a petition is classified, as identified by documentation supplied to the Commission and any supporting information obtained by the Commission.

(2) A determination of whether or not domestic production of the article that is the subject of the petition exists, taking into account the report of the Secretary of Commerce under section 3(c)(1) of the Act, and, if such production exists, whether or not a domestic producer of the article objects to the duty suspension or reduction. (3) A determination of whether or not the duty suspension or reduction is available to any person that imports the article that is the subject of the duty suspension or reduction.

(4) An estimate of the amount of loss in revenue to the United States that would no longer be collected if the duty suspension or reduction takes effect.

(5) A determination of whether or not the duty suspension or reduction is available to any person that imports the article that is the subject of the duty suspension or reduction.

(6) The likely beneficiaries of each duty suspension or reduction, including whether the petitioner is a likely beneficiary.

(b) The preliminary report will also include the following information:

(1) A list of petitions for duty suspensions and reductions that meet the requirements of the Act without modifications.

(2) A list of petitions for duty suspensions and reductions for which the Commission recommends technical corrections (i.e., corrections to the article description that do not otherwise substantially alter the scope or HTS classification of the articles covered by the petition) in order to meet the requirements of the Act, with the correction specified.

(3) A list of petitions for duty suspensions and reductions for which the Commission recommends modifications to the scope of the articles that are the subject of the petitions in order to address objections by domestic producers to such petitions, with the modifications specified.

(5) A list of the following:

(i) Petitions for duty suspensions and reductions that the Commission has determined do not contain the information required under section 3(b)(2) of the Act.

(ii) Petitions for duty suspensions and reductions with respect to which the Commission has determined the petitioner is not a likely beneficiary.

(iii) The duty suspension or reduction that is the subject of the petition exists, whether or not a domestic producer of the article objects to the duty suspension or reduction.

(iv) The estimated loss in revenue to the United States from the duty suspension or reduction does not exceed $500,000 in a calendar year during which the duty suspension or reduction would be in effect; and

(v) The duty suspension or reduction is available to any person importing the articles that is the subject of the duty suspension or reduction.

(b) Exceptions. (1) In calculating the estimated revenue loss required under the Act, the Commission may base its estimates in whole or in part on the estimated values of imports submitted by petitioners in their petitions.

(2) The Commission may disclose some or all of the confidential business information provided to the Commission in petitions and public comments to the U.S. Department of Commerce for use in preparing its report to the Commission and the Committees, and to the U.S. Department of Agriculture and CBP for use in providing information for Commerce’s report.

§ 220.14 Application of other Commission rules.

Commission rules applicable to the initiation and conduct of investigations, including rules set out in subpart B of part 201 of this chapter (except § 201.9 (methods employed in obtaining information), § 201.14(a) (computation of time), and § 201.15 (attorneys or agents)), shall not apply to Commission proceedings under this part.

By order of the Commission.

Issued: September 21, 2016.

Lisa R. Barton,
Secretary to the Commission.

[FR Doc. 2016–23229 Filed 9–29–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, and 558

[Docket No. FDA–2016–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Change of Sponsor’s Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA, we) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during July and August 2016. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect a change of a sponsor’s address.
FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during July and August 2016, as listed in table 1. In addition, FDA is informing the public of the availability of the regulations to amend part 558 (21 CFR part 558) to remove these DLCs. Also, FDA is amending the animal drug regulations to revise a human food safety warning for tulathromycin injectable solution in 21 CFR 522.2630 and to correct a cross-reference for combination medicated feeds in §558.128 (21 CFR 558.128). These actions are being taken to improve the accuracy of the regulations.

The restrictions for veterinary feed directive (VFD) drugs in part 558 are being revised to reflect a uniform text. In addition, we are revising §558.59 to reflect a current format. These actions are being taken to improve the clarity of the regulations. 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 Parts 520, 522, 524, and 529

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

**TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING JULY AND AUGUST 2016**

<table>
<thead>
<tr>
<th>Approval date</th>
<th>File No.</th>
<th>Sponsor</th>
<th>Product name</th>
<th>Species</th>
<th>Effect of the action/indications for use</th>
<th>Public documents</th>
</tr>
</thead>
<tbody>
<tr>
<td>July 20, 2016</td>
<td>141–459</td>
<td>Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.</td>
<td>BRAVECTO (fluralaner topical solution) for Dogs.</td>
<td>Dogs, cats</td>
<td>Original approval for killing adult fleas, for the treatment and prevention of flea infestations, and for the treatment and control of tick infestations in dogs and cats.</td>
<td>FOI Summary.</td>
</tr>
</tbody>
</table>
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, 520, 522, 524, 529, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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


