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.

OFFICE OF PERSONNEL MANAGEMENT

5 CFR Part 532

RIN 3206–AI01

Prevailing Rate Systems; Survey Order Month Change for Jefferson, New York, Nonappropriated Fund Wage Area

AGENCY: Office of Personnel Management.

ACTION: Proposed rule.

SUMMARY: The Office of Personnel Management is issuing a proposed rule to change the survey order month beginning with the next full-scale survey for the Jefferson, NY, nonappropriated fund (NAF) Federal Wage System wage area from March to April. This change is expected to improve the survey data yield and to allow the Department of Defense to better balance its survey workload.

DATES: Comments must be received by October 2, 1997. The survey order month change from March to April for the Jefferson NAF wage area would begin with the fiscal year 1998 full-scale survey.

ADDRESSES: Send or deliver comments to Donald J. Winstead, Assistant Director for Compensation Policy, Human Resources Systems Service, Office of Personnel Management, Room 7H31, 1900 E Street NW., Washington, DC 20415, or FAX: (202) 606–4264.

FOR FURTHER INFORMATION CONTACT: Angela Graham Humes, (202) 606-2848.

SUPPLEMENTARY INFORMATION: The Department of Defense, the lead agency for the Jefferson NAF wage area, requested that beginning with the 1998 full-scale survey, the survey order month be changed from March to April. The 1996 full-scale survey was the initial survey in the Jefferson wage area and satisfied minimum survey adequacy requirements. This proposed change in survey order month would avoid the inclement March weather in the Jefferson NAF wage area and thereby is expected to improve wage survey participation and data yield. In addition, the new survey month would allow the Department of Defense to better balance its survey workload by moving the Jefferson survey from a heavy workload month to a light workload month. The April survey order month would delay the Jefferson wage schedule effective date by only 1 month.

The Federal Prevailing Rate Advisory Committee reviewed this recommendation and by consensus recommended approval.

Regulatory Flexibility Act

I certify that these regulations would not have a significant economic impact on a substantial number of small entities because they would affect only Federal agencies and employees.

List of Subjects in 5 CFR Part 532

Administrative practice and procedure, Freedom of information, Government employees, Reporting and recordkeeping requirements, Wages.

Office of Personnel Management.

James B. King,

Director.

Accordingly, OPM proposes to amend 5 CFR Part 532 as follows:

PART 532—PREVAILING SYSTEMS

1. The authority citation for part 532 continues to read as follows:

Authority. 5 U.S.C. 5343, 5346; § 532.707 also issued under 5 U.S.C. 552.

Appendix B to Subpart B of 532—[Amended]

2. Appendix B to subpart B is amended for Jefferson, New York, by revising the beginning month of survey listing from March to April.

[FR Doc. 97–23221 Filed 8–29–97; 8:45 am]

BILLING CODE 6325–01–M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 97–NM–95–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 777–200 Series Airplanes Equipped With Air Cruisers Evacuation Slide/Rafts

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes the adoption of a new airworthiness directive (AD) that is applicable to certain Boeing Model 777–200 series airplanes. This proposal would require modifying the sliding surface of the door 1 left and door 1 right evacuation slide/rafts. This proposal is prompted by a report of injuries to evacuees using the slide/raft to exit the airplane; the evacuees were unable to achieve adequate initial sliding speed and adequate momentum to carry them expeditiously down the slide/raft. The actions specified by the proposed AD are intended to prevent evacuee overload of the slide/rafts, and consequent impeded evacuation and injury to the evacuees.

DATES: Comments must be received by October 14, 1997.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–95–AD, 1601 Lind Avenue SW, Renton, Washington 98055–4056. Comments may be inspected at this location between 9:00 a.m. and 3:00 p.m., Monday through Friday, except Federal holidays.

The service information referenced in the proposed rule may be obtained from Boeing Commercial Airplane Group, P.O. Box 3707, Seattle, Washington 98124–2207. This information may be examined at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW, Renton, Washington.

