proposed rulemaking, providing an opportunity for public comment.

G. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires that agencies review proposed and final rules for their potential economic impact on small entities, including small businesses, and prepare regulatory flexibility analyses. 5 U.S.C. 603 and 604. The RFA applies to any rule that is subject to notice and comment procedures under section 553 of the APA. *Id.* As explained, the Commission has determined that notice and comment are not necessary for this direct final rule. Thus, the RFA does not apply. We also note the limited nature of this document, which merely updates the incorporation by reference to reflect the mandatory CPSC standard that takes effect under section 104 of the CPSIA.

H. Paperwork Reduction Act

The standard for children's folding chairs and stools contains information-collection requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The revisions made no changes to that section of the standard. Thus, the revisions will have no effect on the information-collection requirements related to the standard.

I. Environmental Considerations

The Commission's regulations provide a categorical exclusion for the Commission's rules from any requirement to prepare an environmental assessment or an environmental impact statement where they ''have little or no potential for affecting the human environment.'' 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required.

J. Preemption

Section 26(a) of the CPSA, 15 U.S.C. 2075(a), provides that where a consumer product safety standard is in effect and applies to a product, no state or political subdivision of a state may either establish or continue in effect a requirement dealing with the same risk of injury unless the state requirement is identical to the federal standard. Section 26(c) of the CPSA also provides that states or political subdivisions of states may apply to the CPSC for an exemption from this preemption under certain circumstances. Section 104(b) of the CPSIA deems rules issued there under ''consumer product safety rules.'' Therefore, once a rule issued under section 104 of the CPSIA takes effect, it will preempt in accordance with section 26(a) of the CPSA.

K. Effective Date

Under the procedure set forth in section 104(b)(4)(B) of the CPSIA, when a voluntary standard organization revises a standard upon which a consumer product safety standard was based, the revision becomes the CPSC standard within 180 days of notification to the Commission, unless the Commission determines that the revision does not improve the safety of the product, or the Commission sets a later date in the **Federal Register**. The statutory effective date of 180 days falls on July 4, 2020, a legal holiday and a weekend. Therefore, the Commission is setting the effective date of the rule on the next business day, July, 6, 2020. As discussed in the preceding section, this is a direct final rule. Unless we receive a significant adverse comment within 30 days, the rule will become effective on July 6, 2020.

L. The Congressional Review Act

The Congressional Review Act (CRA; 5 U.S.C. 801–808) states that, before a rule may take effect, the agency issuing the rule must submit the rule, and certain related information, to each House of Congress and the Comptroller General. 5 U.S.C. 801(a)(1). The submission must indicate whether the rule is a ''major rule.'' The CRA states that the Office of Information and Regulatory Affairs (OIRA) determines whether a rule qualifies as a ''major rule.'' Pursuant to the CRA, this rule does not qualify as a ''major rule,'' as defined in 5 U.S.C. 804(2). To comply with the CRA, the Office of the General Counsel will submit the required information to each House of Congress and the Comptroller General.

List of Subjects in 16 CFR Part 1232

Consumer protection, Imports, Incorporation by reference, Infants and children, Law enforcement, Safety, Toys.

For the reasons stated above, the Commission amends Title 16 CFR chapter II as follows:

PART 1232—SAFETY STANDARD FOR CHILDREN'S FOLDING CHAIRS AND STOOLS

■ 1. Revise the authority citation for part 1232 to read as follows:

Authority: Sec. 104, Pub. L. 110–314, 122 Stat. 3016 (15 U.S.C. 2056a); Sec 3, Pub. L. 112–28, 125 Stat. 273.

■ 2. Revise § 1232.2 to read as follows:

§ 1232.2 Requirements for children's folding chairs and stools.

Each children's folding chair and stool shall comply with all applicable provisions of ASTM F2613–19, *Standard Consumer Safety Specification for Children's Chairs and Stools,* approved on November 1, 2019. The Director of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain a copy of this ASTM standard from ASTM International, 100 Barr Harbor Drive, P.O. Box C700, West Conshohocken, PA 19428–2959 USA; phone: 610–832–9585; *www.astm.org.* A read-only copy of the standard is available for viewing on the ASTM website at *https://www.astm.org/READINGLIBRARY/.* You may inspect a copy at the Division of the Secretariat, U.S. Consumer Product Safety Commission, Room 820, 4330 East-West Highway, Bethesda, MD 20814, telephone 301–504–7923, or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html.*

Alberta E. Mills,

Secretary, U.S. Consumer Product Safety Commission.

[FR Doc. 2020–06334 Filed 3–31–20; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 500, 510, 520, 522, 524, 526, 556, and 558

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawal of Approval of New Animal Drug Applications; Change of Sponsor; Change of Sponsors' Name and Addresses

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA or 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 October, November, and December 2019. FDA is 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 make technical amendments to improve the accuracy of the regulations.

DATES: This rule is effective March 30, 2020.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7500 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 October, November, and December 2019, 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 office of the Dockets Management Staff (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: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room*. Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book*.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2019

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 11, 2019.	200–652	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sophia, Bulgaria.	Monensin and decoquinate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with DECCOX (decoquinate) Type A medicated articles in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–148	FOI Summary.
October 11, 2019.	200–653	Do	Monensin, tylosin phosphate, and decoquinate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with TYLOVET (tylosin phosphate) and DECCOX (decoquinate) Type A medicated articles in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–149	FOI Summary.
October 11, 2019.	200–654	Do	Monensin and tilmicosin phosphate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with TILMOVET (tilmicosin phosphate) Type A medicated article in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–343	FOI Summary.
October 11, 2019.	200–655	Do	Monensin and tilmicosin phosphate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with PULMOTIL (tilmicosin phosphate) Type A medicated article in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–343	FOI Summary.
October 11, 2019.	200–656	Do	Monensin, tylosin phosphate, and decoquinate Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with TYLAN (tylosin phosphate) and DECCOX (decoquinate) Type A medicated articles in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–149	FOI Summary.
October 11, 2019.	200–658	Do	Monensin and melengestrol acetate Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with MGA (melengestrol acetate Type A medicated article) in the manufacture of Type C medicated feeds as a generic copy of NADA 125–476	FOI Summary.
October 11, 2019.	200–659	Do	Monensin, ractopamine hydrochloride, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with ACTOGAIN (ractopamine hydrochloride Type A medicated article) and MGA (melengestrol acetate Type A medicated articles) in the manufacture of Type C medicated feeds as a generic copy of NADA 141–234	FOI Summary.
October 11, 2019.	200–660	Do	Monensin, tylosin phosphate, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with TYLOVET (tylosin phosphate) Type A medicated article, and MGA (melengestrol acetate Type A medicated article) in the manufacture of Type C medicated feeds as a generic copy of NADA 138–870	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING OCTOBER, NOVEMBER, AND DECEMBER 2019—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
October 11, 2019.	200–661	Do	Monensin, tylosin phosphate, and melengestrol acetate Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with TYLAN (tylosin phosphate) Type A medicated article, and MGA (melengestrol acetate Type A medicated article) in the manufacture of Type C medicated feeds as a generic copy of NADA 138–870	FOI Summary.
October 11, 2019.	200–662	Do	Monensin and ractopamine hydrochloride Type B and Type C medicated feeds.	Cattle	Original approval for use of MONOVET 90 (monensin Type A medicated article) with ACTOGAIN (ractopamine hydrochloride Type A medicated article) in the manufacture of Type B and Type C medicated feeds as a generic copy of NADA 141–225	FOI Summary.
October 29, 2019.	200–635	Mizner Bioscience LLC, 225 NE Mizner Blvd., Suite 760, Boca Raton, FL 33432.	Clomipramine Hydrochloride Tablets.	Dogs	Original approval as a generic copy of NADA 141–120	FOI Summary.
November 14, 2019.	141–518	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	BRAVECTO PLUS (fluralaner and moxidectin topical solution) Solution.	Cats	Original approval for the prevention of heartworm disease and for the treatment of infections with intestinal roundworm and hookworm; kills adult fleas and is indicated for the treatment and prevention of flea infestations, and the treatment and control of tick infestations for 2 months in cats and kittens	FOI Summary.
November 20, 2019.	200–663	Norbrook Laboratories Ltd., Station Works, County Down, Newry, BT35 6JP, UK.	SELARID (selamectin) Topical Solution.	Dogs and cats.	Original approval as a generic copy of NADA 141–152	FOI Summary.
November 25, 2019.	141–513	Kindred Biosciences, Inc., 1555 Bayshore Hwy., Suite 200, Burlingame, CA 94010.	ZIMETA (dipyrone injection).	Horses	Original approval for control of pyrexia in horses	FOI Summary.
December 9, 2019.	141–528	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	CREDELIO CAT (lotilaner) Chewable Tablets.	Cats	Original approval for killing adult fleas, and for the treatment and prevention of flea infestations for 1 month in cats and kittens	FOI Summary.
December 9, 2019.	200–546	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin, 18, EI.	BIMAGARD 12.5% (tiamulin hydrogen fumarate) Liquid Concentrate for Swine.	Swine	Original approval as a generic copy of NADA 140–916	FOI Summary.
December 19, 2019.	200–615	Vetoquinol USA, Inc., 4250 N. Sylvania Ave., Fort Worth, TX 76137.	IMOXI (imidacloprid and moxidectin) Topical Solution for Dogs.	Dogs	Original approval as a generic copy of NADA 141–251	FOI Summary.
December 30, 2019.	111–636	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LINCOMIX (lincomycin hydrochloride) Soluble Powder.	Honeybees	Supplemental approval of a tolerance for residues of lincomycin in honey	FOI Summary.
December 30, 2019.	008–862	Do	TERRAMYCIN (oxytetracycline hydrochloride) Soluble Powder.	Honeybees	Supplemental approval of a tolerance for residues of oxytetracycline in honey	FOI Summary.
December 30, 2019.	013–076	Elanco US Inc. 2500 Innovation Way, Greenfield, IN 46140.	TYLAN (tylosin tartrate) Soluble.	Honeybees	Supplemental approval of a tolerance for residues of tylosin in honey	FOI Summary.

