Compliance: Required as indicated, unless accomplished previously.

To prevent temporary loss of braking action due to the freezing of moisture on the input plunger of the brake control valve during steep descent, accomplish the following:

Requirements of AD 93–21–04

Lubrications

(a) Within 3 days after February 4, 1994 (the effective date of AD 93–21–04, amendment 39–8801), and thereafter at intervals not to exceed 3 days, lubricate, with grease, the sliding shaft of the input plunger of the brake control valve assembly, per Canadair Regional Jet Alert Service Bulletin S.B.A601R–32–016, dated October 14, 1993, until modification of the brake control valve, as required by paragraph (b) of this AD, is accomplished.

New Actions Required by This AD

Modification

(b) Within 12 months after the effective date of this AD: Modify the brake control valve assembly by accomplishing all the actions (including the application of grease to the grease fittings) specified in Bombardier Service Bulletin 601R–32–017, dated November 9, 1993, per the service bulletin. Such modification terminates the repetitive lubrications of the sliding shaft of the input plunger of the brake control valve assembly required by paragraph (a) of this AD.

Repetitive Lubrications

(c) Within 1,500 flight hours after doing the modification required by paragraph (b) of this AD, and thereafter at intervals not to exceed 1,500 flight hours, lubricate with grease the brake control valve per paragraph 2.B.(18) of the Accomplishment Instructions of Bombardier Service Bulletin 601R–32–017, dated November 9, 1993.

Alternative Methods of Compliance

(d)(1) In accordance with 14 CFR 39.19, the Manager, New York Aircraft Certification Office (ACO), FAA, is authorized to approve alternative methods of compliance for this AD.

(2) Alternative methods of compliance, approved previously in accordance with AD 93–21–04, amendment 39–8801, are approved as alternative methods of compliance with paragraph (a) of this AD.

Incorporation by Reference

(e) The actions shall be done in accordance with Canadair Regional Jet Alert Service Bulletin S.B.A601R–32–016, dated October 14, 1993; and Bombardier Service Bulletin 601R–32–017, dated November 9, 1993; as applicable.

(1) The incorporation by reference of Bombardier Service Bulletin 601R–32–017, dated November 9, 1993, is approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51.

(2) The incorporation by reference of Canadair Regional Jet Alert Service Bulletin S.B.A601R–32–016, dated October 14, 1993, was approved previously by the Director of the Federal Register as of February 4, 1994 (59 FR 2952, January 20, 1994).

(3) Copies of these service bulletins may be obtained from Bombardier, Inc., Canadair, Aerospace Group, P.O. 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 (ACO), 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 1: The subject of this AD is addressed in Canadian airworthiness directive CF–93–26R2, dated January 18, 1994.

Effective Date

(f) This amendment becomes effective on July 11, 2003.

Issued in Renton, Washington, on May 28, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–13975 Filed 6–5–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Acepromazine Maleate Injection

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for the use of acepromazine maleate injectable solution in dogs, cats, and horses as a tranquilizer.

DATES: This rule is effective June 6, 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.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed ANADA 200–319 that provides for use of Acepromazine Maleate (acepromazine maleate) Injection as a tranquilizer. Phoenix Scientific's Acepromazine Maleate Injection is approved as a generic copy of Fort Dodge Animal Health's PROMACE Injectable approved under NADA 015–030. The ANADA is approved as of March 25, 2003, and the regulations are amended in 21 CFR 522.23 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 Subject in 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 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.

§ 522.23 [Amended]

■ 2. Section 522.23 *Acepromazine maleate injection* is amended in paragraph (b), introductory text, by removing ''No. 000856'' and by adding in its place ''Nos. 000856 and 059130''.

Dated: May 27, 2003.

Steven F. Sundlof,

Center for Veterinary Medicine.

[FR Doc. 03–14348 Filed 6–5–03; 8:45 am]

BILLING CODE 4160–01–S