Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.1222a [Amended]

2. Section 522.1222a *Ketamine hydrochloride injection* is amended in paragraph (c) by removing the number ''057319'' and adding in its place ''059130''.

Dated: March 31, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–10914 Filed 4–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Flunixin Meglumine

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 Agri Laboratories, Ltd. The ANADA provides for use of flunixin meglumine injection in horses for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic.

EFFECTIVE DATE: April 28, 1997.

FOR FURTHER INFORMATION CONTACT: Sandra K. Woods, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1617.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed ANADA 200–061, which provides for intravenous or intramuscular use of flunixin meglumine injection in horses for alleviation of inflammation and pain associated with musculoskeletal disorders and visceral pain associated with colic. Flunixin meglumine is for veterinary prescription use only.

Approval of ANADA 200–061 for Agri Laboratories' flunixin meglumine injection is as a generic copy of Schering-Plough's Banamine® (flunixin meglumine) Solution (injection) NADA 101–479. The ANADA is approved as of September 11, 1996, and the regulations are amended in 21 CFR 522.970(b) to reflect the approval. The basis for 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The firm has submitted an abbreviated environmental assessment. In response, FDA has prepared a finding of no significant impact. The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 522.970 is amended by revising paragraph (b) to read as follows:

§ 522.970 Flunixin meglumine solution.

* * * * *

(b) *Sponsors.* See Nos. 000061, 000856, 057561, and 059130 in § 510.600(c) of this chapter.

* * * * *

Dated: April 8, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–10910 Filed 4–25–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

Certain Other Dosage Form New Animal Drugs; Gentamicin Sulfate

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 Med-Pharmex, Inc. The ANADA provides for the use of gentamicin sulfate solution in the dipping treatment of turkey hatching eggs as an aid in the reduction or elimination of certain organisms.

EFFECTIVE DATE: April 28, 1997.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767, has filed ANADA 200–191, which provides for use of Gentasol (gentamicin sulfate solution) in the dipping treatment of turkey hatching eggs as an aid in the reduction or elimination of the following organisms from turkey hatching eggs: *Arizona hinshawii* (paracolon), *Salmonella st. paul*, and *Mycoplasma meleagridis*.

The ANADA is approved as a generic copy of Schering Plough's NADA 92–523, Garasol® Solution (gentamicin sulfate veterinary). ANADA 200–191 is approved as of March 24, 1997, and the regulations are amended in 21 CFR 529.1044b to reflect the approval. The basis for 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore,