

between other countries, if that person has reached his or her 60th birthday unless there is another pilot in the flight deck crew who has not yet attained 60 years of age.

(e) No pilot may:

(1) Serve as a pilot in operations under this part if that person has reached his or her 65th birthday.

(2) Serve as a pilot in command in operations under this part between the United States and another country, or in operations between other countries, if that person has reached his or her 60th birthday unless there is another pilot in the flight deck crew who has not yet attained 60 years of age.

■ 8. Amend § 121.411 by revising paragraph (e) to read as follows:

§ 121.411 Qualifications: Check airmen (airplane) and check airmen (simulator).

* * * * *

(e) Check airmen who have reached their 65th birthday or who do not hold an appropriate medical certificate may function as check airmen, but may not serve as pilot flightcrew members in operations under this part.

* * * * *

9. Amend § 121.412 by revising paragraph (e) to read as follows:

§ 121.412 Qualifications: Flight instructors (airplane) and flight instructors (simulator).

* * * * *

(e) Flight instructors who have reached their 65th birthday or who do not hold an appropriate medical certificate may function as flight instructors, but may not serve as pilot flightcrew members in operations under this part.

* * * * *

■ 10. Amend § 121.440 by adding paragraphs (d), (e), and (f) to read as follows:

§ 121.440 Line checks.

* * *

(d) No certificate holder may use the services of any person as a pilot in operations under this part unless the certificate holder evaluates every 6 months the performance, through a line check, of each pilot of the certificate holder who has attained 60 years of age. Notwithstanding the foregoing, a certificate holder is not required to conduct for a 6-month period a line check under this paragraph of a pilot serving as a second-in-command if the pilot has undergone a regularly scheduled simulator evaluation during that period.

(e) No pilot who has attained 60 years of age may serve as a pilot in operations under this part unless the certificate holder has evaluated the pilot's

performance every 6 months, through a line check. Notwithstanding the foregoing, a certificate holder is not required to conduct for a 6-month period a line check under this paragraph of a pilot serving as a second-in-command if the pilot has undergone a regularly scheduled simulator evaluation during that period.

(f) The training program provisions of § 121.401(b) do not apply to pilots who have attained 60 years of age and serve in operations under this part.

Issued in Washington, DC, on July 8, 2009.

J. Randolph Babbitt,

Administrator.

[FR Doc. E9-16777 Filed 7-14-09; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

[Docket No. FDA-2009-N-0665]

New Animal Drugs; Ceftiofur Sodium

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 original abbreviated new animal drug application (ANADA) filed by Cephazone Pharma, LLC. The ANADA provides for the use of ceftiofur sodium powder for injection as a solution in dogs, horses, cattle, swine, day old chickens, turkey poults, sheep, and goats as therapy for various bacterial infections.

DATES: This rule is effective July 15, 2009.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767, filed ANADA 200-420 that provides for use of Ceftiofur Sodium Sterile Powder, as an injectable solution, in dogs, horses, cattle, swine, day-old chickens, turkey poults, sheep, and goats as therapy for various bacterial infections. Cephazone Pharma, LLC's Ceftiofur Sodium Sterile Powder is approved as a generic copy of NAXCEL (ceftiofur sodium) Sterile Powder for Injection, sponsored by

Pharmacia & Upjohn Co., a Division of Pfizer, Inc., under NADA 140-338. The ANADA is approved as of May 27, 2009, and the regulations are amended in 21 CFR 522.313c to reflect the approval.

In addition, Cephazone Pharma, LLC, has not been previously listed in the animal drug regulations as a sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to add entries for this firm.

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.

The agency has determined under 21 CFR 25.33 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

21 CFR Part 510

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

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 510.600, in the table in paragraph (c)(1) alphabetically add an entry for "Cephazone Pharma, LLC"; and in the table in paragraph (c)(2) numerically add an entry for "068330" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

Firm name and address	Drug labeler code
Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767	068330

Drug labeler code	Firm name and address
068330	Cephazone Pharma, LLC, 250 East Bonita Ave., Pomona, CA 91767

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 4. In § 522.313c, revise paragraph (b) to read as follows:

§ 522.313c Ceftiofur sodium

(b) *Sponsors.* See Nos. 000009 and 068330 in § 510.600(c) of this chapter.

Dated: July 8, 2009.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
[FR Doc. E9-16734 Filed 7-14-09; 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-2009-N-0665]

Implantation or Injectable Dosage Form New Animal Drugs; Flunixin

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 original abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The

ANADA provides for the use of flunixin meglumine injectable solution in swine.

DATES: This rule is effective July 15, 2009.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed ANADA 200-476 that provides for use of Flunixin Injection -S in swine for various bacterial infections. Norbrook Laboratories, Ltd.'s Flunixin Injection -S is approved as a generic copy of BANAMINE-S (flunixin meglumine) injectable solution, sponsored by Schering-Plough Animal Health Corp. under NADA 101-479. The ANADA is approved as of June 22, 2009, and the regulations are amended in 21 CFR 522.970 to reflect the approval.

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.

The agency has determined under 21 CFR 25.33 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 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. In § 522.970, revise paragraphs (b)(1) and (b)(4) to read as follows:

§ 522.970 Flunixin.

(b) * * *

(1) See Nos. 000061 and 055529 for use as in paragraph (e) of this section.

(4) See Nos. 059130 and 061623 for use as in paragraphs (e)(1) and (e)(2) of this section.

Dated: July 8, 2009.

Bernadette Dunham,
Director, Center for Veterinary Medicine.
[FR Doc. E9-16735 Filed 7-14-09; 8:45 am]
BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

[Docket No. FDA-2009-N-0665]

New Animal Drugs for Use in Animal Feeds; Lasalocid; Roxarsone

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 an original new animal drug application (NADA) filed by Alpharma Inc. The NADA provides for use of single-ingredient Type A medicated articles containing lasalocid and roxarsone to formulate two-way combination drug Type C medicated feeds for use in growing turkeys.

DATES: This rule is effective July 15, 2009.

FOR FURTHER INFORMATION CONTACT: Timothy Schell, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8116, e-mail: timothy.schell@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Alpharma Inc., 440 Rte. 22, Bridgewater, NJ 08807, filed NADA 141-293 that provides for use of AVATEC (lasalocid sodium) and 3-NITRO (roxarsone) single-ingredient Type A medicated articles to formulate two-way combination drug Type C medicated feeds for use in growing turkeys. The NADA is approved as of May 22, 2009, and the regulations are amended in 21 CFR 558.311 and § 558.530 (21 CFR 558.530) to reflect the approval.