

airplanes. Because the heat release and smoke testing requirements of § 25.853 are part of the type certification basis for the Model CL-600-2C10, -2D15 and -2D24 airplanes, these special conditions are applicable to the Model CL-600-2C10, -2D15 and -2D24 airplanes. Should Bombardier apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Seats do not have to meet these special conditions when installed in compartments that are not otherwise required to meet the test requirements of CFR part 25, Appendix F, parts IV and V, for example, airplanes that do not have § 25.853, Amendment 25-61 or later, in their certification basis and those airplanes that do not need to comply with the requirements of 14 CFR 121.312.

Conclusion

This action affects only certain novel or unusual design features on Bombardier Inc. Model CL-600-2B19, -2C10, -2D15 and -2D24 series airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, the FAA has determined that prior public notice and comment are unnecessary and good cause exists for adopting these special conditions upon issuance. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

Authority Citation

■ The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Bombardier Inc. Model CL-600-2B19, -2C10, -2D15 and -2D24 series airplanes.

1. Except as provided in paragraph 3 of these special conditions, compliance with heat release and smoke emission testing requirements per 14 CFR part 25 and Appendix F, parts IV and V, is required for seats that incorporate non-traditional, large non-metallic panels that may either be a single component or multiple components in a concentrated area in their design.

2. The applicant may designate up to and including 1.5 square feet of non-traditional, non-metallic panel material per seat place that does not have to comply with special condition Number 1, above. A triple seat assembly may have a total of 4.5 square feet excluded on any portion of the assembly (e.g., outboard seat place 1 square foot, middle 1 square foot, and inboard 2.5 square feet).

3. Seats do not have to meet the test requirements of 14 CFR part 25 and Appendix F, parts IV and V, when installed in compartments that are not otherwise required to meet these requirements. Examples include:

a. Airplanes with passenger capacities of 19 or less,

b. Airplanes that do not have § 25.853, Amendment 25-61 or later, in their certification basis and do not need to comply with the requirements of 14 CFR 121.312, and

c. Airplanes exempted from § 25.853, Amendment 25-61 or later.

4. Only airplanes associated with new seat certification programs approved after the effective date of these special conditions will be affected by the requirements in these special conditions. Previously certificated interiors on the existing airplane fleet and follow-on deliveries of airplanes with previously certificated interiors are not affected.

Issued in Renton, Washington, on May 18, 2009.

Ali Bahrami,

*Manager, Transport Airplane Directorate
Aircraft Certification Service.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA-2009-N-0665]

New Animal Drugs; Change of Sponsor; Fomepizole

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for a new animal drug application (NADA) for fomepizole solution for injection from Jazz Pharmaceuticals, Inc., to Paladin Labs (USA), Inc.

DATES: This rule is effective June 5, 2009.

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8307, e-mail: david.newkirk@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Jazz Pharmaceuticals, Inc., 3180 Porter Dr., Palo Alto, CA 94304, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 141-075 for ANTIZOL-VET (fomepizole) to Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904. Accordingly, the agency is amending the regulations in 21 CFR 522.1004 to reflect the transfer of ownership.

Following these changes of sponsorship, Jazz Pharmaceuticals, Inc., is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for this sponsor.

In addition, Paladin Labs (USA), Inc., is not currently listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this sponsor.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1) remove the entry for “Jazz Pharmaceuticals, Inc.” and alphabetically add a new entry for “Paladin Labs, Inc.”; and in the table in paragraph (c)(2) remove the entry for “068727” and numerically add a new entry for “046129” to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* *
Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904	046129
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
046129	Paladin Labs (USA), Inc., 160 Greentree Dr., suite 101, Dover, DE 19904
* *	* * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.1004 [Amended]

■ 4. In paragraph (b) of § 522.1004, remove “068727” and add in its place “046129”.

Dated: June 1, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2009-0385]

RIN 1625-AA09

Drawbridge Operation Regulation; Sturgeon Bay Ship Canal, Sturgeon Bay, WI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard proposes to temporarily revise the operating regulations for the Maple-Oregon Bridge at Mile 4.17 over the Sturgeon Bay Ship Canal in Sturgeon Bay, WI. This action was requested by the Wisconsin Department of Transportation (Wisconsin DOT) to facilitate vehicular traffic in downtown Sturgeon Bay during the rehabilitation of the Michigan Street Bridge at Mile 4.30 over the Sturgeon Bay Ship Canal. This final rule is expected to reflect the need for bridge openings for the Maple-Oregon Bridge during the Michigan Street Bridge rehabilitation and still provide for the reasonable needs of navigation.

DATES: This temporary final rule is effective from 6 a.m. on June 1, 2009 to 6 p.m. on November 15, 2010.

ADDRESSES: Documents indicated in this preamble as being available in the docket, are part of docket USCG-2009-0385 and are available by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG-2009-0385 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Blair Stanifer, Bridge Management Specialist, Coast Guard Ninth District; telephone 216-902-6086, e-mail: William.B.Stanifer@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are “impracticable, unnecessary, or contrary to the public interest.” Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the request to revise the operating schedule for this temporary final rule included extensive preliminary coordination with known affected marine entities, Wisconsin DOT, and the City of Sturgeon Bay, WI, and resulted in a temporary drawbridge schedule that would not significantly impact either vehicular traffic or known navigation.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective in less than 30 days after publication in the **Federal Register**. As noted above the Coast Guard has conducted extensive preliminary coordination with known affected marine entities, the Wisconsin DOT and the City of Sturgeon Bay, WI and determined that the impact on navigation will be minimal as the bridge will continue to open on demand for commercial vessels and public vessels and on the hour for recreational vessels from March 15 through December 31, and from January 1 through March 14, for any vessel provided at least notice is given at least 12 hours advance. This is the same schedule under which the Michigan Street Bridge currently operates under 33 CFR 117.1101. During renovation the Michigan Street Bridge will remain in the open position and vehicular traffic is expected to use the Maple-Oregon Bridge as an alternate route. Repeated openings would likely cause significant congestion on the vehicular approaches to the bridge. Hourly openings will allow vehicular traffic to plan accordingly and will minimally affect recreational vessels.

Background and Purpose

Wisconsin DOT requested a temporary change to the operating schedule of the Maple-Oregon Bridge at Mile 4.17 over the Sturgeon Bay Ship Canal to facilitate the rehabilitation of the Michigan Street Bridge. The Maple-Oregon Double-Leaf Bascule Bridge navigation span provides for a design clearance of 25 feet above Mean Low