Miscellaneous

The regulations in §§ 113.215(c)(2)(vii) and 113.216(c)(2)(vii) provide that prevaccination and postvaccination sera from a satisfactory potency test shall be submitted to the National Veterinary Services Laboratories (NVSL) for testing by APHIS. The testing referred to in those paragraphs is now performed by APHIS' Center for Veterinary Biologics-Laboratory, and not by NVSL, so we would amend §§ 113.215(c)(2)(vii) and 113.216(c)(2)(vii) to reflect that change.

Executive Order 12866 and Regulatory Flexibility Act

This proposed rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

Currently, only 7 of the approximately 135 licensed veterinary biologics manufacturers produce Bovine Virus Diarrhea Vaccine, Killed Virus, and Bovine Rhinotracheitis Vaccine, Killed Virus, and would thus be affected by this proposal. According to the standards of the Small Business Administration, most veterinary biologics establishments would be classified as small entities.

This proposed rule would amend the standard requirements in § 113.215 for Bovine Virus Diarrhea Vaccine, Killed Virus, and in § 113.216 for Bovine Rhinotracheitis Vaccine, Killed Virus, by specifying that the effectiveness of the antibody titers based on host animal studies is the basis for determining the potency of the vaccine. We believe that the antibody titer elicited in the manufacturer's host animal protection study would be more indicative of the efficacy of the vaccine than the titer currently specified in the regulations. This change would affect all licensed manufacturers of veterinary biologics producing Bovine Virus Diarrhea Vaccine, Killed Virus, and Bovine Rhinotracheitis Vaccine, Killed Virus. However, we do not expect that there would be any increase in costs for the biologics manufacturers affected by this proposed rule. The changes should actually be cost neutral for most affected manufacturers because those manufacturers would not be required to change the way that their products are manufactured or tested.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action would not have a significant economic impact on a substantial number of small entities.

Executive Order 12372

This program/activity is listed in the category of Federal Domestic Assistance under No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (*See* 7 CFR part 3015, subpart V.)

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule would not preempt any State or local laws, regulations, or policies unless they present an irreconcilable conflict with this rule. The Virus-Serum-Toxin Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

This proposed rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 9 CFR Part 113

Animal biologics, Exports, Imports, Reporting and recordkeeping requirements.

Accordingly, we propose to amend 9 CFR part 113 as follows:

PART 113—STANDARD REQUIREMENTS

1. The authority citation for part 113 would continue to read as follows:

Authority: 21 U.S.C. 151–159; 7 CFR 2.22, 2.80, and 371.4.

2. In § 113.215, paragraphs (c)(2)(v) and (c)(2)(vii) would be revised to read as follows.

§ 113.215 Bovine Virus Diarrhea Vaccine, Killed Virus.

* * * * *

(c) * * *

(2) * * *

(v) *Test interpretation.* If the controls have not remained seronegative at 1:2, the test is a No Test (NT) and may be repeated. If at least four of the five vaccinates in a valid test have not developed 50 percent endpoint titers that are at least 80 percent of the geometric mean antibody titer developed in the vaccinates in the host animal protection study provided for in paragraph (b) of this section, the serial is unsatisfactory except as provided in paragraph (c)(2)(vi) of this section.

* * * * *

(vii) The prevaccination and postvaccination sera from a satisfactory potency test shall be submitted to the Center for Veterinary Biologics-Laboratory for confirmatory testing.

3. In § 113.216, paragraphs (c)(2)(v) and (c)(2)(vii) would be revised to read as follows.

§ 113.216 Bovine Rhinotracheitis Vaccine, Killed Virus.

* * * * *

(c) * * *

(2) * * *

(v) *Test interpretation.* If the three controls have not remained seronegative at 1:2, the test is a No Test (NT), and may be repeated. If at least four of the five vaccinates in a valid test have not developed 50 percent endpoint titers that are at least 80 percent of the geometric mean antibody titer developed in the vaccinates in the host animal protection study provided for in paragraph (b) of this section, the serial is unsatisfactory, except as provided in paragraph (c)(2)(vi) of this section.

* * * * *

(vii) The prevaccination and postvaccination sera from a satisfactory potency test shall be submitted to the Center for Veterinary Biologics-Laboratory for testing by the Animal and Plant Health Inspection Service.

Done in Washington, DC, this 30th day of September 2003.