II. Withdrawals of Approval

Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, has requested that FDA withdraw approval of the NADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Product name	21 CFR section
055–036	PRINCILLIN (ampicillin trihydrate) Capsules	520.90c.
055–050	PRINCILLIN (ampicillin trihydrate) Soluble Powder	520.90e.
055–056	PRINCILLIN (ampicillin trihydrate) Bolus	520.90f.
055–061	PRINCILLIN ''125'' For Oral Suspension	520.90d.
055–068	BOVICLOX (cloxacillin benzathine)	526.464b.
065–013	Dihydrostreptomycin (dihydrostreptomycin sulfate)	522.650.
065–493	JETPEN (penicillin G benzathine and penicillin G procaine) Aqueous Suspension	522.1696a.
065–500	TANDEM PEN (penicillin G procaine)	522.1696b.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 055–036, 055–050, 055–056, 055–061, 055–068, 065–013, 065–493, and 065–500, and all supplements and amendments thereto, is withdrawn, effective March 30, 2020. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these actions.

III. Changes of Sponsor

Cooperative Research Farms, Box 69, Charlotteville, NY 12036, has informed FDA that it has transferred ownership of, and all rights and interest in, approved NADA 119–253 for Cattle Block M (monensin) a free-choice Type C medicated cattle feed to Wildcat Feeds, 215 NE Strait Ave., Topeka, KS 66616. Following this change of sponsorship, Cooperative Research Farms is no longer the sponsor of an approved application.

Dechra, Ltd., Snaygill Industrial Estate, Keighley Rd., Skipton, North Yorkshire, BD23 2RW, United Kingdom, has informed FDA that it has transferred ownership of, and all rights and interest in, approved ANADA 200–273 for VETRO–GEN Veterinary Ophthalmic Ointment to Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101.

Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria, has informed FDA that it has transferred ownership of, and all rights and interest in, approved NADA 141–472 for virginiamycin and diclazuril Type C medicated feed to Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.

Accordingly, we are amending the regulations to reflect these changes.

IV. Change of Sponsors' Name and Addresses

Putney, Inc., One Monument Sq., suite 400, Portland, ME 04101, has informed FDA that it has changed its name and address to Dechra Veterinary Products LLC, 7015 College Blvd., suite 525, Overland Park, KS 66211. In addition, Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137 has informed FDA that it has changed its address to PO Box 162059, Fort Worth, TX 76161. Accordingly, we are amending § 510.600(c) (21 CFR 510.600(c)) to reflect these changes.

