

11-2A which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to alter the description of VOR Federal Airway V-10. This action would alter the airway by establishing an extension from Revloc, PA, to Lancaster, PA. The change to the airway is necessary due to the unreliability of the Harrisburg, PA, very high frequency omnidirectional radio range and tactical air navigational aid. The proposed change would simplify the routings, improve navigation, and make better use of the airspace in this area. Section 71.123 of part 71 of the Federal Aviation Regulations was republished in Handbook 7400.6G dated September 4, 1990.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Aviation safety, VOR Federal airways.

The Proposed Amendment

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) as follows:

PART 71—DESIGNATION OF FEDERAL AIRWAYS, AREA LOW ROUTES, CONTROLLED AIRSPACE, AND REPORTING POINTS

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g); Revised Pub. L. 97-449, January 12, 1983; 14 CFR 11.69.

§ 71.123 [Amended]

2. Section 71.123 is amended as follows:

V-10 [Amended]

By removing the words "Clarion, PA, 222° radials; Revloc, PA." and substituting the words "Revloc, PA, 300°T(309°M) radials; Revloc; INT Revloc 107°T(116°M) and Lancaster, PA, 280°T(289°M) radials; Lancaster."

Issued in Washington, DC, on February 26, 1991.

Harold W. Becker,

Manager, Airspace—Rules and Aeronautical Information Division.

[FR Doc. 91-5523 Filed 3-7-91; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 356

[Docket No. 91N-0033]

Over-the Counter Dental and Oral Health Care Drug Products for Antiplaque Use; Safety and Efficacy Review; Extension of Submission Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Request for data and information; extension of submission period.

SUMMARY: The Food and Drug Administration (FDA) is extending to June 17, 1991, the period for submission of data and information on ingredients contained in products bearing antiplaque and antiplaque-related claims, such as "for the reduction or prevention of plaque, tartar, calculus, film, sticky deposits, bacterial build-up, and gingivitis." This action responds to two requests to extend the submission period for an additional 90 days.

DATES: Data and information to be submitted by June 17, 1991.

ADDRESSES: Submissions should be sent to the Division of OTC Drug Evaluation (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 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 September 19, 1990 (55 FR 38560), FDA announced a call-for-

data for ingredients contained in products bearing antiplaque and antiplaque-related claims such as "for the reduction or prevention of plaque, tartar, calculus, film, sticky deposits, bacterial build-up, and gingivitis." The agency stated that it will review the submitted data to determine whether these products are generally recognized as safe and effective and not misbranded for their labeled uses. Those interested in supplying data and information were given until March 18, 1991. This call-for-data is part of the agency's ongoing review of over-the-counter (OTC) oral health-care drug products.

The agency has received two requests to extend the submission period for an additional 90 days. A manufacturers' association informed the agency that a number of its members would not be able to adequately respond before the submission period closes because these members must consult with and obtain the concurrence of a number of corporate officials, including a considerable number located outside the United States, prior to submitting comments and/or data. The association stated that this proceeding for OTC dental and oral health-care drug products for antiplaque use is of considerable interest and importance both to the association and to its members. Therefore, the association requested a 90-day extension of the submission period, until June 17, 1991, to allow adequate time to assemble the necessary data and information and to prepare submissions.

A manufacturer stated that it intends to submit data concerning the safety and effectiveness of several ingredients in response to the agency's announcement of a call-for-data on ingredients contained in products making antiplaque and antiplaque-related claims. The manufacturer noted that its major toothpaste research laboratory is located in the United Kingdom, and some of the data needed to establish the safety and effectiveness of these ingredients is located in different parts of the world. The manufacturer also stated that collecting information on the safety and effectiveness of these ingredients throughout the world represents an extensive logistic problem. The manufacturer added that the inherent delay in overseas communication and transportation has prolonged the preparation of these documents because documents prepared by scientists overseas cannot be readily transmitted to the United States and Vice versa. In addition, the manufacturer noted that the generation of submissions

requires extensive summarization and review of available data to bring the documents up-to-date and to put the documents into the format required by the agency. The manufacturer requested, as did the manufacturer's association, that the agency grant a 90-day extension of the submission period to June 17, 1991.

FDA has carefully considered these requests and believes that additional time to allow full opportunity for informed submissions is in the public interest. An extension of the submission period will assure that the agency will have comprehensive data and information on ingredients in products bearing antiplaque claims for the Dental Products Panel to evaluate. Thus, the agency considers a 90-day extension of the data submission period to be appropriate.