FOR FURTHER INFORMATION CONTACT: Jim Cashdollar, Aerospace Engineer, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office,

1601 Lind Avenue SW, Renton, Washington; telephone (425) 227–2785; fax (425) 227–1181.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested persons are invited to participate in the making of the proposed rule by submitting such written data, views, or arguments as they may desire. Communications shall identify the Rules Docket number and be submitted in triplicate to the address specified above. All communications received on or before the closing date for comments, specified above, will be considered before taking action on the proposed rule. The proposals contained in this notice may be changed in light of the comments received.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the proposed rule. All comments submitted will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested persons. A report summarizing each FAA-public contact concerned with the substance of this proposal will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 97–NM–95–AD.'' The postcard will be date stamped and returned to the commenter.

Availability of NPRMs

Any person may obtain a copy of this NPRM by submitting a request to the FAA, Transport Airplane Directorate, ANM–103, Attention: Rules Docket No. 97–NM–95–AD, 1601 Lind Avenue SW, Renton, Washington 98055–4056.

Discussion

The FAA has received a report indicating that, during a full-scale evacuation demonstration on a Boeing Model 777 series airplane equipped with Air Cruisers evacuation slide/rafts, evacuees were injured because they were unable to achieve adequate initial sliding speed and adequate momentum to carry them expeditiously to the toe end of the door 1 evacuation slide/raft. Investigation revealed a shallow sliding angle of the slide/raft, which resulted in delayed descent of the evacuees down the slide/raft; this, in turn, resulted in evacuee overload of the slide/raft. This condition, if not corrected, could result in impeded evacuation and injury to the evacuees.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 777–25A0035, dated December 2, 1996, which describes procedures for modifying the sliding surface of the door 1 left and door 1 right evacuation slide/rafts. (The alert service bulletin references Air Cruisers Company Service Bulletin S.B. 777–107–25–02, dated October 29, 1996, as an additional source of service information for accomplishment of the modification.) The modification involves the application of dry lubricant McLube 1720L to a specified area of the sliding area of the sliding lane of each evacuation slide/raft, and the subsequent reidentification of the slide/rafts. Accomplishment of the modification will improve the initial evacuee sliding speed to provide adequate momentum to carry evacuees through to the toe ends of the slides.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of this same type design, the proposed AD would require modifying the sliding surface of the door 1 left and door 1 right evacuation slide/rafts. The actions would be required to be accomplished in accordance with the alert service bulletin described previously.

Cost Impact

There are approximately 43 Boeing Model 777–200 series airplanes of the affected design in the worldwide fleet. The FAA estimates that 16 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 4 work hours per airplane to accomplish the proposed actions, and that the average labor rate is $60 per work hour. Required parts would be provided by the manufacturer at no cost to the operators. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $3,840, or $240 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the proposed requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted.

Regulatory Impact

The regulations proposed herein would not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this proposal would not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

For the reasons discussed above, I certify that this proposed regulation (1) is not a ''significant regulatory action'' under Executive Order 12866; (2) is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979); and (3) if promulgated, will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act. A copy of the draft regulatory evaluation prepared for this action is contained in the Rules Docket. A copy of it may be obtained by contacting the Rules Docket at the location provided under the caption **ADDRESSES**.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Safety.

The Proposed Amendment

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

PART 39—AIRWORTHINESS DIRECTIVES

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

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Boeing: Docket 97–NM–95–AD.

Applicability: Model 777–200 series airplanes, line positions 2 through 48, excluding line positions 10, 41, 43, and 47; equipped with Air Cruisers evacuation slide/rafts, as identified in Air Cruisers Service Bulletin S.B. 777–107–25–02; certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (b) of this AD. The request should include an assessment of the effect of the modification, alteration, or

repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent evacuee overload of the slide/raft, and consequent impeded evacuation and injury to the evacuees, accomplish the following:

(a) Within 180 days after the effective date of this AD, modify the sliding surfaces of the door 1 left and door 1 right evacuation slide/rafts, in accordance with Boeing Alert Service Bulletin 777–25A0035, dated December 2, 1996.

