

### Inspection and Corrective Action

(a) For airplanes equipped with windshield units that have accumulated fewer than 2,500 total flight cycles as of the effective date of this AD: Within 6 months after 3 the effective date of this AD, accomplish a one-time general visual inspection of the aft edges of the left and right main windshields to determine whether a placard having part number (P/N) CSB-NP-139321-002-1 is installed, per the Accomplishment Instructions of Bombardier Service Bulletin 601R-56-004, dated August 16, 2001.

(1) If a placard having P/N CSB-NP-139321-002-1 is installed, no further action is required by this AD.

(2) If a placard having a P/N other than CSB-NP-139321-002-1 is installed, before further flight, accomplish the corrective actions (including modifying the main windshields by replacing nine of the hi-lok pins installed in the lower forward corner of the windshields with hi-lok pins having a reduced diameter shank, installing a placard having the correct P/N on the inner retainer near the part identification placard located along the aft edge of the window, and replacing any torn or deformed gasket), per the Accomplishment Instructions of the service bulletin.

**Note 2:** For the purposes of this AD, a general visual inspection is defined as: "A visual examination of an interior or exterior area, installation, or assembly to detect obvious damage, failure, or irregularity. This level of inspection is made from within touching distance unless otherwise specified. A mirror may be necessary to enhance visual access to all exposed surfaces in the inspection area. This level of inspection is made under normally available lighting conditions such as daylight, hangar lighting, flashlight, or droplight and may require removal or opening of access panels or doors. Stands, ladders, or platforms may be required to gain proximity to the area being checked."

**Note 3:** Bombardier Service Bulletin 601R-56-004, dated August 16, 2001, references PPG Industries, Inc., Service Bulletin CSB-NP-139321-002, Revision C, dated July 31, 2001, as an additional source of service information for accomplishment of the modification of the left and right main windshields.

### Alternative Methods of Compliance

(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, New York Aircraft Certification Office (ACO), FAA. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, New York ACO.

**Note 4:** Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York ACO.

### Special Flight Permit

(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.

### Incorporation by Reference

(d) The actions shall be done in accordance with Bombardier Service Bulletin 601R-56-004, dated August 16, 2001. The incorporation by reference of that document was approved previously by the Director of the Federal Register as of August 14, 2003 (68 FR 41059, July 10, 2003). Copies may be obtained from Bombardier, Inc., Canadair, Aerospace Group, PO Box 6087, Station Centre-ville, Montreal, Quebec H3C 3G9, Canada. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the FAA, New York Aircraft Certification Office, 10 Fifth Street, Third Floor, Valley Stream, New York; or at the *Office of the Federal Register*, 800 North Capitol Street, NW., suite 700, Washington, DC.

**Note 5:** The subject of this AD is addressed in Canadian airworthiness directive CF-2001-35R1, dated September 27, 2001.

### Effective Date

(e) The effective date of this amendment remains August 11, 2003.

Issued in Renton, Washington, on August 11, 2003.

**Neil D. Schalekamp,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 522

#### Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for an additional dose of trenbolone acetate and estradiol implant for use in feedlot steers for increased rate of weight gain and improved feed efficiency.

**DATES:** This rule is effective August 15, 2003.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl.,

Rockville, MD 20855, 301-827-8549, e-mail: [lluther@cvm.fda.gov](mailto:lluther@cvm.fda.gov).

**SUPPLEMENTARY INFORMATION:** Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200-346. The supplemental ANADA provides for the use of COMPONENT TE-200 (trenbolone acetate and estradiol), a subcutaneous implant containing 200 milligrams (mg) trenbolone acetate and 20 mg estradiol in steers fed in confinement for slaughter for increased rate of weight gain and improved feed efficiency. Ivy Laboratories' COMPONENT TE-200 is approved as a generic copy of Intervet, Inc.'s REVALOR-200, approved under NADA 140-992. The application is approved as of April 21, 2003, and the regulations are amended in 21 CFR 522.2477 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 in 21 CFR Part 522

Animal drugs.

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

#### PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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