Kevin Shea,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–25252 Filed 10–3–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2003–NM–49–AD]

RIN 2120–AA64

Airworthiness Directives; Boeing Model 767–200, –300, and –300F Series Airplanes

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 all Boeing Model 767–200, –300, and –300F series airplanes. This proposal

would require repetitive inspections of the aft pressure bulkhead web, and corrective action, if necessary. This action is necessary to detect and correct fatigue cracks in the aft pressure bulkhead web, which could result in uncontrolled rapid decompression. This action is intended to address the identified unsafe condition.

DATES: Comments must be received by November 20, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Transport Airplane Directorate, ANM–114, Attention: Rules Docket No. 2003–NM–49–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056. Comments may be inspected at this location between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays. Comments may be submitted via fax to (425) 227–1232. Comments may also be sent via the Internet using the following address: *9-anm-nprmcomment@faa.gov.* Comments sent via fax or the Internet must contain ''Docket No. 2003–NM–49–AD'' in the subject line and need not be submitted in triplicate. Comments sent via the Internet as attached electronic files must be formatted in Microsoft Word 97 or 2000 or ASCII text.

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: Suzanne Masterson, Airframe Branch, ANM–120S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 917–6441; fax (425) 917–6590.

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 action may be changed in light of the comments received.

Submit comments using the following format:

- Organize comments issue-by-issue. For example, discuss a request to change the compliance time and a request to change the service bulletin reference as two separate issues.
- For each issue, state what specific change to the proposed AD is being requested.
- Include justification (*e.g.*, reasons or data) for each request.

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 action must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket Number 2003–NM–49–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–114, Attention: Rules Docket No. 2003–NM–49–AD, 1601 Lind Avenue, SW., Renton, Washington 98055–4056.

Discussion

The FAA has received reports of fatigue cracks at the aft pressure bulkhead web on Boeing Model 737 and 747 series airplanes. This condition, if not detected and corrected, could result in uncontrolled rapid decompression.

The aft pressure bulkhead web on Boeing Model 767–200, –300, and –300F series airplanes is almost identical to that on the affected Boeing Model 737 and 747 series airplanes. Therefore, those Boeing Model 767–200, –300, and –300F series airplanes may be subject to the unsafe condition revealed on the Boeing Model 737 and 747 series airplanes.

Other Relevant Rulemaking

The FAA has previously issued AD 1999–08–23, amendment 39–11132 (64 FR 19879, May 10, 1999), applicable to certain Boeing Model 737 series airplanes. That AD requires repetitive inspections to detect cracking in the web of the aft pressure bulkhead at body station 1016 at the aft fastener row attachment to the ''Y'' chord; and corrective actions, if necessary. This proposed AD would not affect the current requirements of that AD.

The FAA has also previously issued AD 2000–15–08, amendment 39–11840 (65 FR 47255, September 6, 2000), applicable to certain Boeing Model 747 series airplanes. That AD requires repetitive inspections for damage or cracking of the aft pressure bulkhead; cracking of the bulkhead web-to-Y-ring lap joint area; cracking of the upper segment of the bulkhead web; and cracking of the upper and lower segments of the aft bulkhead web. This proposed AD would not affect the current requirements of that AD.

Explanation of Relevant Service Information

The FAA has reviewed and approved Boeing Alert Service Bulletin 767–53A0087, dated October 21, 1999, which describes procedures for performing repetitive high frequency eddy current inspections for fatigue cracking of the aft pressure bulkhead web and contacting Boeing for repair or inspection instructions. Accomplishment of the actions specified in the service bulletin is intended to adequately address the identified unsafe condition.

Explanation of Requirements of Proposed Rule

Since an unsafe condition has been identified that is likely to exist or develop on other products of similar type design, the proposed AD would require accomplishment of the actions specified in the service bulletin described previously, except as discussed below.

Differences Between Proposed Rule and Service Bulletin

Operators should note that, although the service bulletin specifies that the manufacturer may be contacted for disposition of certain repair conditions, this proposal would require the repair of those conditions to be accomplished per a method approved by the FAA, or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the FAA to make such findings.

Operators should also note that, although the service bulletin specifies that the manufacturer may be contacted for certain inspection details, this proposal would require an alternative method of compliance to be approved as required by sections 39.15, 39.17, and 39.19 of the Code of Federal Regulations (14 CFR 39.15, 39.17, 39.19).

Operators should also note that, although the service bulletin does not

list a grace period in the compliance times, this proposal adds a grace period to the compliance times. The FAA finds that such a grace period will keep airplanes from being grounded unnecessarily.

