

seats that incorporated non-traditional, large, non-metallic panels in lieu of the traditional metal covered by fabric. The Seattle Aircraft Certification Office and Transport Standards Staff reviewed this design and determined that it represented the kind and quantity of material that should be required to pass the heat release and smoke emissions requirements. We have determined that special conditions would be promulgated to apply the standards defined in § 25.853(d) to seats with large non-metallic panels in their design.

### Applicability

Although smoke testing requirements of § 25.853 per Appendix F, parts IV and V, are not part of the part 25 certification basis for the Bombardier DHC-8-100 and -301 series airplanes, these special conditions are applicable if the airplanes were manufactured after 8/19/1990 and are in 14 CFR part 121 service. Part 121 requires applicable interior panels to comply with § 25.853 and Appendix F, parts IV and V, regardless of the certification basis. It is not our intent to require seats with large non-metallic panels to meet § 25.853 and Appendix F, parts IV and V, if they are installed in cabins of airplanes that are not required to meet these standards.

Because the heat release and smoke testing requirements of § 25.853 are part of the type certification basis for the DHC-8-200 series, models 311 and 315 of the -300 series, and DHC-8-400 series airplanes, these special conditions are applicable to the DHC-8-200 series, models 311 and 315 of the -300 series, and DHC-8-400 series airplanes for all types of operations. 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 14 CFR part 25 and 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 do not need to comply with the requirements of 14 CFR 121.312, do not have to comply with these special conditions.

### Conclusion

This action affects only certain novel or unusual design features on Bombardier Inc. DHC-8-100, -200, and -400 series airplanes and in models -311 and -315 in -300 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. DHC-8-100 series, DHC-8-200 series, models 311 and 315 of the -300 series, and DHC-8-400 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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**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 25

[Docket No. NM406; Special Conditions No. 25-384-SC]

#### Special Conditions: Bombardier Inc. Model CL-600-2B19, -2C10, -2D15 and -2D24 Airplanes; Passenger Seats with Non-Traditional, Large, Non-Metallic Panels

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions; request for comments.

**SUMMARY:** These special conditions are issued for Bombardier Inc. model CL-600-2B19, -2C10, -2D15 and -2D24 airplanes. These airplanes will have a novel or unusual design feature(s) associated with seats that include non-traditional, large, non-metallic panels that would affect survivability during a post-crash fire event. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

**DATES:** The effective date of these special conditions is May 18, 2009.

We must receive your comments by July 20, 2009.

**ADDRESSES:** You must mail two copies of your comments to: Federal Aviation Administration, Transport Airplane Directorate, Attn: Rules Docket (ANM-

113), Docket No. NM406, 1601 Lind Avenue, SW., Renton, Washington 98057-3356. You may deliver two copies to the Transport Airplane Directorate at the above address. You must mark your comments: Docket No. NM406 You can inspect comments in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4 p.m.

**FOR FURTHER INFORMATION CONTACT:** Alan Sinclair, FAA, Airframe/Cabin Safety Branch, ANM-115, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue, SW., Renton, Washington 98057-3356; telephone (425) 227-2195; facsimile (425) 227-1232; electronic mail [alan.sinclair@faa.gov](mailto:alan.sinclair@faa.gov).

**SUPPLEMENTARY INFORMATION:** The FAA has determined that notice and opportunity for prior public comment hereon are impracticable because these procedures would significantly delay issuance of the design approval and thus delivery of the affected aircraft. In addition, the substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon issuance.

#### Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data. We ask that you send us two copies of written comments.

We will file in the docket all comments we receive, as well as a report summarizing each substantive public contact with FAA personnel about these special conditions. You can inspect the docket before and after the comment closing date. If you wish to review the docket in person, go to the address in the **ADDRESSES** section of this preamble between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

We will consider all comments we receive by the closing date for comments. We will consider comments filed late if it is possible to do so without incurring expense or delay. We may change these special conditions based on the comments we receive.

If you want us to let you know we received your comments on these special conditions, send us a pre-addressed, stamped postcard on which

the docket number appears. We will stamp the date on the postcard and mail it back to you.

#### Background

On July 1, 2008, Bombardier Inc. 400 Cote Vertu West, Dorval, Quebec, Canada H4S 1Y9 applied for a design change to Type Certificate No. A21EA for installation of seats that include non-traditional, large, non-metallic panels in the following Bombardier Inc. airplanes: Model CL-600-2B19, Model CL-600-2C10, Model CL-600-2D15 and Model CL-600-2D24. These airplanes, which are currently approved under Type Certificate No. A21EA, are swept-wing, T-tail, twin-engine, fuselage mounted turbofan-powered, single aisle, medium sized transport category airplanes.

