Firm name and address	Drug labeler code
* * * * * * *	
Wellmark International, 1100 East Woodfield Rd., suite 500, Schaumburg, IL 60173	011536
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
011536	Wellmark International, 1100 East Woodfield Rd., suite 500, Schaumburg, IL 60173
* * * * * * *	

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18824 Filed 7–25–00; 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; Ivermectin Sustained-Release Bolus

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 Merial Ltd. The supplemental NADA provides for changes to labeling of ivermectin sustained-release bolus for cattle.

DATES: This rule is effective July 26, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, filed a supplement to NADA 140–988 that provides for use of Ivomec® (ivermectin) SR bolus for cattle. The supplement provides for reducing the predicted duration of effectiveness in labeling from approximately 135 days to approximately 130 days, based on bolus stability data. The supplement is approved as of June 21, 2000, and the regulations in 21 CFR 520.1197 are amended 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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 25.24(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 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 part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.1197 [Amended]

2. Section 520.1197 *Ivermectin sustained-release bolus* is amended in paragraph (d)(2) by removing the parenthetical phrase ''(approximately 135 days)'' and by adding in its place '' (approximately 130 days)''.

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18827 Filed 7–25–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 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 12 approved new animal drug applications (NADA's) from Merial Ltd. to Phoenix Scientific, Inc.

DATES: This rule is effective July 26, 2000.

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: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, has informed FDA that it has transferred ownership of, and all rights and interests in, the following approved NADA's to Phoenix Scientific, Inc., 3915 South 48th St. Terrace, PO Box 6457, St. Joseph, MO 64506–0457:

NADA No.	Product Name
033–157	SPECTAM® (spectinomycin) Scour Halt
040–040	SPECTAM® (spectinomycin) Injection
045–416	BUTATRON™ (phenylbutazone) Injection
048–287	Oxytetracycline-50 (oxytetracycline) Injection
055–002	TEVOCIN (chloramphenicol) Injection
093–483	SPECTAM® (spectinomycin) Injectable
119–142	PVL Iron Dextran Injectable
123–815	Dexamethasone Sodium Phosphate Injection
124–241	PVL Oxytocin Injection
128–089	ZONOMETH (dexamethasone) Sterile Solution
200–147	GENTA–JECT® (gentamicin sulfate) Injection
200–153	NEO 200 (neomycin sulfate) Oral Solution

Accordingly, the agency is amending the regulations in parts 520 and 522 (21 CFR parts 520 and 522) in §§ 520.1485, 520.2122, 522.390, 522.540, 522.1044, 522.1183, 522.1662a, 522.1680, and 522.2120 to reflect the transfer of ownership. An entry for Phoenix Scientific, Inc., already exists in § 522.1720 *Phenylbutazone Injection* following the approval of a supplemental ANADA 200–126 (61 FR 54332, October 18, 1996).

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 Parts 520 and 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 520 and 522 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.1485 [Amended]

2. Section 520.1485 *Neomycin sulfate oral solution* is amended in paragraph (b) by removing ''050604''.

§ 520.2122 [Amended]

3. Section 520.2122 *Spectinomycin dihydrochloride oral solution* is amended in paragraph (b)(1) by removing ''050604'' and adding in its place ''059130''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.390 [Amended]

5. Section 522.390 *Chloramphenicol injection* is amended in paragraph (b) by removing ''050604'' and adding in its place ''059130''.

§ 522.540 [Amended]

6. Section 522.540 *Dexamethasone injection* is amended in paragraphs (d)(2)(i) and (e)(2) by removing ''050604'' and adding in its place ''059130''.

§ 522.1044 [Amended]

7. Section 522.1044 *Gentamicin sulfate injection* is amended in paragraph (b)(4) by removing ''050604'' and adding in its place ''059130''.

§ 522.1183 [Amended]

8. Section 522.1183 *Iron hydrogenated dextran injection* is amended in paragraph (e)(1) by removing ''050604'' and adding in its place ''059130''.

§ 522.1662a [Amended]

9. Section 522.1662a *Oxytetracycline hydrochloride injection* is amended in paragraph (i)(2) by removing ''050604'' and adding in its place ''059130''.

§ 522.1680 [Amended]

10. Section 522.1680 *Oxytocin injection* is amended in paragraph (b) by removing ''050604'' and adding in its place ''059130''.

§ 522.2120 [Amended]

11. Section 522.2120 *Spectinomycin dihydrochloride injection* is amended in paragraph (b) by removing ''050604'' and adding in its place ''059130''.

Dated: July 18, 2000.

Claire M. Lathers,

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

[FR Doc. 00–18828 Filed 7–25–00; 8:45 am]

BILLING CODE4160–01–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 Abbott Laboratories. The ANADA provides for intramuscular use of ketamine hydrochloride injection in cats for restraint or as the sole anesthetic agent for diagnostic or minor, brief, surgical procedures that do not require skeletal muscle relaxation, and in nonhuman primates for restraint. The drug is for veterinary prescription use only.