§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * * *	
American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160	063323
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
063323	American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160
* * * * * * *	

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.1081 [Amended]

4. Section 522.1081 *Chorionic gonadotropin for injection; chorionic gonadotropin suspension* is amended in paragraph (a)(2)(ii) by removing ''Nos. 000469 and 058639'' and adding in its place ''Nos. 058639 and 063323''.

Dated: August 27, 1998.

Margaret Ann Miller,

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

[FR Doc. 98–25909 Filed 9–28–98; 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; Ketamine Hydrochloride 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 Lloyd, Inc. The ANADA provides for veterinary prescription use of ketamine hydrochloride injection in cats for restraint or as an anesthetic and in subhuman primates for restraint.

EFFECTIVE DATE: September 29, 1998.

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.

SUPPLEMENTARY INFORMATION: Lloyd, Inc., 604 W. Thomas Ave., P.O. Box A, Shenandoah, IA 51601–0130, filed ANADA 200–055 that provides for veterinary prescription use of VetaKet™ ketamine hydrochloride injection, intramuscularly, in cats for restraint or as sole anesthetic agent for diagnostic or minor, brief surgical procedures that do not require skeletal muscle relaxation and in subhuman primates for restraint.

Lloyd, Inc.'s ANADA 200–055 ketamine hydrochloride injection is approved as a generic copy of Fort Dodge Animal Health's NADA 45–290 Vetalar® (ketamine hydrochloride injection). The ANADA is approved as of August 3, 1998, and the regulations are amended in 21 CFR 522.1222a(c) 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 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 La., 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.

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.

§ 522.1222a [Amended]

2. Section 522.1222a *Ketamine hydrochloride injection* is amended in paragraph (c) by removing ''and

059130'' and by adding in its place ''059130, and 061690.''

Dated: August 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–25910 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Narasin and Bacitracin Methylene Disalicylate with Roxarsone

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 new animal drug application (NADA) filed by Alpharma Inc. The supplemental NADA provides for using approved narasin, bacitracin methylene disalicylate (BMD), and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds.

EFFECTIVE DATE: September 29, 1998

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of supplemental NADA 140–852 which provides for combining approved Monteban® (45 grams per pound (g/lb) narasin), BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb bacitracin methylene disalicylate), and 3–Nitro® (45.4, 90, or 227 g/lb roxarsone) Type A medicated articles to make Type C medicated broiler chicken feeds. The Type C medicated broiler chicken feed containing 54 to 72 g/t narasin, 50 g/t bacitracin methylene disalicylate, and 22.7 to 45.4 g/t roxarsone is used for prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The Type C medicated broiler chicken feed containing 54 to 72 g/t narasin, 100 to 200 g/t bacitracin methylene disalicylate, and 22.7 to 45.4 g/t roxarsone is used for prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

The supplemental NADA is approved as of July 29, 1998, and the regulations are amended by adding 21 CFR 558.363(a)(6), (d)(1)(viii), and (d)(1)(ix) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make Type C medicated feed from a Category II drug. Under section 512(m) of the act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104–250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of Type A medicated articles to make Type C medicated feeds as provided in supplemental NADA 140–852 is limited to manufacture in a licensed feed mill.

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 supplemental 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) 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 558

Animal drugs, Animal feeds.

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 558 is amended as follows:

PART 558 —NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.363 is amended by adding paragraphs (a)(6), (d)(1)(viii), and (d)(1)(ix) to read as follows:

§ 558.363 Narasin.

(a) * * *

(6) To 046573: 45 grams per pound with 10, 25, 30, 40, 50, 60, or 75 grams per pound bacitracin methylene disalicylate and 45.4, 90, or 227 grams per pound roxarsone, paragraphs (d)(1)(viii) and (d)(1)(ix) of this section.

* * * * *

(d) * * *

(1) * * *

(viii) *Amount per ton*. Narasin, 54 to 72 grams, and bacitracin methylene disalicylate, 50 grams, with roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use*. For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations*. For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do not feed to laying hens. Do not allow adult turkeys, horses, or other equines access to narasin formulations. Ingestion of narasin by these species has been fatal. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdose or lack of water intake may result in leg weakness or paralysis. Narasin as provided by 000986, bacitracin methylene disalicylate and roxarsone by 046573 in § 510.600(c) of this chapter.

(ix) *Amount per ton*. Narasin, 54 to 72 grams, and bacitracin methylene disalicylate, 100 to 200 grams, with roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use*. For prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations*. For broiler chickens only. Feed continuously as sole ration. Withdraw 5 days before slaughter. Do