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

* * * * *

(c) * * *

(1) * * *

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

(2) * * *

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.