Interested persons may, on or before June 17, 1991, submit to the Division of OTC Drug Evaluation (address above) submissions of data and information on ingredients contained in products bearing antiplaque and antiplaque-related claims, as described above. Eight copies of the data and information must be submitted, as discussed in the *Federal Register* of September 19, 1990 (55 FR 38560 at 38562).

Dated: March 4, 1991.

Ronald G. Chesemore,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 91-5496 Filed 3-7-91; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD13 91-01]

Drawbridge Operation Regulations; Cowlitz River, WA

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: At the request of the City of Kelso the Coast Guard is considering a change to the regulations governing the Allen Street Bridge across the Cowlitz River, mile 5.5, at Kelso, Washington, to provide that the draw need not be opened for the passage of vessels. This proposal is being made because no requests have been made to open the draw since at least 1983. This action should relieve the bridge owner of the burden of maintaining the machinery and having a person available to open the draw and should still provide for the reasonable needs of navigation.

DATES: Comments must be received on or before April 22, 1991.

ADDRESSES: Comments should be mailed to Commander (oan), Thirteenth Coast Guard District, 915 Second Avenue, Seattle, Washington 98174-1067. The comments and other materials referenced in this notice will be available for inspection and copying at 915 Second Avenue, room 3410. Normal office hours are between 7:45 a.m. and 4:15 p.m., Monday through Friday, except holidays. Comments may also be hand-delivered to this address.

FOR FURTHER INFORMATION CONTACT: John E. Mikesell, Chief, Bridge Section, Aids to Navigation and Waterways Management Branch, (Telephone: (206) 553-5864).

SUPPLEMENTARY INFORMATION: Interested persons are invited to participate in this proposed rulemaking by submitting written views, comments, data, or arguments. Persons submitting comments should include their names and addresses, identify the bridge, and give reasons for concurrence with, or any recommended changes in, the proposal. Persons desiring acknowledgment that their comments have been received should enclose a stamped, self-addressed postcard or envelope.

The Commander, Thirteenth Coast Guard District, will evaluate all communications received and determine a course of final action on this proposal. The proposal regulations may be changed in light of comments received.

Drafting Information

The drafters of this notice are: John E. Mikesell, project officer, and Lieutenant Deborah K. Schram, project attorney.

Discussion of the Proposed Regulations

Existing regulations provide that the Allen Street Bridge open upon 24 hours advance notice for normal openings and two hours advance notice for emergency openings, when so requested by the Cowlitz County Department of Emergency Services. No openings have been required since at least 1983. The proposed change would provide that the bridge need not open for the passage of vessels. Since the May 18, 1980 volcanic eruption of Mount Saint Helens and its subsequent mud flow down the Cowlitz River, the channel has been severely silted-in and is passable only by small shallow draft vessels. The Cowlitz River Navigation Project has not been maintained by the Corps of Engineers since 1980. Prior to 1980, the navigation channel was maintained to river mile 4. The channel has not been maintained upstream of mile 4 for more than 25

years. Should emergency dredging be required upstream of the Allen Street Bridge, the necessary equipment would be transported overland to the work site.

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12291, and it has been determined that the proposed rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Economic Assessment and Certification

These proposed regulations are considered to be non-major under Executive Order 12291 on Federal Regulation and nonsignificant under the Department of Transportation regulatory policies and procedures (44 FR 11034; February 26, 1979).

The economic impact of this proposal is expected to be so minimal that a full regulatory evaluation is unnecessary. Because of its present silted-in condition, the waterway is not being used for commercial navigation. When the waterway is restored, either through natural flushing or dredging, low profile tugs could easily pass under the bridge. Since the economic impact of this proposal is expected to be minimal, the Coast Guard certifies that, if adopted, it will not have a significant economic impact on a substantial number of small entities.

List of Subjects in 33 CFR Part 117

Bridges.

Proposed Regulations

In consideration of the foregoing, the Coast Guard proposes to amend part 117 of title 33, Code of Federal Regulations as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

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

Authority: 33 U.S.C. 499; 49 CFR 1.46; 33 CFR 1.05-1(g).]

2. Section 117.1037 is revised to read as follows:

§ 117.1037 Cowlitz River.

(a) The draw of the Burlington Northern railroad bridge, mile 1.5, shall operate as follows:

(1) The draw shall open on signal if at least 24 hours notice is given.

(2) In the event of an emergency declared by the Cowlitz County Department of Emergency Services, the