V. Technical Amendments

FDA is making the following amendments to improve the readability and accuracy of the animal drug regulations:

- The contact information in 21 CFR 500.1410, which provides for the incorporation by reference of the residue assay method for *n*-methyl-2-pyrrolidone, is being updated.
- We are removing entries for ''Strategic Veterinary Pharmaceuticals, Inc.'' from the lists of sponsors of approved applications in § 510.600(c) and the drug labeler code for KC Pharmacal from 21 CFR 520.260.
- The indications for use of oxytetracycline soluble powder in honey bees at 21 CFR 520.1660d are amended to reflect current labeling.
- The single section for euthanasia injectable solutions at 21 CFR 522.900 is being removed and separate sections for the active pharmaceutical ingredients are added at 21 CFR 522.1697 and 522.2092.
- The section heading in 21 CFR 524.1742 for ''*N*-(Mercaptomethyl) phthalimide *S*-(*O,O*-dimethyl phosphorodithioate) emulsifiable liquid'' is amended to read ''Phosmet emulsifiable liquid''.
- The entries in 21 CFR parts 556 and 558 for coumaphos for which approval of the last approved application was withdrawn in 2018 (83 FR 48940, September 28, 2018) are being removed.
- The entries in part 556 (21 CFR part 556) are being removed for tolerances of residues of erythromycin in swine tissues, of virginiamycin in turkey tissues, and of new animal drugs for which approval of their applications has been withdrawn.
- Cross-references to related approved uses of new animal drugs in part 556 and to related tolerances for drugs approved for use in food-producing animals in 21 CFR parts 520, 522, 524, and 558 are being corrected.
- A redundant cross-reference for related tolerances in 21 CFR 558.355 for use of monensin in medicated feeds is being removed and reserved.
- The acceptable daily intake of total residues of ivermectin and tolerances for residues of ivermectin in cattle liver and muscle in § 556.344 are being corrected.
- The acceptable daily intake of total residues of tildipirosin in § 556.733 is being corrected.
- The regulations in 21 CFR 520.2260b for sulfamethazine sustained-release boluses and in 21 CFR 522.1662a for oxytetracycline hydrochloride injection are being reformatted to present the tolerance cross-reference in a consistent location.
- Typographical errors are being corrected wherever they have been found.

VI. Legal Authority

This final rule is issued under section 512(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C.360b(i)), which requires **Federal Register** publication of ''notice[s] . . . effective as a regulation,'' of the conditions of use of approved new animal drugs. This rule sets forth technical amendments to the regulations to codify recent actions on approved new animal drug applications and corrections to improve the accuracy of the regulations, and as such does not impose any burden on regulated entities.

Although denominated a rule pursuant to the FD&C Act, this document 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. Likewise, this is not a rule subject to Executive Order 12866, which defines a rule as ''an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency.''

List of Subjects

21 CFR Part 500

Animal drugs, Animal feeds, Cancer, Incorporation by reference, Labeling, Packaging and containers, Polychlorinated biphenyls (PCBs).

21 CFR Parts 520, 522, 524, and 526

Animal drugs.

21 CFR Part 556

Animal drugs, Food.

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, 21 CFR parts 500, 510, 520, 522, 524, 526, 556, and 558 are amended as follows:

PART 500—GENERAL

■ 1. The authority citation for part 500 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 353, 360b, 371, 379e.

■ 2. In § 500.1410, revise paragraph (a) to read as follows:

§ 500.1410 N-methyl-2-pyrrolidone.

(a) *Standard for residues.* No residues of *n*-methyl-2-pyrrolidone may be found in the uncooked edible tissues of cattle as determined by a method entitled ''Method of Analysis: *N*-methyl-2-

pyrrolidone,'' September 26, 2011, Center for Veterinary Medicine, Food and Drug Administration, which is incorporated by reference with the approval of the Director of the Federal Register under 5 U.S.C. 522(a) and 1 CFR part 51. To obtain a copy of the analytical method, please submit a Freedom of Information request to: *https://www.accessdata.fda.gov/scripts/foi/FOIRequest/requestinfo.cfm*; or go to: *https://www.fda.gov/about-fda/center-veterinary-medicine/cvm-foia-electronic-reading-room*. You may inspect a copy at the office of the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 301–827–6860, between 9 a.m. and 4 p.m., Monday through Friday or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *www.archives.gov/federal-register/cfr/ibr-locations.html*.

