DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Furosemide

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 First Priority, Inc. The ANADA provides for oral use of furosemide syrup for the treatment of edema in dogs.

DATES: This rule is effective December 27, 2005.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1069, e-mail: *linda.wilmot@fda.gov*.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200–373 for Furosemide Syrup 1% for oral use in dogs for the treatment of edema. First Priority, Inc.'s, Furosemide Syrup 1% is approved as a generic copy of Intervet, Inc.'s, LASIX (furosemide) Syrup 1%, approved under NADA 102–380. ANADA 200–373 is approved as of November 18, 2005, and the regulations are amended in 21 CFR 520.1010 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 Division of Dockets Management (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.

FDA 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 congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1010 [Amended]

■ 2. Section 520.1010 is amended in paragraph (b)(3) by removing ''No. 059130'' and by adding in its place ''Nos. 058829 and 059130''.

Dated: December 12, 2005.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 05–24440 Filed 12–23–05; 8:45 am]

BILLING CODE 4160–01–S

FEDERAL MEDIATION AND CONCILIATION SERVICE

29 CFR Part 1404

Proposed Changes to Arbitration Policies, Functions, and Procedures

AGENCY: Federal Mediation and Conciliation Service.

ACTION: Final rule.

SUMMARY: The Federal Mediation and Conciliation Service (FMCS) is amending 29 CFR part 1404, Arbitration Services. The amendments are intended to set forth the criteria and procedures for listing on the arbitration roster, removal from the arbitration roster, and expedited arbitration processing. Other changes include how parties may request arbitration lists or panels and fees associated with the arbitrators. The purpose of these changes is to facilitate the management and administration of the arbitration roster.

DATES: Effective December 27, 2005.

FOR FURTHER INFORMATION CONTACT: Maria A. Fried, General Counsel and Federal Register Liaison, FMCS, 2100 K Street, NW., Washington, DC 20427. Telephone (202) 606–5444, FAX (202) 606–5345.

SUPPLEMENTARY INFORMATION: FMCS amends 29 CFR part 1404. The original regulation was issued in June 1997. The amendments set forth procedures for the listing and removal of arbitrators from the arbitration roster maintained by FMCS, procedures for requesting arbitration lists and panels, and the nomination of arbitrators.

Pursuant to 29 U.S.C. 171(b) and 29 CFR part 1404, FMCS offers panels of arbitrators for selection by labor and management to resolve grievances and disagreements arising under their collective bargaining agreements and to deal with the fact finding and interest arbitration issues as well.

Title II of the Labor Management Relations Act of 1947 (Pub. L. 90–101) as amended in 1959 (Pub. L. 86–257) and 1974 (Pub. L. 93–360), states that it is the labor policy of the United States that ''the settlement of issues between employers and employees through collective bargaining may be advanced by making available full and adequate governmental facilities for conciliation, mediation, and voluntary arbitration to encourage employers and representatives of their employees to reach and maintain agreements concerning rates of pay, hours, and working conditions, and to make all reasonable efforts to settle their differences by mutual agreement reached through conferences and collective bargaining or by such methods as may be provided for in any applicable agreement for the settlement of disputes.'' Under its regulations at 29 CFR part 1404, FMCS has established policies and procedures for its arbitration function dealing with all arbitrators listed on the FMCS Roster of Arbitrators, all applicants for listing on the Roster, and all persons or parties seeking to obtain from FMCS either names or panels of names of arbitrators listed on the Roster in connection with disputes which are to be submitted to arbitration or fact-finding. FMCS strives to maintain the highest quality of dispute resolution experts on its roster. FMCS now amends 29 CFR part 1404 to update its procedures and facilitate the maintenance and administration of its arbitration roster.

Regulatory Flexibility Act

The Director, in accordance with the Regulatory Flexibility Act (5 U.S.C. 606(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The fees assessed by FMCS for requests for panels are nominal and should not cause any significant economic effect on small entities which may request arbitration panels.