§510.600 [Amended]

2. Revise §510.600 as follows:

a. In the table in paragraph (c)(1):
   i. In the entries for “Cronus Pharma LLC”, “HQ Specialty Pharma Corp.”, “OXIS International, Inc.”, “Pharmage LLC”, “Putney, Inc.”, “SmartVet USA, Inc.”, and “Wildlife Laboratories, Inc.”, remove “Suite” and in its place add “suite”;
   ii. In the entry for “Merial, Inc.”, remove “Bldg.” and in its place add “bldg.”;
   iii. In the entry for “Nexcyon Pharmaceuticals, Inc.”, remove “644 West Washington Ave., Madison, WI 53719” and in its place add “P.O. Box 259158, Madison, WI 53725”;

b. In the table in paragraph (c)(2):
   i. In the entries for “024991”, “026637”, “042791”, “053923”, “069043”, “069254”, and “086001”, remove “Suite” and in its place add “suite”;
   ii. In the entry for “050604”, remove “Bldg.” and in its place add “bldg.”;
   iii. In the entry for “050929”, remove “644 West Washington Ave., Madison, WI 53719” and in its place add “P.O. Box 259158, Madison, WI 53725”.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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


4. In §520.928, revise paragraph (c) to read as follows:

§520.928 Firocoxib tablets.

(c) Conditions of use—(1) Dogs—(i) Amount. 5 mg/kg (2.27 mg/lb) body weight. Administer once daily for osteoarthritis. Administer approximately 2 hours before soft tissue or orthopedic surgery.

(ii) Indications for use. For the control of pain and inflammation associated with osteoarthritis; and for the control of postoperative pain and inflammation associated with soft-tissue and orthopedic surgery.

(iii) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) Horses—(i) Amount. Administer one 57-mg tablet to horses weighing 800 to 1,300 lb once daily for up to 14 days.

(ii) Indications for use. For the control of pain and inflammation associated with osteoarthritis.

(iii) Limitations. Do not use in horses intended for human consumption.

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

6. The authority citation for part 522 continues to read as follows:


7. Add §522.224 to read as follows:

§522.224 Bupivacaine.

(a) Specifications. Each milliliter (mL) of liposomal suspension contains 13.3 milligrams (mg) bupivacaine.

(b) Sponsor. See No. 086002 in §510.600(c) of this chapter.

(c) Conditions of use in dogs—(1) Amount. Administer 5.3 mg/kg (0.4 mL/kg) by infiltration injection into the tissue layers at the time of incisional closure.

(2) Indications for use. For single-dose infiltration into the surgical site to provide local postoperative analgesia for cranial cruciate ligament surgery in dogs.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

8. In §522.1870, revise paragraphs (a), (c)(1)(i) and (iii), and (c)(2)(i) and (iii) to read as follows:

§522.1870 Praziquantel.

(a) Specifications. Each milliliter (mL) of solution contains 56.8 milligrams of praziquantel.

* * * * *

(c) * * * * *

(1) * * *

(i) Amount. Administer by subcutaneous or intramuscular injection for cats and kittens under 5 lb, 0.2 mL; 5 to 10 lb, 0.4 mL; 11 lb and over, 0.6 mL maximum.

* * * * *

(iii) Limitations. Federal law restricts the drug to use by or on the order of a licensed veterinarian.

(2) * * * *

(i) Amount. Administer by subcutaneous or intramuscular injection for cats and kittens under 5 lb, 0.2 mL; 5 to 10 lb, 0.4 mL; 11 lb and over, 0.6 mL maximum.

* * * * *

(ii) Indications for use. For the control of pain and inflammation associated with osteoarthritis.

(3) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

9. In §522.2630, revise paragraph (d)(1)(iii)(A) to read as follows:

§522.2630 Tulathromycin.

(A) Cattle intended for human consumption must not be slaughtered within 18 days from the last treatment. This drug is not approved for use in female dairy cattle 20 months of age or older, including dry dairy cows. Use in these cattle may cause drug residues in milk and/or in calves born to these cows. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

* * * * *

10. Revise §522.2640 to read as follows:

§522.2640 Tylosin.

(a) Specifications. Each milliliter (mL) of solution contains 50 or 200 milligrams (mg) of tylosin activity (as tylosin base).