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PART 510—NEW ANIMAL DRUGS

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

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

■ 4. In § 510.600:

■ a. In the table in paragraph (c)(1):

■ i. Remove the entry for ''Cooperative Research Farms'';

■ ii. Add entries for ''Dechra Veterinary Products LLC'' and ''Mizner Bioscience LLC'' in alphabetical order;

■ iii. Remove the entries for ''Putney, Inc.'' and ''Strategic Veterinary Pharmaceuticals, Inc.'';

■ iv. Revise the entry for ''Virbac AH, Inc.''; and

■ v. Add an entry for ''Wildcat Feeds'' in alphabetical order; and

■ b. In the table in paragraph (c)(2):

■ i. Revise the entry for ''026637'';

■ ii. Remove the entry for ''051267'';

■ iii. Revise the entry for ''051311'';

■ iv. Remove the entry for ''054628''; and

■ v. Add entries for ''086039'' and ''086113'' in numerical order.

The revisions and additions 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
* * * * * * *	
Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211	026637
* * * * * * *	
Mizner Bioscience LLC, 225 NE Mizner Blvd., Suite 760, Boca Raton, FL 33432	086039
* * * * * * *	
Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161	051311
* * * * * * *	
Wildcat Feeds, 215 NE Strait Ave., Topeka, KS 66616	086113
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
026637	Dechra Veterinary Products LLC, 7015 College Blvd., Suite 525, Overland Park, KS 66211.
* * * * * * *	
051311	Virbac AH, Inc., PO Box 162059, Fort Worth, TX 76161.
* * * * * * *	
086039	Mizner Bioscience LLC, 225 NE Mizner Blvd., Suite 760, Boca Raton, FL 33432.
* * * * * * *	
086113	Wildcat Feeds, 215 NE Strait Ave., Topeka, KS 66616.
* * * * * * *	

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.88c [Amended]

■ 6. In § 520.88c(c), remove ''§ 556.510'' and in its place add ''§ 556.38''.

§§ 520.90b and 520.90c [Redesignated as §§ 520.90a and 520.90b]

■ 7. Redesignate §§ 520.90b and 520.90c as §§ 520.90a and 520.90b.

§§ 520.90d and 520.90e [Removed]

■ 8. Remove §§ 520.90d and 520.90e.

§ 520.90f [Redesignated as § 520.90c and Amended]

■ 9. Redesignate § 520.90f as § 520.90c and in newly redesignated § 520.90c, revise paragraphs (b) and (d) to read as follows:

§ 520.90c Ampicillin boluses.

* * * * *

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

* * * * *

(d) *Conditions of use in nonruminating calves*—(1) *Amount.* 5 milligrams per pound of body weight twice daily not to exceed 4 days.

(2) *Indications for use.* Oral treatment of bacterial enteritis (colibacillosis) caused by *E. coli.*

(3) *Limitations.* Treated calves must not be slaughtered for food during treatment and for 7 days after the last treatment. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 520.260 [Amended]

■ 10. In § 520.260(b)(2), remove ''No. 038782 for 884 or 1,768 milligram or 4.42 gram capsules;''.

§ 520.455 [Amended]

■ 11. In § 520.455(b), remove ''No. 058198'' and in its place add ''Nos. 058198 and 086039''.

§§ 520.903d and 520.903e [Redesignated as §§ 520.903c and 520.903d]

■ 12. Redesignate §§ 520.903d and 520.903e as §§ 520.903c and 520.903d.

§ 520.1263c [Redesignated as § 520.1263b]

■ 13. Redesignate § 520.1263c as § 520.1263b.

■ 14. Revise § 520.1286 to read as follows:

§ 520.1286 Lotilaner.

(a) *Specifications.* Each chewable tablet contains:

(1) For use in dogs: 56.25, 112.5, 225, 450, or 900 milligrams (mg) lotilaner; or

(2) For use in cats: 12 or 48 mg lotilaner.

(b) *Sponsor.* See No. 058198 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Dogs*—(i) *Amount.* Administer orally once a month at the recommended minimum dosage of 9 mg/lb (20 mg/kg).

(ii) *Indications for use.* Kills adult fleas, and for the treatment and prevention of flea infestations (*Ctenocephalides felis*), and the treatment and control of tick infestations (*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick), and *Rhipicephalus sanguineus* (brown dog tick)) for 1 month in dogs and puppies 8 weeks of age or older and weighing 4.4 pounds or greater.

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

(2) *Cats*—(i) *Amount.* Administer orally once a month at the recommended minimum dosage of 2.7 mg/lb (6 mg/kg).

