(vi) Payment of fees must be by check or money order made payable to the U.S. Treasury.

(vii) Requesters may not file multiple requests at the same time, each seeking portions of a document or documents, solely in order to avoid payment of fees. When the Commission reasonably believes that a requester, or a group of requesters acting in concert, is attempting to break a request down into a series of requests for the purpose of evading assessment of fees, or otherwise reasonably believes that two or more requests constitute a single request, the Commission may aggregate any such requests accordingly. The Commission will not aggregate multiple requests on unrelated subjects from a requester. Aggregated requests may qualify for an extension of time under § 388.110(b).

(3) *Fees for unsuccessful search.* The Commission may assess charges for time spent searching, even if it fails to locate the records, or if records located are determined to be exempt from disclosure. If the Commission estimates that search charges are likely to exceed $25, it will notify the requester of the estimated amount of search fees, unless the requester has indicated in advance willingness to to pay fees as high as those anticipated. The requester can meet with Commission personnel with the object of reformulating the request to meet his or her needs at a lower cost.

(4) *Interest—notice and rate.* The Commission will assess interest charges on an unpaid bill starting on the 31st day following the day on which the billing was sent. Interest will be at the rate prescribed in 31 U.S.C. 3717 and will accrue from the date of the billing.

(5) *Advance payments.* The Commission will require a requester to make an advance payment, *i.e.*, payments before work is commenced or continued on a request, if:

(i) The Commission estimates or determines that allowable charges that a requester may be required to pay are likely to exceed $250. The Commission will notify the requester of the estimated cost and either require satisfactory assurance of full payment where the requester has a history of prompt payment of fees, or require advance payment of charges if a requester has no history of payment; or

(ii) A requester has previously failed to pay a fee charged in a timely fashion. The Commission will require the requester to pay the full amount owed plus any applicable interest, and to make an advance payment of the full amount of the estimated fee before the Commission will begin to process a new request or a pending request from that requester. When the Commission requires advance payment or an agreement to pay under this paragraph, or under § 388.108(a)(5), the administrative time limits prescribed in this part will begin only after the Commission has received the required payments, or agreements.

* * * * *

Kimberly D. Bose,

Secretary.

[FR Doc. E8–18040 Filed 8–5–08; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. 2008–N–0039]

Oral Dosage Form New Animal Drugs; Oxfendazole Suspension

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 Fort Dodge Animal Health, Division of Wyeth. The supplemental NADA provides for revised scientific nomenclature for an internal parasite for which oxfendazole suspension is used orally in cattle.

DATES: This rule is effective August 6, 2008.

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of Wyeth, 800 Fifth St. NW., Fort Dodge, IA 50501, filed a supplement to NADA 140–854 for SYNANTHIC (oxfendazole) Bovine Dewormer Suspension, approved for oral use in cattle for the removal of various internal parasites. The supplemental NADA provides for revised scientific nomenclature for a parasite. The supplemental application is approved as of July 7, 2008, and the regulations are amended in 21 CFR 520.1630 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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.

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.

■ 2. In § 520.1630, in paragraph (e)(2)(ii), remove ''*C. mcmasteri*'' and in its place add ''*C. surnabada*''; and revise paragraph (e)(2)(iii) to read as follows:

§ 520.1630 Oxfendazole suspension.

* * * * *

(e) * * *

(2) * * *

(iii) *Limitations.* Cattle must not be slaughtered until 7 days after treatment. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

Dated: July 24, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–18092 Filed 8–5–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA–2008–N–0039]

Oral Dosage Form New Animal Drugs; Amprolium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

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 Phibro Animal Health. The supplemental NADA provides for label revisions associated with a previous change of sponsorship and other minor changes for amprolium concentrate solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis. The product approval is being codified for the first time.

DATES: This rule is effective August 6, 2008.

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Phibro Animal Health, 65 Challenger Rd., 3d floor, Ridgefield Park, NJ 07660, filed a supplement to NADA 13–663 that provides for the use of COCCIPROL (amprolium) 9.6% Oral Solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis. The supplemental NADA provides for label revisions associated with a previous change of sponsorship and other minor changes. The supplemental NADA is approved as of July 8, 2008, and the regulations are amended in 21 CFR 520.100 to reflect the approval. The product approval is being codified for the first time. Also, § 520.100 is revised to reflect current pathogen spelling.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

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.

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 Subject 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.

■ 2. In § 520.100, revise paragraph (b), remove paragraph (d), redesignate paragraph (e) as paragraph (d), and revise new paragraphs (d)(2)(i)(A) and (d)(2)(i)(B) to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) *Sponsors.* See sponsors in 510.600(c) of this chapter.

(1) No. 016592 for use of products described in paragraph (a) of this section as in paragraph (d) of this section.

(2) Nos. 051311 and 066104 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(3) No. 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(2) of this section.

* * * * *

(d) * * *

(2) * * *

(i) * * * (A) As an aid in the prevention of coccidiosis caused by *Eimeria bovis* and *E. zurnii*, administer 5 mg per kilogram (mg/kg) body weight for 21 days during periods of exposure or when experience indicates that coccidiosis is likely to be a hazard.

(B) As an aid in the treatment of coccidiosis caused by *E. bovis* and *E. zurnii*, administer 10 mg/kg body weight for 5 days.

* * * * *

Dated: July 28, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E8–18093 Filed 8–5–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

[Docket No. FDA–2008–N–0039]

Implantation or Injectable Dosage Form New Animal Drugs; Ceftiofur Hydrochloride

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 new animal drug application (NADA) filed by Pharmacia and Upjohn Co., a Division of Pfizer, Inc. The NADA provides for the veterinary prescription use of a ceftiofur hydrochloride injectable suspension for treatment of various bacterial infections in swine and cattle.

DATES: This rule is effective August 6, 2008.

FOR FURTHER INFORMATION CONTACT: Donald A. Prater, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8343, e-mail: *donald.prater@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., a Division of Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed NADA 141–288 that provides for veterinary prescription use of EXCENEL RTU EZ (ceftiofur hydrochloride) Sterile Suspension, used for treatment of various bacterial infections in swine and cattle. The NADA is approved as of July 1, 2008, and the regulations are amended in 21 CFR 522.313b to reflect the approval. A swine pathogen is also being revised to reflect current scientific nomenclature.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Division of Dockets Management (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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

The agency has determined under § 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.

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 Subject in 21 CFR Part 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under