(b) Sponsors. See sponsors in §510.600(c) of this chapter as follows:

(1) No. 0000986 for use of 50- or 200-mg/mL solutions as in paragraph (e) of this section.

(2) Nos. 000010 and 061623 for use of a 200-mg/mL solution as in paragraphs (e)(1) and (2) of this section.

(c) Related tolerances. See §556.740 of this chapter.

(d) Special considerations. Labeling must bear the warning statements: “Do not administer to horses or other equines. Injection of tylosin in equines has been fatal.”

(e) Conditions of use—(1) Beef cattle and nonlactating dairy cattle—(i) Amount. Administer 8 mg per pound (mg/lb) of body weight by intramuscular injection once daily for not more than 5 consecutive days. Continue treatment 24 hours after symptoms disappear.

(ii) Indications for use. Treatment of bovine respiratory complex (shipping fever, pneumonia) usually associated with Pasteurella multocida and Arcanobacterium pyogenes; foot rot (necrotic pododermatitis) and calf diphtheria caused by Fusobacterium necrophorum and metritis caused by A. pyogenes.
PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

11. The authority citation for part 524 continues to read as follows:

12. Add § 524.998 to read as follows:

§ 524.998 Fluralaner.
(a) Specifications. Each milliliter of solution contains 280 milligrams (mg) fluralaner.
(b) Sponsor. See No. 000061 in § 510.600(c) of this chapter.
(c) Conditions of use—(1) Dogs—(i) Amount. Administer 4 mg/lb of body weight by intramuscular injection twice daily for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. If tylosin medicated drinking water is used as a followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.
(ii) Indications for use. Treatment of swine arthritis caused by Mycoplasma hyosynoviae; swine pneumonia caused by Pasteurella spp.; swine erysipelas caused by Erysipelothrix rhusiopathiae; swine dysentery associated with Treponema hydysenteriae when followed by appropriate medication in the drinking water and/or feed.
(iii) Limitations. Do not inject more than 5 mL per site. Adverse reactions, including shock and death may result from overdosage in baby pigs. It is recommended that tylosin 50-mg/mL injection be used in pigs weighing less than 25 lbs. Swine intended for human consumption must not be slaughtered within 14 days of the last use of this drug product.
(2) Swine—(i) Amount. Administer 4 mg/lb of body weight by intramuscular injection twice daily for not more than 3 consecutive days. Continue treatment 24 hours after symptoms disappear. If tylosin medicated drinking water is used as a followup treatment for swine dysentery, the animal should thereafter receive feed containing 40 to 100 grams of tylosin per ton for 2 weeks to assure depletion of tissue residues.
(ii) Indications for use. Treatment of swine arthritis caused by Mycoplasma hyosynoviae; swine pneumonia caused by Pasteurella spp.; swine erysipelas caused by Erysipelothrix rhusiopathiae; swine dysentery associated with Treponema hydysenteriae when followed by appropriate medication in the drinking water and/or feed.
(iii) Limitations. Do not inject more than 5 mL per site. Adverse reactions, including shock and death may result from overdosage in baby pigs. It is recommended that tylosin 50-mg/mL injection be used in pigs weighing less than 25 lbs. Swine intended for human consumption must not be slaughtered within 14 days of the last use of this drug product.
(3) Dogs and cats—(i) Amount. Administer 3 to 5 mg/lb of body weight by intramuscular injection at 12- to 24-hour intervals.
(ii) Indications for use—(A) Dogs. Treatment of upper respiratory infections such as bronchitis, tracheobronchitis, tracheitis, laryngitis, tonsillitis, and pneumonia caused by Staphylococci spp., hemolytic Streptococci spp., and Pasteurella multocida.
(B) Cats. Treatment of upper respiratory infections when caused by Staphylococci spp. and hemolytic Streptococci spp. and for feline pneumonia when caused by tylosin-resistant organisms.
(iii) Limitations. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

13. The authority citation for part 529 continues to read as follows:

§ 529.400 [Amended]
14. In § 529.400, in paragraph (a), remove footnote 1.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

15. The authority citation for part 558 continues to read as follows:

§ 558.58 [Amended]
16. In § 558.58, in paragraph (e)(6), remove “3.6” and in its place add “36.6”.
17. Revise § 558.59 to read as follows:

§ 558.59 Apramycin.
(a) Specifications. Each pound of Type A article contains 75 grams apramycin (as apramycin sulfate).
(b) Sponsor. See No. 058198 in § 510.600(c) of this chapter.
(c) [Reserved]
(d) Related tolerances. See § 556.52 of this chapter.
(e) Conditions of use in swine—(1) Amount. Feed at 150 grams apramycin per ton of Type C medicated feed as the sole ration for 14 consecutive days.
(2) Indications for use. For control of porcine colibacillosis (weanling pig scours) caused by susceptible strains of Escherichia coli.
(3) Limitations. Withdraw 28 days before slaughter.

