animal drug regulations to reflect approval of an original abbreviated new animal drug application (ANADA) filed by Belcher Pharmaceuticals, Inc. The ANADA provides for veterinary prescription use of carprofen caplets in dogs.

DATES: This rule is effective December 5, 2007.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0169, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., Suite 420, Largo, FL 33773, filed ANADA 200–397 for VETPROFEN (carprofen) Caplets. The ANADA provides for veterinary prescription use in dogs for the relief of pain and inflammation associated with osteoarthritis, and for the control of postoperative pain associated with soft tissue and orthopedic surgeries. Belcher Pharmaceuticals, Inc.'s VETPROFEN Caplets are approved as a generic copy of RIMADYL Caplets, sponsored by Pfizer, Inc., under NADA 141–053. The ANADA is approved as of November 7, 2007, and 21 CFR 520.309 is amended to reflect the approval.

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

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 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(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

21 CFR Part 510

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

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 parts 510 and 520 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. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Belcher Pharmaceuticals, Inc.'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''062250'' to read as follows:

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

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* *
Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., suite 420, Largo, FL 33773	062250
* * *	* *

(2) * * *

Drug labeler code	Firm name and address
* *	* * *
062250	Belcher Pharmaceuticals, Inc., 12393 Belcher Rd., suite 420, Largo, FL 33773
* *	* * *

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.309 [Amended]

■ 4. In paragraph (b)(2) of § 520.309, remove ''No. 000115'' and add in its place ''Nos. 000115 and 062250''.

Dated: November 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–23516 Filed 12–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Monensin

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 Elanco Animal Health. The supplemental NADA revises the concentration of monensin in two-way Type B and Type C medicated feeds containing monensin and tylosin to cattle fed in confinement for slaughter and a revision to bacterial pathogen nomenclature.

DATES: This rule is effective December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 104–646 that provides for use of RUMENSIN (monensin USP) and TYLAN (tylosin phosphate) Type A medicated articles to make dry and liquid two-way combination medicated feeds for cattle fed in confinement for slaughter. The supplemental NADA provides for an increased level of monensin in combination Type B and Type C medicated feeds and a revision to bacterial pathogen nomenclature. The supplemental NADA is approved as of October 30, 2007, and the regulations in 21 CFR 558.355 are amended 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(a)(2) 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 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 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.355, revise paragraphs (f)(3)(ii) and (f)(3)(xii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(ii) *Amount per ton*. Monensin, 5 to 40 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use*. Cattle fed in confinement for slaughter: For improved feed efficiency; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

(*b*) *Limitations*. Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 480 milligrams of monensin and 60 to 90 milligrams of tylosin per head per day. Combination drug liquid Type B medicated feeds may be used to manufacture dry Type C medicated feeds and shall conform to mixing instructions as in § 558.625(c) of this chapter.

* * * * *

(xii) *Amount per ton*. Monensin, 10 to 40 grams; plus tylosin, 8 to 10 grams.

(*a*) *Indications for use*. Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

(*b*) *Limitations*. Feed only to cattle being fed in confinement for slaughter. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligrams monensin per pound of body weight per day, depending upon the severity of challenge, up to maximum of 480 milligrams per head per day; and 60 to 90 milligrams of tylosin per head per day.

* * * * *

Dated: November 20, 2007.

Bernadette Dunham,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. E7–23519 Filed 12–4–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Monensin USP

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 Elanco Animal Health. The supplemental NADA removes the requirement for 30-day expiration on labeling of monensin Type C medicated feeds for several classes of cattle and goats.

DATES: This rule is effective December 5, 2007.

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0223, e-mail: *daniel.benz@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95–735 that provides for use of RUMENSIN 80 (monensin) Type A medicated articles. The supplement removes the requirement for 30-day expiration on labeling of monensin Type C medicated feeds for several classes of cattle and goats. The supplemental NADA is approved as of November 9, 2007, and the regulations in 21 CFR 558.355 are amended to reflect the approval.

In addition, the regulations are being amended to remove a redundant entry for combination use of monensin USP and melengestrol acetate, with or without tylosin phosphate, in medicated feed for heifers fed in confinement for slaughter. This action is being taken to improve the clarity of the regulations.

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 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 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

■ 2. In § 558.355, remove and reserve paragraphs (d)(2), (d)(3), and (f)(3)(viii); and revise paragraph (f)(6)(i)(*b*)(*1*) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(6) * * *

(i) * * *

(*b*) * * *

(*1*) *Feed continuously*. Feed only to goats being fed in confinement. Do not