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 parts 510 and 520 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Contemporary Products, Inc.'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''055462'' to read as follows:

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

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * * * * *	*
Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764–6067	055462
* * * * * *	*

(2) * * *

Drug labeler code	Firm name and address
*	* * * * * *
055462	Contemporary Products, Inc., 3788 Elm Springs Rd., Springdale, AR 72764–6067
*	* * * * * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.2158a [Amended]

4. Section 520.2158a *Streptomycin sulfate oral solution* is amended in paragraph (b) by removing the phrase ''No. 033008'' and adding in its place '' Nos. 033008 and 055462''.

Dated: August 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–25904 Filed 9–28–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Fujisawa USA, Inc., to American Pharmaceutical Partners, Inc.

EFFECTIVE DATE: September 29, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Fujisawa USA, Inc., Deerfield, IL 60015–2548, has informed FDA that it has transferred ownership of, and all rights and interests in, NADA 100–840 (Chorionic Gonadotropin) to American Pharmaceuticals Partners, Inc., 2045 North Cornell Ave., Melrose Park, IL 60160. Accordingly, the agency is amending the regulations in 21 CFR 510.600 and 522.1081 to reflect the transfer of ownership. The agency is also amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by removing Fujisawa USA, Inc., because the firm is no longer the sponsor of any approved NADA's, and by alphabetically adding a new listing for American Pharmaceuticals Partners, Inc.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''Fujisawa USA, Inc.,'' and by alphabetically adding an entry for ''American Pharmaceutical Partners, Inc.,'' and in the table in paragraph (c)(2) by removing the entry for ''000469'' and by numerically adding an entry for ''063323'' to read as follows:

§ 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