Changes to 14 CFR Part 39/Effect on the Proposed AD

On July 10, 2002, the FAA issued a new version of 14 CFR part 39 (67 FR 47997, July 22, 2002), which governs the FAA's airworthiness directives system. The regulation now includes material that relates to altered products, special flight permits, and alternative methods of compliance (AMOCs). Because we have now included this material in part 39, only the office authorized to approve AMOCs is identified in each individual AD.

Change to Labor Rate Estimate

We have reviewed the figures we have used over the past several years to calculate AD costs to operators. To account for various inflationary costs in the airline industry, we find it necessary to increase the labor rate used in these calculations from $60 per work hour to $65 per work hour. The cost impact information, below, reflects this increase in the specified hourly labor rate.

Cost Impact

There are approximately 848 airplanes of the affected design in the worldwide fleet. The FAA estimates that 357 airplanes of U.S. registry would be affected by this proposed AD, that it would take approximately 14 work hours per airplane to accomplish the proposed inspection, and that the average labor rate is $65 per work hour. Based on these figures, the cost impact of the proposed AD on U.S. operators is estimated to be $324,870, or $910 per airplane, per inspection cycle.

The cost impact figures discussed above are 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 proposed AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

The regulations proposed herein would not have a substantial direct effect 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, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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 2003–NM–49–AD.

Applicability: Model 767–200, –300, –300F series airplanes, as listed in Boeing Alert Service Bulletin 767–53A0087, dated October 21, 1999; certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To detect and correct fatigue cracks in the aft pressure bulkhead web, which could result in uncontrolled rapid decompression, accomplish the following:

Initial and Repetitive Inspections

(a) Do high frequency eddy current inspections of the aft pressure bulkhead web, per the Accomplishment Instructions of Boeing Alert Service Bulletin 767–53A0087, dated October 21, 1999; at the later of the applicable ''Threshold'' and ''Grace Period'' times specified in Table 1 of this AD. Table 1 as follows:

TABLE 1.—COMPLIANCE TIMES FOR INSPECTION

For	Compliance times	
	Threshold	Grace period
(1) Group 1 airplanes as identified in the service bulletin.	Prior to the accumulation of 37,500 total flight cycles.	Within 18 months or within 3,000 flights after the effective date of this AD, whichever comes first.
(2) Group 2 and 3 airplanes as identified in the service bulletin.	Prior to the accumulation of 50,000 total flight cycles.	Within 18 months or within 3,000 flights after the effective date of this AD, whichever comes first.
(3) Group 4 airplanes as identified in the service bulletin.	Prior to the accumulation of 40,000 total flight cycles.	Within 18 months or within 3,000 flights after the effective date of this AD, whichever comes first.

(b) If no crack is found during any inspection required by paragraph (a), repeat the high frequency eddy current inspections at intervals specified in paragraphs (b)(1) or (b)(2) of this AD, as applicable:

(1) For Group 1 and 2 airplanes, at intervals not to exceed 6,000 flight cycles, per the Accomplishment Instructions of Boeing Alert Service Bulletin 767–53A0087, dated October 21, 1999.

(2) For Group 3 and 4 airplanes, at intervals not to exceed 12,000 flight cycles, per the Accomplishment Instructions of Boeing Alert Service Bulletin 767–53A0087, dated October 21, 1999.

Corrective Actions

(c) If any crack is found during any inspection required by paragraph (a) or (b) of this AD and Boeing Alert Service Bulletin 767–53A0087, dated October 21, 1999, specifies to contact Boeing for repair: Before further flight, repair per a method approved by the Manager, Seattle Aircraft Certification Office (ACO), FAA; or per data meeting the type certification basis of the airplane approved by a Boeing Company Designated Engineering Representative who has been authorized by the Manager, Seattle ACO, to make such findings. For a repair method to be approved, the approval must specifically reference this AD.

Previously Installed Repairs

(d) If previously installed repairs are installed in the inspection area, and Boeing Alert Service Bulletin 767–53A0087, dated October 21, 1999, specifies to contact Boeing for inspection details, an alternative method of compliance must be approved as required by sections 39.15, 39.17, and 39.19 of the Code of Federal Regulations (14 CFR 39.15, 39.17, 39.19).

Alternative Methods of Compliance

(e) In accordance with 14 CFR 39.19, the Manager, Seattle Aircraft Certification Office, FAA, is authorized to approve alternative methods of compliance for this AD.

