(2) while the Board believes that an estimate should be provided within a reasonable period of time the Board does not believe that the regulation should contain a specific time limit in view of the wide ranging types of requests that could be made; and (3) the cap of $1,000.00 for waiver of fees without approval of the three-member Board reflects the desire of the Board itself to maintain close control over expenditures by the agency. Accordingly, the Board has not amended the text of the proposed rule.

The Board, in conjunction with the Office of Management and Budget, has determined that this is not a significant regulatory action for purposes of Executive Order 12866. Therefore, no regulatory impact analysis is required. There are no information collections associated with this rule.

List of Subjects in 20 CFR Part 200

Railroad employees, Railroad retirement, Railroad unemployment insurance.

For the reasons set out in the preamble, title 20, chapter II, part 200 of the Code of Federal Regulations is amended as follows:

PART 200—GENERAL ADMINISTRATION

1. The authority citation for part 200 continues to read as follows:

Authority: 45 U.S.C. 231f(b)(5) and 45 U.S.C. 362; § 200.4 also issued under 5 U.S.C. 552; § 200.5 also issued under 5 U.S.C. 552a; § 200.6 also issued under 5 U.S.C. 552b; and § 200.7 also issued under 31 U.S.C. 3717.

2. Section 200.4 is amended by adding paragraphs (o) and (p) to read as follows:

§ 200.4 Availability of information to public.

* * * * *

(o) *Custom tailored information services; Fees charged.* This paragraph and paragraph (p) of this section set forth the policy of the Railroad Retirement Board with respect to the assessment of a fee for providing custom tailored information where requested. Except as provided in paragraphs (o)(4)(vii) and (p) of this section, a fee shall be charged for providing custom tailored information.

(1) *Definition: Custom tailored information.* Custom tailored information is information not otherwise required to be disclosed under this part but which can be created or extracted and manipulated, reformatted, or otherwise prepared to the specifications of the requester from existing records. For example, the Board needs to program computers to provide data in a particular format or to compile selected items from records, provide statistical data, ratios, proportions, percentages, etc. If this data is not already compiled and available, the end product would be the result of custom tailored information services.

(2) *Providing custom tailored information.* The Board is not required to provide custom tailored information. It will do so only when the appropriate fees have been paid as provided in paragraph (o)(4) of this section and when the request for such information will not divert staff and equipment from the Board's primary responsibilities.

(3) *Requesting custom tailored information.* Information may be requested in person, by telephone, or by mail. Any request should reasonably describe the information wanted and may be sent to the Director of Administration, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092.

(4) *Fee schedule.* Requests for custom tailored information are chargeable according to the following schedule:

(i) *Manual searching for records.* Full cost of the time of the employees who perform the service, even if records cannot be found, management and supervisory costs, plus the full costs of any machine time and materials the employee uses. Consulting and other indirect costs will be assessed as appropriate.

(ii) *Photocopying or reproducing records on magnetic tapes or computer diskettes.* The charge for making photocopies of any size document shall be $.10 per copy per page. The charge for reproducing records on magnetic tapes or computer diskettes is the full cost of the operator's time plus the full cost of the machine time and the materials used.

(iii) *Use of electronic data processing equipment to obtain records.* Full cost for the service, including computer search time and computer runs and printouts, and the time of computer programmers and operators and of other employees.

(iv) *Certification or authentication.* Full cost of certification and authentication.

(v) *Providing other special services.* Full cost of the time of the employee who performs the service, management and supervisory costs, plus the full costs of any machine time and materials the employee uses. Consulting and other indirect costs will be assessed as appropriate.

(vi) *Special forwarding arrangements.* Full cost of special arrangements for forwarding material requested.

(vii) *Statutory supersession.* Where a Federal statute prohibits the assessment of a charge for a service or addresses an aspect of that charge, the statute shall take precedence over this paragraph (o).

(p) *Assessment of a fee with respect to the provision of custom tailored information where the identification of the beneficiary is obscure and where provision of the information can be seen as benefiting the public generally.* When the identification of a specific beneficiary with respect to the provision of custom tailored information is obscure, the service can be considered primarily as benefiting broadly the general public, and the estimated cost of providing the information is less than $1,000.00, the Director of Administration shall determine whether or not a fee is to be charged. In any such case where the cost is $1,000.00 or more, the request shall be referred by the Director of Administration to the three-member Board for a determination whether or not a fee is to be assessed.

