

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable 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 Phoenix Scientific, Inc. The ANADA provides for use of furosemide solution by intramuscular or intravenous injection in horses, cattle, dogs, and cats.

DATES: This rule is effective April 15, 2002.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th Street Ter., P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-293 that provides for veterinary prescription use of Furosemide Injection 5% by intramuscular or intravenous administration in horses, cattle, dogs, and cats. Phoenix's Furosemide Injection 5% is approved as a generic copy of Intervet, Inc.'s LASIX Injectable Solution, approved under NADA 34-478. ANADA 200-293 is approved as of December 18, 2001, and the regulations are amended in 21 CFR 522.1010 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 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 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.

§ 522.1010 [Amended]

2. Section 522.1010 *Furosemide* is amended in paragraph (b)(3) by removing "No. 057926" and by adding in its place "Nos. 057926 and 059130".

Dated: March 1, 2002.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 02-9014 Filed 4-12-02; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 252

[T.D. ATF-477]

RIN 1512-AC44

Delegation of Authority

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Treasury decision, final rule.

SUMMARY: This final rule places ATF authorities concerning the exportation of liquors with the "appropriate ATF officer" and requires that persons file documents required with the "appropriate ATF officer" or in accordance with the instructions for the ATF form. Also, this final rule removes the definitions of, and references to, specific officers subordinate to the Director and the word "region" in reference to ATF. Concurrently with this Treasury Decision, ATF Order 1130.27 is being issued and will be available to the public as specified in

this rule. Through this order, the Director has delegated all of the authorities concerning the exportation of liquors to the appropriate ATF officers and specified the ATF officers with whom applications, notices, and other reports, which are not ATF forms, are filed.

EFFECTIVE DATE: This rule is effective April 15, 2002.

FOR FURTHER INFORMATION CONTACT:

Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Room 5003, Washington, DC 20226 (telephone 202-927-8210 or e-mail to alctob@atfhq.atf.treas.gov).

SUPPLEMENTARY INFORMATION:

Background

Pursuant to Treasury Order 120-01 (formerly 221), dated June 6, 1972, the Secretary of the Treasury delegated to the Director of the Bureau of Alcohol, Tobacco and Firearms (ATF), the authority to enforce, among other laws, the provisions of chapter 51 of the Internal Revenue Code of 1986 (IRC) and the Federal Alcohol Administration (FAA) Act. The Director has subsequently delegated certain of these authorities to appropriate subordinate officers by way of various means, including by regulation, ATF delegation orders, regional directives, or similar delegation documents. As a result, to ascertain which particular officer is authorized to perform a particular function under chapter 51 of the IRC or the FAA Act, each of these various delegation instruments must be consulted. Similarly, each time a delegation of authority is revoked or redelegated, each of the delegation documents must be reviewed and amended as necessary.

ATF has determined that this multiplicity of delegation instruments complicates and hinders the task of determining which ATF officer is authorized to perform a particular function. ATF also believes these multiple delegation instruments exacerbate the administrative burden associated with maintaining up-to-date delegations, resulting in an undue delay in reflecting current authorities.

Accordingly, this final rule rescinds all authorities of the Director in part 252 that were previously delegated and places those authorities with the "appropriate ATF officer." Most of the authorities of the Director that were not previously delegated are also placed with the "appropriate ATF officer." Along with this final rule, ATF is publishing ATF Order 1130.27, Delegation of the Director's Authorities