factor only analysis performed online at an applicant's facility.

Final Action

Effective October 1, 1997, the Agency will apply a 12.5-percent increase to Administrative Fees in 7 CFR 800.71, Table 1 (3), and will delete fees for Additional Service (assessed in addition to all other fees) in Table 1 (3)(ii).

Good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** (5 U.S.C. 553) because an October 1, 1997, effective date corresponds to the beginning of the 1998 fiscal year and the start of a new accounting cycle.

List of Subjects in 7 CFR Part 800:

Administrative practice and procedure; Grain.

For the reasons set out in the preamble, 7 CFR Part 800 is amended as follows:

PART 800—GENERAL REGULATIONS

1. The authority citation for Part 800 continues to read as follows:

Authority: Pub. L. 94–582, 90 Stat. 2867, as amended (7 U.S.C. 71 *et seq.*)

2. Section 800.71 is amended by revising Table 1(3) in Schedule A of paragraph (a) to read as follows:

§ 800.71 Fees assessed by the Service.

(a)

* * * * *

Schedule A—Fees for Official Inspection and Weighing Services Performed in the United States

TABLE 1.—FEES FOR OFFICIAL SERVICES PERFORMED AT AN APPLICANT'S FACILITY IN AN ONSITE FGIS LABORATORY [1]

* * * * *

(3) Administrative Fee (assessed in addition to all other applicable fees, only one administrative fee will be assessed when inspection and weighing services are performed on the same carrier).	
(i) All outbound carriers (per-metric-ton) [4]	
(a) 1–1,000,000	$0.1013
(b) 1,000,001–1,500,000	.0923
(c) 1,500,001–2,000,000	.0473
(d) 2,000,001–5,000,000	.0360
(e) 5,000,001–7,000,000	.0192
(f) 7,000,001 +	.0023

[1] Fees for original inspection and weighing, reinspection, and appeal inspection service include, but are not limited to, sampling, grading, weighing, prior to loading stowage examinations, and certifying results performed within 25 miles of an employee's assigned duty station. Travel and related expenses will be charged for service outside 25 miles as found in § 800.72 (a).

* * * * *

[4] The administrative fee is assessed on an accumulated basis beginning at the start of the Service's fiscal year (October 1 each year).

* * * * *

Dated: September 12, 1997.

James R. Baker,

Administrator.

[FR Doc. 97–24814 Filed 9–17–97; 8:45 am]

BILLING CODE 3410–EN–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

New Animal Drugs; Change of Sponsor Address

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 address for K. C. Pharmacal, Inc.

EFFECTIVE DATE: September 18, 1997.

FOR FURTHER INFORMATION CONTACT: Judith O'Haro, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–3664.

SUPPLEMENTARY INFORMATION: K. C. Pharmacal, Inc., 1310 Atlantic, P.O. Box 7496, North Kansas City, MO 64116, has informed FDA of a change of sponsor address to K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor address.

List of Subjects in 21 CFR Part 510

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

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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (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 revising the sponsor address for ''K. C. Pharmacal, Inc.'' and in the table in paragraph (c)(2) in the entry for ''038782'' by revising the sponsor address 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
* * *	* * * *
K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214	038782
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
038782	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214
* * *	* * * *

Dated: September 4, 1997.

George A. Mitchell,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 97–24736 Filed 9–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Cyclosporine

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 Schering-Plough Animal Health. The supplemental NADA provides for use of cyclosporine ophthalmic ointment on dogs for management of chronic superficial keratitis (CSK) and changing the approved label claim to management of chronic keratoconjunctivitis sicca (KCS).

EFFECTIVE DATE: September 18, 1997.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health, Schering-Plough Corp., P.O. Box 529, Kenilworth, NJ 07033, has filed supplemental NADA 141–052 Optimmune® (cyclosporine) ophthalmic ointment that provides for use on dogs for the management of chronic superficial keratitis (CSK) and changing the approved label claim from treatment to management of chronic keratoconjunctivitis sicca (KCS) in dogs. The term management reflects the complexity of the therapy for the diseases. The drug is limited to use by or on the order of a licensed veterinarian. The supplement is approved as of August 26, 1997, and the regulations are revised in 21 CFR 524.575(c)(2) 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 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)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval for use in nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning August 26, 1997, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new indication for management of CSK in dogs.

FDA has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. FDA's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

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

2. Section 524.575 is amended by revising paragraph (c)(2) to read as follows:

§ 524.575 Cyclosporine ophthalmic ointment.

* * * * *

(c) * * *

(2) *Indications for use.* For management of chronic keratoconjunctivitis sicca (KCS) and chronic superficial keratitis (CSK) in dogs.

* * * * *

Dated: September 10, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–24850 Filed 9–17–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 812

[Docket No. 96N–0299]

Investigational Device Exemptions; Treatment Use

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is establishing procedures to allow for the treatment use of investigational devices. These procedures are intended to facilitate the availability of promising new therapeutic and diagnostic devices to desperately ill patients as early in the device development process as possible, i.e., before general marketing begins, and to obtain additional data on the device's safety and effectiveness. These procedures apply to patients with serious or immediately life-threatening diseases or conditions for which no comparable or satisfactory alternative device, drug, or other therapy exists.

DATES: The regulation is effective January 16, 1998.