. The ADA recommended that either animal caries or remineralization studies be required for this category of products to guard against the potential inactivation of the fluoride agent by a nontherapeutic additive.

The Cosmetic, Toiletry and Fragrance Association (CTFA) (Ref. 2) subsequently submitted a request to extend the period for submission of comments on FDA's proposed rulemaking to allow time to comment on ADA's comments. The CTFA stated that the ADA's position regarding the efficacy of a fluoride dentifrice product differs significantly from the agency's proposals in the tentative final monograph for OTC anticaries drug products as published in the *Federal Register* of June 15, 1988. The CTFA stated that the issues raised in the ADA's comments are complex and will require some extensive review and analysis, which will necessitate the scheduling of several meetings of its members to discuss the issues. Based on the anticipated time needed to meet and develop comments, the CTFA stated that it would need approximately 150 days to adequately address the issues raised by ADA and requested an extension of the comment period until March 13, 1989.

FDA has carefully considered the request and believes that a reopening of the record to allow full opportunity for informed comments on the amendment to the tentative final monograph regarding appropriate testing requirements for dentifrices with fluoride/abrasive systems that have not been clinically tested or that contain an ingredient that inhibits calculus formation is in the public interest. Accordingly, the record is reopened for the receipt of comments until March 13, 1989. Comments may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m. Monday through Friday.

References

- (1) Comment No. C00070, Docket No. 80N-0042, Dockets Management Branch.
- (2) Comment No. EXT00005, Docket No. 80N-0042, Dockets Management Branch.

Dated: February 10, 1989.

Alan L. Hoeting,

Acting Associate Commissioner for Regulatory Affairs.

[FR Doc. 89-3865 Filed 2-17-89; 8:45 am]

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DEPARTMENT OF STATE

Office of Foreign Missions

22 CFR Part 151

[Dept. Reg. SD-224]

Compulsory Liability Insurance for Foreign Missions and Personnel

AGENCY: Office of Foreign Missions, State.

ACTION: Proposed rule.

SUMMARY: The Office of Foreign Missions of the Department of State proposes to amend 22 CFR 151.4, which sets minimum limits of liability for motor-vehicle insurance for foreign diplomatic missions and their personnel. The minimum limits are changed from "not less than \$300,000 combined single limit for all bodily injury liability and property damage liability arising from a single incident," to "not less than \$100,000 per person and \$300,000 per incident for bodily injury liability and \$100,000 per incident for property damage or \$300,000 combined single limit for all bodily injury liability and property damage liability arising from a single incident." The adequacy of the changed minimum limits was confirmed as part of the Study and Report concerning the Status of Individuals with Diplomatic Immunity in the United States presented to Congress on March 18, 1988, as mandated by the Foreign Relations Authorization Act, Fiscal Years 1988 and 1989, section 137, Pub. L. 100-204. The changed minimum limits also more accurately reflects the Office of Foreign Missions practice and the availability of insurance policies since combined single limit policies are not available in all cases.

DATES: Comments must be submitted on or before March 23, 1989.

ADDRESSES: U.S. Department of State, Office of Foreign Missions, Insurance Tracking Unit, 3005 Massachusetts Avenue NW., Washington, DC 20008.

FOR FURTHER INFORMATION CONTACT: E. Richard Atkinson, Senior Operations

Officer, Office of Foreign Missions (202) 673-6266.

SUPPLEMENTARY INFORMATION: Section 6 of the Diplomatic Relations Act required the President to establish, by regulation, liability insurance requirements to be met by each mission, members of the mission and their families, and those officials of the United Nations who are entitled to diplomatic immunity. The President delegated this function to the Secretary of State, who issued regulations on May 21, 1979. Congress amended section 6 in 1983 to substitute the Director of the Office of Foreign Missions within the Department of State for the President, and added the condition that the liability insurance requirements "reasonably be expected to afford adequate compensation to victims."

The Director of the Office of Foreign Missions has determined that an adequate level of liability insurance is provided by policies with limits of \$100,000 per person and \$300,000 per incident for bodily injury and \$100,000 per incident for property damage or \$300,000 combined single limit for all bodily injury and property damage from a single incident. The adequacy of these minimum limits was confirmed as part of the Study and Report concerning the Status of Individuals with Diplomatic Immunity in the United States presented to Congress on March 18, 1988, as mandated by the Foreign Relations Authorization Act, Fiscal Years 1988 and 1989, section 137, Pub. L. 100-204. These minimum limits also reflect the Office of Foreign Missions practice and the availability of insurance policies since combined single limit policies are not available in all cases.

List of Subjects in 22 CFR Part 151

Aircrafts, Foreign officials, Insurance, Motor vehicles, Vessels.

For reasons set forth in the preamble, Title 22, Chapter I of the Code of Federal Regulations, Part 151 is proposed to be amended as follows:

PART 151—[AMENDED]

1. The authority citation for Part 151 continues to read as follows:

Authority: Sec. 6, Diplomatic Relations Act (Pub. L. 95-393; 22 U.S.C. 254e) as amended (Pub. L. 98-164, sec. 602; 22 U.S.C. 254e).

2. Section 151.4 is revised to read as follows:

§ 151.4 Minimum limits for motor vehicle insurance.

The insurance shall provide not less than \$100,000 per person and \$300,000 per incident for bodily injury liability