Commission staff in response to circumstances similar to those surrounding the request (including adverse Letters), and must identify any conditions imposed by prior Letters as prerequisites for the issuance of those Letters. Citation of a representative sample of prior Letters is sufficient where a comprehensive recitation of prior Letters on a given topic would be repetitious or would not assist the staff in considering the request.

(7) Requests may ask that, if the requested exemptive relief, no-action position or interpretative guidance is denied, the staff consider granting alternative relief or adopting an alternative position.

(d) *Filing Requirements.* Each request for a Letter must comply with the following filing requirements:

(1) The request must be in writing and signed.

(2) The request must be filed with the Director, Division of Trading and Markets, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Request must be submitted electronically using the e-mail address tmletters@cftc.gov; *Provided*, That a properly signed paper copy of the request is provided to the Division of Trading and Markets within ten days for purposes of verification of the electronic transmission. The Director will route the request to the appropriate Division or the Office of the General Counsel.

(e) *Form of Staff Response.* No response to any request governed by this section is effective unless it is in writing, signed by appropriate Commission staff, and transmitted in final form to the recipient. Failure by Commission staff to respond to a request for a Letter does not constitute approval of the request. Nothing in this section shall preclude Commission staff from responding to a request for a Letter by way of endorsement or any other abbreviated, written form of response.

(f) *Withdrawal of Requests.* (1) A request for a Letter may be withdrawn by filing with Commission staff a written request for withdrawal, signed by the person on whose behalf the Letter was sought or by that person's authorized representative, that states whether the person on whose behalf the Letter was sought will proceed with the proposed transaction or activity.

(2) Where a request has been submitted by an authorized representative of the person on whose behalf a Letter is sought, the authorized representative may withdraw from representation at any time without explanation, *Provided*, That Commission staff is promptly so notified.

(g) *Failure to Pursue a Request.* In the event that Commission staff requests additional information or analysis from a requester and the requester does not provide that information or analysis within thirty calendar days, Commission staff generally will issue a denial of the request; *Provided, however*, that Commission staff in its discretion may issue an extension of time to provide the information and or analysis.

(h) *Confidential Treatment.* Confidential treatment of a request for a Letter must be requested separately in accordance with § 140.98 or § 145.9 of this chapter, as applicable.

(i) *Applicability to Other Sections.* The provisions of this section shall not affect the requirements of, or otherwise be applicable to:

(A) Notice filings required to be made to claim relief from the Act or from a Commission rule, regulation or order including, without limitations, §§ 4.5, 4.7(a), 4.7(b), 4.12(b), 4.13(b) and 4.14(a)(8) of this chapter; or

(B) Requests for exemption pursuant to Section 4(c) of the Act.

Issued in Washington, DC on December 2, 1998 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 98–32587 Filed 12–9–98; 8:45 am]

BILLING CODE 6351–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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 a supplemental new animal drug application (NADA) filed by Merial Ltd. The supplemental NADA provides for use of gentamicin sulfate injection in the neck of 1 to 3-day-old turkey poults for prevention of early mortality due to susceptible *Arizona paracolon* infections.

EFFECTIVE DATE: December 10, 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: Merial Ltd., 2100 Ronson Rd., Iselin, NJ 08830–3077, filed supplemental NADA 200–147 that provides for subcutaneous use of Genta-Ject® (gentamicin sulfate) injectable solution in the neck of 1 to 3-day-old turkey poults as an aid in the prevention of early mortality due to *A. paracolon* infections susceptible to gentamicin. The supplemental NADA is approved as of October 30, 1998, and the regulations are amended in 21 CFR 522.1044(b)(4) 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 supplemental 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 25.33(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.

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: 21 U.S.C. 360b.

2. Section 522.1044 is amended by revising paragraph (b)(4) to read as follows:

§ 522.1044 Gentamicin sulfate injection.

* * * * *

(b) * * *

(4) See No. 050604 for use of 100 milligram-per-milliliter solution in turkeys as in paragraph (d)(2) of this section and in chickens as in paragraph (d)(3) of this section.

* * * * *

Dated: December 2, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–32741 Filed 12–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522, 524, and 556

Animal Drugs, Feeds, and Related Products; Doramectin

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 two supplemental new animal drug applications (NADA's) filed by Pfizer, Inc. The supplemental NADA's provide for added use of doramectin in cattle for injectable use for additional persistent efficacy for treatment and control of certain gastrointestinal roundworms and lungworms and for topical use for treatment and control of horn flies.

EFFECTIVE DATE: December 10, 1998.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed supplemental NADA 141–061 that provides for subcutaneous and intramuscular use of Dectomax® (doramectin) 1 percent injectable solution in cattle to control infections and to protect from reinfection with *Cooperia oncophora* for 14 days and *Oesophagostomum radiatum* for 28 days after treatment. The new persistent use is in addition to the currently approved use in cattle for treatment and control of various gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites, and to control infections and to protect from reinfection with *Ostertagia ostertagi* for 21 days and *C. punctata* and *Dictyocaulus viviparus* for 28 days after treatment.

Pfizer, Inc., also filed supplemental NADA 141–095 that provides for topical use of Dectomax® (doramectin) 0.5 percent pour-on in beef and nonlactating dairy cattle to treat and control horn flies (*Haematobia irritans*) in addition to its use for treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, and mange mites, and to control infections and to protect from reinfection with *C. oncophora* and *Dictyocaulus viviparus* for 21 days, and *O. ostertagi, C. punctata,* and *O. radiatum* for 28 days after treatment.

The supplemental NADA's are approved as of October 25, 1998, and the regulations are amended in 21 CFR 522.770(d)(1)(ii) and 524.770(d)(2) to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

In addition, a tolerance for doramectin and its residues in cattle muscle has not been previously established. Also, the acceptable daily intake (ADI) for doramectin has not been previously codified. At this time, the regulations are amended in 21 CFR 556.225 to provide for a tolerance for doramectin residues in cattle muscle and an ADI.

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 (21 U.S.C. 360b(c)(2)(F)(iii)), these supplemental approvals for food-producing animals qualify for 3 years of marketing exclusivity beginning October 25, 1998, because the supplements contain substantial evidence of the effectiveness of the drug involved, any 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 supplemental applications and conducted or sponsored by the applicant. Exclusivity applies only to the added indication for use of doramectin injection to control infections and to protect cattle from reinfection with *C. oncophora* for 14 days and *O. radiatum* for 28 days after treatment, and for doramectin topical for the treatment and control of horn flies (*H. irritans*).

The agency has determined under 21 CFR 25.33(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.

List of Subjects

21 CFR Parts 522 and 524

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 522, 524, and 556 are 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: 21 U.S.C. 360b.

2. Section 522.770 is amended by revising paragraph (d)(1)(ii) to read as follows:

§ 522.770 Doramectin.

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use*. For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites. To control infections and to protect from reinfection with *Cooperia oncophora* for 14 days, *Ostertagia ostertagi* for 21 days, and *C. punctata, Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

4. Section 524.770 is amended by revising paragraph (d)(2) to read as follows:

§ 524.770 Doramectin.

* * * * *

(d) * * *

(2) *Indications for use*. For treatment and control of gastrointestinal roundworms, lungworms, eyeworms, grubs, biting and sucking lice, horn flies, and mange mites, and to control infections and to protect from reinfection with *Cooperia oncophora* and *Dictyocaulus viviparus* for 21 days, and *Ostertagia ostertagia, C. punctata,* and *Oesophagostomum radiatum* for 28 days after treatment.

* * * * *