The applicable regulations to airplanes currently approved under Type Certificate No. A21EA do not require seats to meet the more stringent flammability standards required of large, non-metallic panels in the cabin interior. At the time the applicable rules were written, seats were designed with a metal frame covered by fabric, not with large, non-metallic panels. Seats also met the then recently adopted standards for flammability of seat cushions. With the seat design being mostly fabric and metal, the contribution to a fire in the cabin had been minimized and was not considered a threat. For these reasons, seats did not need to be tested to heat release and smoke emission requirements.

Seat designs have now evolved to occasionally include non-traditional, large, non-metallic panels. Taken in total, the surface area of these panels is on the same order as the sidewall and overhead stowage bin interior panels. To provide the level of passenger protection intended by the airworthiness standards, these non-traditional, large, non-metallic panels in the cabin must meet the standards of Title 14 Code of Federal Regulations (14 CFR), part 25, Appendix F, parts IV and V, heat release and smoke emission requirements.

#### Type Certification Basis

Under the provisions of § 21.101 Bombardier must show that the following model airplanes, CL-600-2B19, CL-600-2C10, CL-600-2D15 and CL-600-2D24, as changed, continue to meet the applicable provisions of the regulations incorporated by reference in Type Certificate No. A21AE, or the applicable regulations in effect on the date of application for the change. The regulations incorporated by reference in the type certificate are commonly

referred to as the "original type certification basis."

The regulations incorporated by reference in Type Certificate No. A21AE are for the following models:

- CL-600-2B19, regulation 14 CFR part 25, effective February 1, 1965, including Amendments 25-1 through 25-62;
- CL-600-2C10, regulation 14 CFR part 25, effective February 1, 1965, including Amendments 25-1 through 25-86;
- CL-600-2D15, regulation 14 CFR part 25, effective February 1, 1965, including Amendments 25-1 through 25-86, Amendments 25-88 through Amendments 25-90 and Amendments 25-92 through Amendments 25-98.
- CL-600-2D24, regulation 14 CFR part 25, effective February 1, 1965, including Amendments 25-1 through 25-86, Amendments 25-88 through Amendments 25-90 and Amendments 25-92 through Amendments 25-98.

In addition, the certification basis includes other regulations and special conditions that are not pertinent to these special conditions.

If the Administrator finds that the applicable airworthiness regulations (i.e., 14 CFR part 25) do not contain adequate or appropriate safety standards for the Model CL-600 series airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

In addition to the applicable airworthiness regulations and special conditions, the Model CL-600 series airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36.

The FAA issues special conditions, as defined in § 11.19, under § 11.38 and they become part of the type certification basis under § 21.101.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same novel or unusual design feature, or should any other model already included on the same type certificate be modified to incorporate the same novel or unusual design feature, the special conditions would also apply to the other model.

#### Novel or Unusual Design Features

The Model CL-600 series airplanes will incorporate the following novel or unusual design features: These models offer interior arrangements that include passenger seats that incorporate non-

traditional, large, non-metallic panels in lieu of the traditional metal frame covered by fabric. The flammability properties of these panels have been shown to significantly affect the survivability of occupants of the cabin in the case of fire. These seats are considered a novel design for transport category airplanes that include Amendment 25–61 and Amendment 25–66 in the certification basis, and were not considered when those airworthiness standards were established.

The existing regulations do not provide adequate or appropriate safety standards for seat designs that incorporate non-traditional, large, non-metallic panels. In order to provide a level of safety that is equivalent to that provided by the balance of the cabin, additional airworthiness standards, in the form of special conditions, are necessary. These special conditions supplement § 25.853. The requirements contained in these special conditions consist of applying the identical test conditions required of all other large panels in the cabin, to seats with non-traditional, large, non-metallic panels.

#### Definition of “Non-Traditional, Large, Non-Metallic Panel”

A non-traditional, large, non-metallic panel, in this case, is defined as a panel with exposed-surface areas greater than 1.5 square feet installed per seat place. The panel may consist of either a single component or multiple components in a concentrated area. Examples of parts of the seat where these non-traditional panels are installed include, but are not limited to: seat backs, bottoms and leg/foot rests, kick panels, back shells, credenzas and associated furniture. Examples of traditional exempted parts of the seat include: arm caps, armrest close-outs such as end bays and armrest-styled center consoles, food trays, video monitors and shrouds.

#### Clarification of “Exposed”

“Exposed” is considered to include those panels directly exposed to the passenger cabin in the traditional sense, plus those panels enveloped such as by a dress cover. Traditional fabrics or leathers currently used on seats are excluded from these special conditions. These materials must still comply with § 25.853(a) and § 25.853(c) if used as a covering for a seat cushion, or § 25.853(a) if installed elsewhere on the seat. Non-traditional, large, non-metallic panels covered with traditional fabrics or leathers will be tested without their coverings or covering attachments.

#### Discussion

In the early 1980s the FAA conducted extensive research on the effects of post-crash flammability in the passenger cabin. As a result of this research and service experience, we adopted new standards for interior surfaces associated with large surface area parts. Specifically, the rules require measurement of heat release and smoke emission (part 25, Appendix F, parts IV and V) for the affected parts. Heat release has been shown to have a direct correlation with post-crash fire survival time. Materials that comply with the standards (*i.e.*, § 25.853 entitled “Compartment interiors” as amended by Amendment 25–61 and Amendment 25–66) extend survival time by approximately 2 minutes, over materials that do not comply.

At the time these standards were written, the potential application of the requirements of heat release and smoke emission to seats was explored. The seat frame itself was not a concern because it was primarily made of aluminum and there were only small amounts of non-metallic materials. It was determined that the overall effect on survivability was negligible, whether or not the food trays met the heat release and smoke requirements. The requirements, therefore, did not address seats. The preambles to both the Notice of Proposed Rule Making (NPRM), Notice No. 85–10 (50 FR 15038, April 16, 1985), and the Final Rule at Amendment 25–61 (51 FR 26206, July 21, 1986), specifically note that seats were excluded “because the recently-adopted standards for flammability of seat cushions will greatly inhibit involvement of the seats.”

Subsequently, the Final Rule at Amendment 25–83 (60 FR 6615, March 6, 1995) clarified the definition of minimum panel size: “It is not possible to cite a specific size that will apply in all installations; however, as a general rule, components with exposed-surface areas of one square foot or less may be considered small enough that they do not have to meet the new standards. Components with exposed-surface areas greater than two square feet may be considered large enough that they do have to meet the new standards. Those with exposed-surface areas greater than one square foot, but less than two square feet, must be considered in conjunction with the areas of the cabin in which they are installed before a determination could be made.”

In the late 1990s, the FAA issued Policy Memorandum 97–112–39, “Guidance for Flammability Testing of Seat/Console Installations,” October 17,

1997 (<http://rgl.faa.gov>). That memo was issued when it became clear that seat designs were evolving to include large non-metallic panels with surface areas that would impact survivability during a cabin fire event, comparable to partitions or galleys. The memo noted that large surface area panels must comply with heat release and smoke emission requirements, even if they were attached to a seat. If the FAA had not issued such policy, seat designs could have been viewed as a loophole to the airworthiness standards that would result in an unacceptable decrease in survivability during a cabin fire event.

In October of 2004, an issue was raised regarding the appropriate flammability standards for passenger seats that incorporated non-traditional, large, non-metallic panels in lieu of the traditional metal covered by fabric. The Seattle Aircraft Certification Office and Transport Standards Staff reviewed this design and determined that it represented the kind and quantity of material that should be required to pass the heat release and smoke emissions requirements. We have determined that special conditions would be promulgated to apply the standards defined in § 25.853(d) to seats with large non-metallic panels in their design.

#### Applicability

These special conditions are applicable to Bombardier model CL–600–2B19 airplanes. Because the heat release testing requirements of § 25.853 per Appendix F, part IV are part of the type certification basis for model CL–600–2B19 airplanes, these special conditions are applicable to model CL–600–2B19 airplanes. Although smoke testing requirements of § 25.853 per Appendix F, part V, are not part of the part 25 certification basis for Bombardier Model CL–600–2B19 airplanes, these special conditions are applicable if the airplanes are in 14 CFR part 121 service. Part 121 requires applicable interior panels to comply with § 25.853 and Appendix F, part V, regardless of the certification basis. It is not our intent to require seats with large non-metallic panels to meet § 25.853 and Appendix F, parts V, if they are installed in cabins of airplanes that otherwise are not required to meet these standards. 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.

These special conditions are applicable to Bombardier Inc. Model CL–600–2C10, –2D15 and –2D24

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](mailto: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