(ii) *Indications for use.* Kills adult fleas, and for the treatment and prevention of flea infestations (*Ctenocephalides felis*) for 1 month in cats and kittens 8 weeks of age or older and weighing 2 pounds or greater.

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

■ 15. In § 520.1660d, revise paragraph (d)(2)(ii) to read as follows:

§ 520.1660d Oxytetracycline powder.

* * * * *

(d) * * *

(2) * * *

(ii) *Indications for use.* For control of American foulbrood caused by *Paenibacillus larvae.*

* * * * *

§§ 520.1696b, 520.1696c, and 520.1696d [Redesignated as §§ 520.1696a, 520.1696b, and 520.1696c]

■ 16. Redesignate §§ 520.1696b, 520.1696c, and 520.1696d as §§ 520.1696a, 520.1696b, and 520.1696c.

§ 520.2218 [Amended]

■ 17. In § 520.2218(c), remove ''§§ 556.670 and 556.685'' and in its place add ''§§ 556.660, 556.670, and 556.685''.

§ 520.2260b [Amended]

■ 18. In § 520.2260b, redesignate paragraphs (a) through (f) and (g) as paragraphs (b) through (g) and (a), respectively.

■ 19. In § 520.2455, add paragraph (b)(4) to read as follows:

§ 520.2455 Tiamulin.

* * * * *

(b) * * *

(4) No. 061133 for product described in paragraph (a)(2) of this section.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 21. In § 522.650, revise paragraph (b) to read as follows:

§ 522.650 Dihydrostreptomycin sulfate injection.

* * * * *

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

* * * * *

■ 22. Add § 522.728 to read as follows:

§ 522.728 Dipyrone.

(a) *Specifications.* Each milliliter of solution contains 500 milligrams (mg) dipyrone.

(b) *Sponsor.* See No. 086078 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* Administer 30 mg per kilogram of body weight (13.6 mg per pound) by intravenous injection, once or twice daily at a 12-hour interval for up to 3 days.

(2) *Indications for use.* For control of pyrexia in horses.

(3) *Limitations.* Do not use in horses intended for human consumption. Do not use in any food-producing animals, including lactating dairy animals. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§ 522.900 [Removed]

■ 23. Remove § 522.900.

§ 522.1367 [Amended]

■ 24. In § 522.1367(c)(1)(i), remove ''§ 520.1350(c)'' and in its place add ''§ 520.1367(c)''.

§ 522.1662a [Amended]

■ 25. In § 522.1662a:

■ a. Redesignate paragraphs (a) through (e) as paragraphs (b) through (f);

■ b. Further redesignate newly redesignated paragraphs (c)(3)(i)(*a*) through (*c*) and (c)(3)(ii)(*a*) through (*c*) as paragraphs (c)(3)(i)(A) through (C) and (c)(3)(ii)(A) through (C), respectively;

■ c. Further redesignate newly redesignated paragraphs (e)(3)(i)(*a*) through (*c*) as paragraphs (e)(3)(i)(A) through (C);

■ d. Further redesignate newly redesignated paragraphs (e)(3)(ii)(*a*) and (*b*) and paragraphs (e)(3)(ii)(A) and (B);

■ e. Further redesignate newly redesignated paragraphs (e)(3)(iii)(*a*) through (*c*) as paragraphs (e)(3)(iii)(A) through (C);

■ f. In newly redesignated paragraph (e)(3)(iii)(C), remove ''paragraph (d)(3)(iii)(*c*) of this section'' and in its place add ''this paragraph (e)(3)(iii)(C)'';

■ g. Further redesignate newly redesignated paragraphs (f)(3)(i)(*a*) through (*c*) and (f)(3)(ii)(*a*) through (*c*) as paragraphs (f)(3)(i)(A) through (C) and (f)(3)(ii)(A) through (C), respectively;

■ h. Redesignate paragraphs (g)(3)(i)(*a*) through (*c*) and (g)(3)(ii)(*a*) through (*c*) as paragraphs (g)(3)(i)(A) through (C)

and (g)(3)(ii)(A) through (C), respectively; and

■ i. Redesignate paragraph (k) as paragraph (j) and paragraph (l) as paragraph (a).

§ 522.1696a [Amended]

■ 26. In § 522.1696a(b)(1) and (2) and (d)(2)(iii), remove ‘‘, 055529,’’.