Issued in Renton, Washington, on September 29, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–25230 Filed 10–3–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 356

[Docket No. 81N–033P]

Oral Health Care Drug Products for Over-the-Counter Human Use; Antigingivitis/Antiplaque Drug Products; Establishment of a Monograph; Extension of Comment Period; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Advance notice of proposed rulemaking; extension of comment period; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a document that appeared in the **Federal Register** of August 25, 2003 (68 FR 50991). The document announced that FDA extended to November 25, 2003, the comment period for an advance notice of proposed rulemaking (ANPR) for over-the-counter antigingivitis/antiplaque drug products. The ANPR was published in the **Federal Register** of May 29, 2003 (68 FR 32232). The document published with an inadvertent error. This document corrects that error.

DATES: Submit written or electronic comments by November 25, 2003. Submit reply comments by February 23, 2004.

FOR FURTHER INFORMATION CONTACT: Joyce Strong, Office of Policy and Planning (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7010.

SUPPLEMENTARY INFORMATION: In FR Doc. 03–21669, appearing on page 50992 in the **Federal Register** of August 25, 2003, the following correction is made:

1. On page 50992, in the second column, under **IV. Comments**, in the sixth line, ''two'' is corrected to read ''three''.

Dated: September 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–25044 Filed 10–3–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF DEFENSE

Department of the Army; Corps of Engineers

33 CFR Part 334

Department of the Air Force, Wisconsin Air National Guard Danger Zone Under Restricted Air Space R–6903, Lake Michigan, Sheboygan County, WI

AGENCY: United States Army Corps of Engineers, Department of Defense.

ACTION: Proposed rule and request for comments.

SUMMARY: The Corps of Engineers is proposing an amendment to its regulations to designate an existing military exercise area as a Danger Zone. The military exercise area is located off the Wisconsin shoreline in Lake Michigan from Manitowoc to Port Washington, as shown on National Oceanographic and Atmospheric Administration (NOAA) Chart 14901 (1999). The Danger Zone will only be activated by the Wisconsin Air National Guard (WiANG) during military exercises. The Air Guard will advise fishermen and mariners in the vicinity when a military exercise is scheduled and thus ensure their safety by alerting them of temporary, potentially hazardous conditions which may exist as a result of the military exercises. There will be no change in the use of the existing military exercise area which is currently shown on aeronautical charts as restricted air space. The area, however, needs to also be marked on navigation charts as a Danger Zone to conform with the restricted air space designation to better insure security and safety for the public.

DATES: Written comments must be submitted on or before November 5, 2003.

ADDRESSES: U.S. Army Corps of Engineers, ATTN: CECW–OR, 441 G Street, NW., Washington, DC 20314–1000.

FOR FURTHER INFORMATION CONTACT: Mr. Frank Torbett, Headquarters Regulatory Branch, Washington, DC at (202) 761–4618, or Mr. Howard J. Ecklund, Corps of Engineers, St. Paul District, Regulatory Branch, at (262) 547–4171.

SUPPLEMENTARY INFORMATION: Pursuant to its authorities in Section 7 of the Rivers and Harbors Act of 1917 (40 Stat. 266; 33 U.S.C. 1) and Chapter XIX, of the Army Appropriations Act of 1919 (40 Stat. 892; 33 U.S.C. 3), the Corps proposes to amend the restricted area regulations in 33 CFR part 334 by adding § 334.145 as a Danger Zone in Lake Michigan offshore from Manitowoc and Sheboygan Counties in Wisconsin, as shown on NOAA Chart 14901 (1999). This is a revision of a similar proposal published in the **Federal Register** on March 11, 2002. This revision is being published because the earlier proposal contained incomplete information and did not adequately explain the reason for the regulation change. As a result, various interested parties expressed concerns regarding the change and its impact on boats using the area. The area to be designated as a Danger Zone already exists as restricted air space R–6903 which is shown on current aeronautical charts. This amendment of the regulation will allow WiANG to request that the U. S. Coast Guard issue a Notice to Mariners when exercises are planned and thus better inform fishermen and mariners of military activities in this area. WiANG intends to continue to schedule this area for use in a similar manner as it has been used during the past 20 years. Historical activity includes, but is not limited to, inert air-to-air and air-to-surface delivery, defensive countermeasures training, and sonar buoy drops.

Procedural Requirements

a. Review Under Executive Order 12866

This proposed rule is issued with respect to a military function of the