■ 33. Amend § 406.133 by revising paragraph (a) introductory text to read as follows:

§ 406.133 Amendments of pleadings.

(a) *Time.* A party must file with the Federal Docket Management System and serve on each other party any amendment to a complaint or an answer as follows:

* * * * *

■ 34. Amend § 406.137 by revising paragraph (a) to read as follows:

§ 406.137 Intervention.

(a) A person may file with the Federal Docket Management System and serve on each other party a motion for leave to intervene as party in an adjudication. Except for good cause shown, a motion for leave to intervene must be filed not later than 10 days before the hearing.

* * * * *

■ 35. Amend § 406.139 by revising paragraphs (b) introductory text and (d) to read as follows:

§ 406.139 Joint procedural or discovery schedule.

* * * * *

(b) *Form and content of schedule.* If the parties agree to a joint procedural or discovery schedule, one of the parties must file with the Federal Docket Management System and serve the joint schedule, setting forth the dates to which the parties have agreed. One of the parties must draft an order establishing a joint schedule for the administrative law judge.

* * * * *

(d) *Order establishing joint schedule.* The administrative law judge must approve the joint schedule filed by the parties by signing the joint schedule and filing it with the Federal Docket Management System.

* * * * *

■ 36. Amend § 406.141 by revising paragraph (c) to read as follows:

§ 406.141 Motions.

* * * * *

(c) *Form and time.* Except for oral motions heard on the record, a motion made prior to the hearing must be in writing. Unless otherwise agreed by the parties or for good cause shown, a party must file any prehearing motion with the Federal Docket Management System and serve each other party not later than 30 days before the hearing.

* * * * *

■ 37. Amend § 406.143 by revising the second sentence in paragraph (b) and by revising the first sentence in paragraph (j)(3) to read as follows:

§ 406.143 Discovery.

* * * * *

(b) * * * A party is not required to file written interrogatories and responses, requests for production of documents or tangible items and responses, and requests for admission and responses with the Federal Docket Management System or submit any of them to the administrative law judge. * * *

* * * * *

(j) * * *

(3) *Notice of deposition.* A party must serve a notice of deposition, stating the time and place of the deposition and the name and address of each person to be examined, on the person to be deposed, must submit the notice to the administrative law judge, and must file the notice with the Federal Docket Management System, and must serve the notice on each party, not later than 7 days before the deposition. * * *

* * * * *

■ 38. Amend § 406.173 by revising the first and second sentence in paragraph (d) to read as follows:

§ 406.173 Interlocutory appeals.

* * * * *

(d) *Procedure.* A party must file with the Federal Docket Management System and serve each other party a notice of interlocutory appeal, with supporting documents, not later than 10 days after the administrative law judge's decision forming the basis of an interlocutory appeal of right or not later than 10 days after the administrative law judge's decision granting an interlocutory appeal for cause. A party must file with the Federal Docket Management System a reply brief, if any, and serve a copy of the reply brief on each party, not later than 10 days after service of the appeal brief. * * *

* * * * *

■ 39. Amend § 406.175 by revising paragraphs (a), (d) introductory text, and (e) introductory text, by revising the third sentence in paragraph (f), and by revising paragraph (g) to read as follows:

§ 406.175 Appeal from initial decision.

(a) *Notice of appeal.* A party may appeal the initial decision, and any decision not previously appealed pursuant to § 406.173, by filing with the Federal Docket Management System and serving on each party a notice of appeal. A party must file the notice of appeal not later than 10 days after entry of the oral initial decision on the record or service of the written initial decision on the parties.

* * * * *

(d) *Appeal briefs.* A party must file the appeal brief with the Federal Docket Management System and serve each party.

* * * * *

(e) *Reply brief.* Unless otherwise agreed by the parties, any party may file a reply brief with the Federal Docket Management System and serve on each other party not later than 35 days after the appeal brief has been served on that party. If the party relies on evidence contained in the record for the reply, the party must specifically refer to the pertinent evidence contained in the record in the reply brief.

* * * * *

(f) * * * A party may file with the Federal Docket Management System a motion for permission to file an additional brief and must serve a copy of the motion on each other party. * * *

(g) *Number of copies.* A party must file the original brief and two copies of the brief with the Federal Docket Management System and serve one copy on each other party.

* * * * *

■ 40. Amend § 406.177 by revising the second sentence in paragraph (a) to read as follows:

§ 406.177 Petition to reconsider or modify a final decision and order of the FAA decisionmaker on appeal.

(a) * * * A party must file a petition to reconsider or modify with the Federal Docket Management System not later than 30 days after service of the FAA decisionmaker's final decision and order on appeal and must serve a copy of the petition on each party. * * *

* * * * *

Issued in Washington, DC on November 28, 2007.

Pamela Hamilton-Powell,

Director, Office of Rulemaking, Aviation Safety.

[FR Doc. E7–23422 Filed 12–4–07; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Carprofen

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 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.