§ 522.1696b [Amended]

■ 27. In § 522.1696b:

■ a. In paragraph (b)(1), remove ‘‘016592, 054771, and 055529’’ and in its place add ‘‘016592 and 054771’’;

■ b. Remove paragraphs (d)(2)(i)(A) and (B); and

■ c. In paragraph (d)(2)(iii)(B), remove ‘‘Nos. 000859 and 055529’’ and in its place add ‘‘No. 016592’’.

■ 28. Add § 522.1697 to read as follows:

§ 522.1697 Pentobarbital and phenytoin.

(a) *Specifications.* Each milliliter (mL) of solution contains 390 milligrams (mg) pentobarbital sodium and 50 mg phenytoin sodium.

(b) *Sponsors.* See Nos. 000061, 051311, and 054925 in § 510.600(c) of this chapter.

(c) *Special considerations.* Product labeling shall bear the following warning statements: ‘‘ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with State and local laws, to prevent consumption of carcass material by scavenging wildlife.’’

(d) *Conditions of use in dogs*—(1) *Amount.* Administer 1 mL per 10 pounds of body weight as a single, bolus intravenous or intracardiac injection.

(2) *Indications for use.* For humane, painless, and rapid euthanasia.

(3) *Limitations.* Do not use in animals intended for food. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

■ 29. Add § 522.2092 to read as follows:

§ 522.2092 Secobarbital and dibucaine.

(a) *Specifications.* Each milliliter (mL) of solution contains 400 milligram (mg) secobarbital sodium and 25 mg dibucaine hydrochloride.

(b) *Sponsor.* See No. 054771 in § 510.600(c) of this chapter.

(c) *Special considerations.* Product labeling shall bear the following warning statements: ‘‘ENVIRONMENTAL HAZARD: This product is toxic to wildlife. Birds and mammals feeding on treated animals may be killed. Euthanized animals must be properly disposed of by deep burial, incineration, or other method in compliance with State and local laws, to prevent consumption of carcass material by scavenging wildlife.’’

(d) *Conditions of use in dogs*—(1) *Amount.* Administer 1 mL per 10 pounds of body weight as a single, bolus intravenous injection.

(2) *Indications for use.* For humane, painless, and rapid euthanasia.

(3) *Limitations.* Do not use in animals intended for food. 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

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

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

■ 31. Add an undesignated center heading before § 524.981 to read as follows:

Fluocinolone Topical and Otic Dosage Forms

■ 32. Add § 524.1001 to read as follows:

§ 524.1001 Furalaner and moxidectin.

(a) *Specifications.* Each milliliter of solution contains 280 milligram (mg) furalaner and 14 mg moxidectin. Each individually packaged tube contains either 112.5 mg furalaner and 5.6 mg moxidectin; 250 mg furalaner and 12.5 mg moxidectin; or 500 mg furalaner and 25 mg moxidectin.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use*—(1) *Amount.* Administer topically as a single dose every 2 months to provide a minimum dose of 18.2 mg/lb (40 mg/kg) fluralaner and 0.9 mg/lb (2 mg/kg) moxidectin.

(2) *Indications for use.* For the prevention of heartworm disease caused by *Dirofilaria immitis* and for the treatment of infections with intestinal roundworm (*Toxocara cati,* 4th stage larvae, immature adults, and adults) and hookworm (*Ancylostoma tubaeforme,* 4th stage larvae, immature adults, and adults); kills adult fleas and is indicated for the treatment and prevention of flea infestations (*Ctenocephalides felis*) and the treatment and control of tick infestations (*Ixodes scapularis* (black-legged tick) and *Dermacentor variabilis* (American dog tick)) for 2 months in cats and kittens 6 months of age and older and weighing 2.6 lb or greater.

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

■ 33. In § 524.1146, revise paragraphs (a) and (b) to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

(a) *Specifications.* Each milliliter of solution contains:

(1) 100 milligrams (mg) imidacloprid and 25 mg moxidectin; or

(2) 100 mg imidacloprid and 10 mg moxidectin.

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

(1) Nos. 000859 and 017030 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(2) No. 000859 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(2) and (3) of this section.

* * * * *

■ 34. In § 524.1742:

■ a. Revise the section heading;

■ b. Redesignate paragraphs (c) and (d) as paragraphs (d) and (c), respectively;

■ c. Add a heading for the table in newly redesignated paragraph (d)(1) introductory text; and

■ d. Further redesignate newly redesignated paragraphs (d)(1)(i)(*a*) and (*b*) as paragraphs (d)(1)(i)(A) and (B).

