TABLE 1.—SUMMARY OF CLINICAL TRIALS WITH HYPERCHOLESTEROLEMICS: PSYLLIUM AND CORONARY HEART DISEASE—Continued

Study	Duration Treatment	Number of Subjects	Supplements (Psyllium, Placebo) Soluble Fiber g/d	Diet Intake of groups: Sat fat % E; CHOL mg/d	Magnitude of PSY Effect[1]	Magnitude of Placebo Effect
Weingand et al. (Ref. 26)	Base: 12 wk Step 1; Tx: 8 wk Step 1+supplement, crossover	23 (16m, 7f)	10.2 g/d bulk laxative, cellulose PSY: ~7 g SF	*SAT fat*: PSY- 8.7%; C- 9% *CHOL*: PSY- 162 mg; C- 203–261 mg	*CHOL*: -9 mg/dL (3.8%) *LDL-C*: -11 mg/dL (6.2%)[1]	*HDL-C*: sig higher in PSY group
Jenkins et al. (Ref. 30)	Base: 2 mo controlled Step 2 diets; Tx: 2- 1 mo Step 2 diets+ cereal, crossover	Study 1: 32 (15m, 17f)	Study 1: 11.4 g/d PSY in cereal (~7.8 g SF), wheat bran	Study 1: *SAT fat*: PSY- 4.6%; C -4.6% *CHOL*: PSY- 31 mg; C- 29 mg *MUFA*: PSY- 6%; C- 6%	Study 1: *CHOL*: -27 mg/dL[1] (9.8%) *LDL-C*: -24 mg/dL[1] (12.6%) *HDL-C*: -6.6 mg/dL (11.3%)[1]	Study 1: *CHOL*: -13.6 (5%)[2] *LDL-C*: -10 (5.5%) *HDL-C*: -2 (3.3%)
		Study 2: 27 (12m, 15f)	Study 2: 12.4 g/d PSY in cereal (~8.4 g SF), wheat bran	Study 2: *SAT fat*: PSY- 6%; C- 6% *CHOL*: PSY- 22 mg; C-22 mg *MUFA*: PSY- 12%; C- 12%	Study 2: *CHOL*: -34 mg/dL[1] (12.6%) *LDL-C*: -27.9 mg/dL[1] (14.9%) *HDL-C*: -4.3 mg/dL[1] (8%)	Study 2: *CHOL*: -29.5 (10.7%)[2] *LDL-C*: -17 (9%)[2] *HDL-C*: -1.4 (2.6%)

[1] Significant differences between treatment and placebo groups unless otherwise indicated.
[2] Significant change across the diet phase.

Abbreviations Used in Table 1

C	Control
CHOL	Blood total cholesterol
d	Day
E	Energy
g	Gram
grp	Group
HDL-C	High density lipoprotein cholesterol
LDL-C	Low density lipoprotein cholesterol
m/f	Number of males, number of females
mg/dL	Milligrams per deciliter
Pla	Placebo
PSY	Psyllium
Sat fat	Saturated fat
SF	Soluble fiber
Sig Dif	Statistically significant difference
Step 1	≤ 30% kcals fat, < 10% kcals sat fat, < 300 mg cholesterol
TDF	Total dietary fiber
Tx	Treatment
wk	Week
~	Approximately
%	Percent

[FR Doc. 98–4074 Filed 2–12–98; 4:18 pm]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 529

Certain Other Dosage Form New Animal Drugs; Isoflurane

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 Rhone-Poulenc Chemicals, Ltd. The ANADA provides for use of isoflurane, USP, as an inhalant for induction and maintenance of general anesthesia in horses and dogs.

EFFECTIVE DATE: February 18, 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: Rhone-Poulenc Chemicals, Ltd., P.O. Box 46, St. Andrew's Rd., Avonmouth, Bristol BS11 9YF, England, UK, filed ANADA 200–237 that provides for inhalant use of isoflurane, USP, for induction and maintenance of general anesthesia in horses and dogs. The drug is limited to use by or on the order of a licensed veterinarian.

Approval of ANADA 200–237 for Rhone-Poulenc Chemicals, Ltd.'s isoflurane is as a generic copy of Ohmeda Pharmaceutical Products Division, Inc.'s NADA 135–773 AErrane® (isoflurane, USP). The ANADA is approved as of December 19, 1997, and the regulations are amended in 21 CFR 529.1186(b) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, the sponsor has not been previously included in the list of sponsors of approved applications in § 510.600 (21 CFR 510.600). The regulations are amended in § 510.600(c)(1) and (c)(2) to reflect the the new sponsor.

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 20855, between 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(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

21 CFR Part 510

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

21 CFR Part 529

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 529 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 an entry for ''Rhone-Poulenc Chemicals, Ltd.,'' and in the table in paragraph (c)(2) by numerically adding an entry for ''059258'' 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
* * *	* * * *
Rhone-Poulenc Chemicals, Ltd., P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK	059258
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
059258	Rhone-Poulenc Chemicals, Ltd., P.O. Box 46, St. Andrews Rd., Avonmouth, Bristol BS11 9YF, England, UK.
* * *	* * * *

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

3. The authority citation for 21 CFR part 529 continues to read as follows:

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

4. Section 529.1186 is amended by revising paragraph (b) to read as follows:

§ 529.1186 Isoflurane.

* * * * *

(b) *Sponsors.* See Nos. 000074, 010019, 012164, and 059258 in § 510.600(c) of this chapter.

* * * * *

Dated: January 30, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–3983 Filed 2–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Difloxacin Tablets

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 new animal drug application (NADA) filed by Fort Dodge Animal Health. The NADA provides for oral use of difloxacin tablets for management of diseases in dogs associated with bacteria susceptible to difloxacin.

EFFECTIVE DATE: February 18, 1998.

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

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Home Products, 800 Fifth St. NW., P.O. Box 518, Fort Dodge, IA 50501, filed NADA 141–096 that provides for oral use of Dicural® (difloxacin) tablets for management of diseases in dogs associated with bacteria susceptible to difloxacin. The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of November 20, 1997, and the regulations are amended by adding new § 520.645 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.

Under section 512(c)(2)(F)(iv) of the Federal Food, Drug, and Cosmetic Act