Note 2: The Boeing alert service bulletin references Air Cruisers Company Service Bulletin S.B. 777–107–25–02, dated October 29, 1996, as an additional source of service information.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Seattle ACO.

Note 3: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Seattle ACO.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on August 26, 1997.

John J. Hickey,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 97–23173 Filed 8–29–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310 and 334

[Docket No. 78N–036L]

RIN 0910–AA01

Laxative Drug Products for Over-the-Counter Human Use; Proposed 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 reopening the administrative record and proposing to amend the tentative final monograph for over-the-counter (OTC) laxative drug products to reclassify the stimulant laxative ingredients danthron and phenolphthalein from Category I (generally recognized as safe and effective and not misbranded) to Category II (not generally recognized as safe and effective or misbranded) and adding these ingredients to a list of nonmonograph active ingredients. FDA is issuing this proposed rulemaking after considering data and information on the safety of danthron and phenolphthalein. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by October 2, 1997. Written comments on the agency's economic impact determination by October 2, 1997. FDA is proposing that any final rule based on this proposal be effective on the date of its 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.

FOR FURTHER INFORMATION CONTACT: Cheryl A. Turner, Center for Drug Evaluation and Research (HFD–560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 21, 1975 (40 FR 12902), 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 laxative, antidiarrheal, emetic, and antiemetic drug products, together with the recommendations of the Advisory Review Panel on OTC Laxative, Antidiarrheal, Emetic, and Antiemetic Drug Products (the Panel), which was the advisory review panel responsible for evaluating data on the active ingredients in these classes. In the advance notice of proposed rulemaking, the Panel recommended Category I status for the OTC stimulant laxative ingredients aloe, bisacodyl, cascara sagrada preparations, danthron, phenolphthalein, and senna preparations (40 FR 12902 at 12908 to 12910). The agency concurred with the Panel's Category I classification of these ingredients in the tentative final monograph published in the **Federal Register** of January 15, 1985 (50 FR 2124 at 2152 to 2156).

II. Danthron

Following publication of the laxative tentative final monograph in 1985, FDA became aware of studies concerning the potential carcinogenic risk of danthron. In January 1987, a leading U.S. pharmaceutical manufacturer informed FDA that it would voluntarily cease manufacture and distribution of products containing danthron. The company's decision was partly in response to published studies in Britain and Japan that strongly suggested that chronic administration of high doses of danthron to rats and mice resulted in development of intestinal and liver tumors and that danthron is, therefore, a potential carcinogen in humans (Refs. 1 and 2). Danthron, in common with other anthraquinone compounds, has also been shown to exhibit a positive mutagenic effect in some in vitro models (Refs. 3 and 4). FDA subsequently initiated a recall that extended to the retail/dispensing level of all danthron-containing drug products, by sending a recall letter to all registered drug firms and distributors (Ref. 5). FDA stated that ''danthron toxicity in humans has not been specifically demonstrated, but because of potential risk, FDA has requested an immediate halt to all manufacturing, relabeling, repackaging, and further distribution of human drug products containing danthron as an ingredient'' (Ref. 6). The agency notes that, although danthron was removed from OTC laxative drug products in 1987, it was not specifically included in part 310 (21 CFR part 310) as a new drug. Therefore, in this rulemaking, the agency is proposing to amend § 310.545 to include danthron as a nonmonograph ingredient.

III. New Information on Phenolphthalein

Recently, FDA became aware of data indicating that phenolphthalein is a potential carcinogen in humans. Under the direction of the National Institute of Environmental Health Science (NIEHS) through the National Toxicology Program (NTP), phenolphthalein was studied for its carcinogenic potential in rats and mice. The National Cancer Institute (NCI) nominated phenolphthalein for study because of its widespread chronic use in OTC laxative drug products and the lack of adequate testing for carcinogenicity in experimental animals. The preliminary findings were reported in a 1995 NTP draft technical report (NTP TR 465, NIH publication No. 95–3390), which indicated that phenolphthalein demonstrated evidence of carcinogenic