

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 sulfate 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-

milliliter solution in chickens as in paragraph (d)(3) of this section.

\* \* \* \* \*

(4) See No. 050604 for use of 100 milligrams-per-milliliter solution in chickens as in paragraph (d)(3) of this section.

\* \* \* \* \*

Dated: May 22, 1995.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-13828 Filed 6-6-95; 8:45 am]

BILLING CODE 4160-01-F

## 21 CFR Part 1220

[Docket No. 95N-0120]

### Regulations Under the Tea Importation Act; Tea Standards

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the establishment of tea standards for the year beginning May 1, 1995, and ending April 30, 1996. The tea standards are provided for under the Tea Importation Act (the Act). The Act prohibits the importation of a tea that is inferior to the annual tea standard. Under the Act, the importation of a tea may be withheld until FDA examines the tea and is sure that it complies with the annual standard.

**DATES:** Effective May 1, 1995; written comments by July 7, 1995.

**ADDRESSES:** Submit written comments to the Docket Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Michelle A. Smith, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

**SUPPLEMENTARY INFORMATION:** Because of the unique nature of the decisionmaking process for establishing annual standards for tea, the procedural protections that are part of this process, and the short period within which standards must be set, FDA has never, since the enactment in 1897 of the Act (21 U.S.C. 41), used notice and comment rulemaking for tea standards.

Each final rule setting the standards is based on the recommendations of the Board of Tea Experts (the board), which is comprised of tea experts who are representative of the tea trade. The

board selects standards each year according to the provisions of the Act. The board bases its selection on tea samples submitted by members of the tea trade to the board. Relying primarily on organoleptic examination, the board selects one tea to represent the standard for each major type of tea imported into the United States. In choosing a standard, the board tries to select one at least equal in quality to that of the previous year. The Act prohibits the importation of a tea that is inferior to the annual tea standard. Under the Act, the importation of a tea may be withheld until FDA examines the tea and is sure that it complies with the annual standard.

The annual meeting of the board is open to the public and is announced in advance in the **Federal Register**. At the annual meeting any interested person may present data, information, or views orally or in writing regarding new standards.

The annual tea standards are prepared and submitted to the Secretary of Health and Human Services by the board (21 CFR 1220.41).

Should a tea importer be dissatisfied with an FDA tea examiner's rejection of a shipment of tea, the importer can refer its complaint to the U.S. Board of Tea Appeals and then to the U.S. Court of Appeals. FDA is unaware of any complaints or arguments having ever occurred concerning a designated standard, despite the many years since the enactment of the Act.

FDA concludes that notice and comment rulemaking to set tea standards is impracticable, contrary to the public interest, and unnecessary by virtue of the factors discussed above, i.e., the unique, longstanding procedures that apply to establishing a standard, the fact that standards are based principally on organoleptic examinations by tea experts, the public participation opportunities already provided, and the timeframes required for issuing annual standards. Hence, the agency is not following notice and comment rulemaking procedures in establishing the final tea standards for 1995.

### Environmental Impact

The agency has determined under 21 CFR 25.24(b)(1) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the tea standards, used by buyers for the U.S. market, protect consumers, importers, and sellers from acceptance of teas that are inferior in purity, quality, and fitness for consumption, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Interested persons may, on or before July 7, 1995, submit to the Dockets Management Branch (address above) written comments regarding this regulation. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any changes in this regulation justified by such comments will be the subject of a further amendment.

### List of Subjects in 21 CFR Part 1220

Administrative practice and procedure, Customs duties and inspection, Imports, Public health, Tea.

Therefore, under the authority delegated to the Secretary of Health and Human Services by the Tea Importation Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 1220 is amended as follows: