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) Any technical changes to the description of the article that is the subject of the petition for the duty suspension or reduction that are necessary for purposes of administration when the article is presented for importation, taking into account the report of the Secretary of Commerce under section 3(c)(2) of the Act.

(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 amount of the duty suspension or reduction that is the subject of the petition to comply with the requirements of the Act, with the modification specified.

(4) 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.

(6) A list of petitions for duty suspensions and reductions that the Commission does not recommend for inclusion in a miscellaneous tariff bill, other than petitions specified in section 3(b)(3)(C)(ii)(V) of the Act.

(c) The Commission will forward to the Committees any additional information submitted to the Commission by the Secretary of Commerce after the Commission transmits its preliminary report.

§ 220.12 Commission final report.

(a) The Commission will submit its final report on each petition for a duty suspension or reduction specified in the preliminary report to the Committees not later than 60 days after the Commission submits its preliminary report. The final report will contain the following information—

(1) The information required to be included in a preliminary report under section 3(b)(3)(C)(i)–(ii) of the Act and updated as appropriate after considering any information submitted by the Committees under section 3(b)(3)(D) of the Act.

(2) A determination of the Commission whether—

(i) The duty suspension or reduction can likely be administered by U.S. Customs and Border Protection;

(ii) 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

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

(b) [Reserved]

§ 220.13 Confidential business information.

(a) *In general.* The Commission will not release information which the Commission considers to be confidential business information within the meaning of § 201.6(a) of this chapter unless the party submitting the confidential business information had notice, at the time of submission, that such information would be released by the Commission, or such party subsequently consents to the release of the information.

(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.

DATES: This rule is effective September 30, 2016.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval Actions

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, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents 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. Persons with access to the Internet may obtain these documents at the CVM FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

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

Approval date	File No.	Sponsor	Product name	Species	Effect of the action/ indications for use	Public documents
July 24, 2016	141–458	Merial, Inc., 3239 Satellite Blvd., bldg. 500, Duluth, GA 30096–4640.	EQUIOXX (firocoxib) Tablets.	Horses	Original approval for the control of pain and inflammation associated with osteoarthritis in horses.	FOI Summary.
July 20, 2016	141–459	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	BRAVECTO (fluralaner topical solution) for Dogs. BRAVECTO (fluralaner topical solution) for Cats.	Dogs, cats	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.	FOI Summary.
August 12, 2016	141–461	Aratana Therapeutics, Inc., 11400 Tomahawk Creek Pkwy., Leawood, KS 66211.	NOCITA (bupivacaine liposome injectable suspension).	Dogs	Original approval to provide local postoperative analgesia for cranial cruciate ligament surgery in dogs.	FOI Summary.
July 1, 2016	200–501	Cross Vetpharm Group Ltd. Broomhill Rd., Tallaght, Dublin 24, Ireland.	Praziquantel (praziquantel) Injection.	Dogs	Original approval of a generic copy of NADA 111–607.	FOI Summary.
August 5, 2016	200–508	Cross Vetpharm Group Ltd. Broomhill Rd., Tallaght, Dublin 24, Ireland.	BILOVET (tylosin) Injection.	Cattle, swine	Original approval of a generic copy of NADA 012–965.	FOI Summary.

II. Change of Sponsor's Address

Nexcyon Pharmaceuticals, Inc., 644 West Washington Ave., Madison, WI 53719 has informed FDA that it has changed its address to P.O. Box 259158, Madison, WI 53725. Accordingly, the regulations at 21 CFR 510.600(c) will be amended to reflect this sponsor's change of address.

III. Technical Amendments

FDA has noticed that drug labeler codes (DLCs) in several sections of part 558 (21 CFR part 558) do not accurately reflect the sponsorship of a new animal drug application. At this time, we are amending part 558 to remove these DLCs. Also, FDA is amending the 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.

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:

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

§ 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.'', ''Pharmgate 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.''; and
■ 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:

Authority: 21 U.S.C. 360b

■ 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.

§ 520.2345c [Amended]

■ 5. In § 520.2345c, remove paragraph (d)(1)(iii).

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 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. 086026 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 dogs and puppies 5 pounds (lb) and under, 0.3 mL; for 6 to 10 lb, 0.5 mL; for 11 to 25 lb, 1.0 mL; if over 25 lb, 0.2 mL/5 lb body weight to a maximum of 3 mL.

* * * * *

(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.

* * * * *

(iii) *Limitations.* Federal law restricts the 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.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(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. 000986 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.*

(iii) *Limitations.* Do not inject more than 10 mL per site. Use a 50-mg/mL solution for calves weighing less than 200 pounds. Cattle intended for human consumption must not be slaughtered within 21 days of the last use of this drug product. This drug product 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. This product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in preruminating calves.

(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 hyodysenteriae* 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 pneumonitis when caused by tylosin-susceptible organisms.

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

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 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 topically as a single dose every 12 weeks according to the label dosage schedule to provide a minimum dose of 11.4 mg/lb (25 mg/kg) body weight. May be administered every 8 weeks in case of potential exposure to *Amblyomma americanum* ticks.

(ii) *Indications for use.* Kills adult fleas; for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Ixodes scapularis* (black-legged tick), *Dermacentor variabilis* (American dog tick), and *Rhipicephalus sanguineus* (brown dog tick)) for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater; for the treatment and control of *A. americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lb or greater.

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

(2) [Reserved]

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 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:

Authority: 21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

§ 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 (e)(1)(i) and (e)(2)(i), remove ''000986'' and in its place add ''058198''.

§ 558.128 [Amended]

■ 19. In § 558.128, in paragraph (e)(7)(xi), remove ''§ 558.600'' and in its place add ″§ 558.612″.

§ 558.195 [Amended]

■ 20. In § 558.195, in paragraph (e)(1)(vi), remove ''000009'' and in its place add ''054771''; and in paragraphs (e)(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 Tylvalocin.

* * * * *

(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 food 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 dockets, 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.