Dated: May 30, 1995.

By Authority of the Board.

For the Board.

Beatrice Ezerski,

Secretary to the Board.

[FR Doc. 95–13845 Filed 6–6–95; 8:45 am]

BILLING CODE 7905–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Dexamethasone 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 Phoenix Pharmaceutical, Inc. The ANADA provides for use of dexamethasone injection in cattle for the treatment of primary bovine ketosis and in dogs, cats, cattle, and horses as an anti-inflammatory agent.

EFFECTIVE DATE: June 7, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Phoenix Pharmaceutical, Inc., 4621 Easton Rd.,

P.O. Box 6457 Farleigh Station, St. Joseph, MO 64506–0457, has filed ANADA 200–108, which provides for intravenous or intramuscular use of Dexamethasone Solution (2 milligrams (mg) of dexamethasone per milliliter (mL)) in cattle for the treatment of primary bovine ketosis and in dogs, cats, cattle, and horses as an anti-inflammatory agent.

Phoenix Pharmaceutical, Inc.'s, ANADA 200–108 for Dexamethasone Solution (2 mg/mL) is approved as a generic copy of Schering-Plough Animal Health Corp.'s NADA 12–559 for Azium® (dexamethasone solution). The ANADA is approved as of April 13, 1995, and the regulations are amended in 21 CFR 522.540(a)(2) 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 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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency'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) between 9 a.m. and 4 p.m., Monday through Friday.

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

2. Section 522.540 is amended by revising paragraph (a)(2) to read as follows:

§ 522.540 Dexamethasone injection.

(a) * * *

(2) *Sponsor.* See Nos. 000061 and 057319 in § 510.600(c) of this chapter.

* * * * *

Dated: May 23, 1995.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 95–13830 Filed 6–6–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Gentamicin Sulfate 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 Sanofi Animal Health, Inc. The ANADA provides for use of gentamicin sultate injection in day-old chickens for the prevention of early mortality caused by *Escherichia coli, Salmonella typhimurium,* and *Pseudomonas aeruginosa* susceptible to gentamicin sulfate.

EFFECTIVE DATE: June 7, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Sanofi Animal Health, Inc., 7101 College Blvd., Overland Park, KS 66210, has filed ANADA 200–147, which provides for use of gentamicin sulfate injection in day-old chickens for the prevention of early mortality caused by *E. coli, S. typhimurium,* and *P. aeruginosa* susceptible to gentamicin sulfate.

Sanofi Animal Health, Inc.'s, ANADA 200–147 for gentamicin sulfate injection (100 milligrams of gentamicin per milliliter (mg/mL) solution) is approved as a generic copy of Schering-Plough Animal Health's NADA 101–862 for Garasol (50 and 100 mg of gentamicin/mL solution) injection. The ANADA is approved as of April 10, 1995, and the regulations are amended in § 522.1044 (21 CFR 522.1044) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the regulation failed to reflect that Schering-Plough's NADA 101–862 was approved for use of 100 mg of gentamicin/mL as well as 50 mg of gentamicin/mL injection. At this time, § 522.1044 is amended to indicate that both concentrations of the drug are approved for use in day-old chickens.

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, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency'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) between 9 a.m. and 4 p.m., Monday through Friday.

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

2. Section 522.1044 is amended by revising paragraphs (a) and (b)(1) and by adding new paragraph (b)(4) to read as follows:

§ 522.1044 Gentamicin sulfate injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains gentamicin sulfate equivalent to either 5, 50, or 100 milligrams of gentamicin.

(b) *Sponsors.* (1) See No. 000061 in § 510.600(c) of this chapter for use of 5 milligrams-per-milliliter solution in swine as in paragraph (d)(4) of this section, for use of 50 milligrams-per-solution in dogs, cats, and chickens as in paragraph (d)(1) and (d)(3) of this section, for use of 100 milligrams-per-