§ 558.68 [Amended]
18. In § 558.68, redesignate paragraphs (c) and (d) as paragraphs (d) and (c); and in paragraphs (o)(1)(i) and (o)(2)(i), remove “000986” and in its place add “058198”.

§ 558.128 [Amended]
19. In § 558.128, in paragraph (o)(7)(xi), remove “§ 558.600” and in its place add “§ 558.612”.

§ 558.195 [Amended]
20. In § 558.195, in paragraph (o)(1)(vi), remove “000009” and in its place add “054771”; and in paragraphs (o)(2)(iii) and (v), remove “000986” wherever it appears and in its place add “058198”.

§ 558.261 [Amended]
21. In § 558.261, redesignate paragraphs (c) and (d) as paragraphs (d) and (c).

§ 558.295 [Amended]
22. In § 558.295, remove and reserve paragraph (b).
23. In § 558.325, revise paragraph (d)(3) to read as follows:

§ 558.325 Lincomycin.
* * * * *
(d) * * *
(3) Labeling of Type A medicated articles and single-ingredient Type B and Type C medicated feeds containing lincomycin intended for use in swine shall bear the following caution statement: “The effects of lincomycin on swine reproductive performance, pregnancy, and lactation have not been determined. Not for use in swine intended for breeding when lincomycin is fed at 20 grams per ton of complete feed.”
* * * * *

§ 558.342 [Amended]
24. In § 558.342, in paragraphs (e)(1)(iv),(ix), (x), and (xi), remove
“000986” wherever it appears and in its place add “058198”.

§ 558.366 [Amended]
25. In § 558.366, in paragraph (d), in the entry for “113.5 (0.0125 pct)”, remove “000986” and in its place add “058198”.

§ 558.618 [Amended]
26. In § 558.618, redesignate paragraphs (c) and (d) as paragraphs (d) and (c).
27. In § 558.633, revise paragraph (d)(1) to read as follows:

§ 558.633 Tyvalocin.
* * * * *
(d) * * *
(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.
* * * * *

Dated: September 21, 2016.

Tracey Forfa,
Deputy Director, Center for Veterinary Medicine.

[FR Doc. 2016–23230 Filed 9–29–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2014–F–0988]

Food Additives Permitted in Feed and Drinking Water of Animals; Feed Grade Sodium Formate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of feed grade sodium formate as a feed acidifying agent in complete swine feeds. This action is in response to a feed additive petition filed by BASF Corp.

DATES: This rule is effective September 30, 2016. Submit either electronic or written objections and requests for a hearing by October 31, 2016. See section V of this document for further information on the filing of objections.

ADDRESSES: You may submit objections and requests for a hearing as follows:

Electronic Submissions
Submit electronic objections in the following way:
• Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Objections submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else’s Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on http://www.regulations.gov.
• If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

Written/Paper Submissions
Submit written/paper submissions as follows:
• Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
• For written/paper objections submitted to the Division of Dockets Management, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA–2014–F–0988 for “Food Additives Permitted in Feed and Drinking Water of Animals; Feed Grade Sodium Formate.” Received objections will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Confidential Submissions—To submit an objection with confidential information that you do not wish to be made publicly available, submit your objections only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your objections and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public docks, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper objections received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Chelsea Trull, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–6729, chelsea.trull@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:
I. Background

In a document published in the Federal Register of July 25, 2014 (79 FR 43325), FDA announced that we had filed a food additive petition (animal use) (FAP 2286) submitted by BASF Corp., 100 Park Ave., Florham Park, NJ 07932. The petition proposed that the regulations for food additives permitted in feed and drinking water of animals be amended to provide for the safe use of feed grade sodium formate as a feed acidifying agent in complete swine feeds. The notice of petition provided for a 30-day comment period on the petitioner’s request for categorical exclusion from preparing an environmental assessment or environmental impact statement.

FDA is amending the regulations for food additives permitted in feed and drinking water of animals; feed grade sodium formate as a feed acidifying agent in complete swine feeds.

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