The revision and addition reads as follows:

§ 524.1742 Phosmet emulsifiable liquid.

* * * * *

(d) * * *

(1) * * *

Table 1 to Paragraph (d)(1)

* * * * *

§ 524.2098 [Amended]

■ 35. In § 524.2098(b), remove ‘‘054771’’ and in its place add ‘‘Nos. 054771 and 055529’’.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

■ 36. The authority citation for part 526 continues to read as follows:

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

§ 526.464b [Removed]

■ 37. Remove § 526.464b.

§ 526.464c [Redesignated as § 526.464b]

■ 38. Redesignate § 526.464c as § 526.464b.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

■ 39. The authority citation for part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

§ 556.40 [Amended]

■ 40. In § 556.40(c), remove ‘‘§§ 520.90e, 520.90f, 522.90a, and 522.90b’’ and in

its place add ''§§ 520.90c, 522.90a, and 522.90b''.

§ 556.165 [Amended]

■ 41. In § 556.165(c), remove ''§§ 526.464a, 526.464b, and 526.464c'' and in its place add ''§§ 526.464a and 526.464b''.

§ 556.168 [Removed]

■ 42. Remove § 556.168.

§ 556.230 [Amended]

■ 43. In § 556.230, remove paragraph (b)(3).

§ 556.304 [Amended]

■ 44. In § 556.304(c), remove ''§§ 522.1077, 522.1079, and 522.1081'' and in its place add ''§§ 522.1079 and 522.1081''.

§ 556.344 [Amended]

■ 45. In § 556.344:

■ a. In paragraph (a), remove ''1 µg/kg'' and in its place add ''5 µg/kg'';

■ b. In paragraph (b)(2)(i), remove ''100 ppb'' and in its place add ''1.6 ppm''; and

■ c. In paragraph (b)(2)(ii), remove ''10 ppb'' and in its place add ''650 ppb''.

■ 46. In § 556.360, add paragraph (b)(3) and revise paragraph (c) to read as follows:

§ 556.360 Lincomycin.

* * * * *

(b) * * *

(3) *Honey.* 750 ppb.

(c) *Related conditions of use.* See §§ 520.1263b, 522.1260, and 558.325 of this chapter.

■ 47. In § 556.500, add paragraph (b)(6) to read as follows:

§ 556.500 Oxytetracycline.

* * * * *

(b) * * *

(6) *Honey.* 750 ppb.

* * * * *

§ 556.510 [Amended]

■ 48. In § 556.510(c), remove ''520.1696b'' and in its place add ''520.1696a''.

§ 556.660 [Amended]

■ 49. In § 556.660(c), remove ''§ 558.582'' and in its place add ''§§ 520.2218 and 558.582''.

§ 556.670 [Amended]

■ 50. In § 556.670, in paragraph (c), remove ''§§ 520.2260a, 520.2260b, 520.2260c, 520.2261a, 520.2261b, 522.2260, 558.140, and 558.630'' and in its place add ''§§ 520.2218, 520.2260a, 520.2260b, 520.2260c, 520.2261a, 520.2261b, 522.2260, 558.140, and 558.630''.

§ 556.685 [Amended]

■ 51. In § 556.685(c), remove ''§§ 520.2325a, 520.2325b, and 558.586'' and in its place add ''§§ 520.2218, 520.2325a, 520.2325b, and 558.586''.

§ 556.733 [Amended]

■ 52. In § 556.733(a), remove ''10 µg/kg'' and in its place add ''50 µg/kg''.

■ 53. In § 556.746, add paragraph (b)(4) to read as follows:

§ 556.746 Tylosin.

* * * * *

(b) * * *

(4) *Honey.* 500 ppb.

* * * * *

§ 556.750 [Amended]

■ 54. In § 556.750, remove paragraph (b)(4).

■ 55. In § 556.765, revise paragraph (b)(1) to read as follows:

§ 556.765 Zilpaterol.

* * * * *

(b) * * *

(1) *Cattle.* (i) Liver (target tissue): 12 ppb.

(ii) Muscle: 10 ppb.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 57. In § 558.55, add paragraph (d)(5) to read as follows:

§ 558.55 Amprolium.

* * * * *

(d) * * *

(5) *Permitted combinations.* Amprolium may also be used in combination with:

(i) Virginiamycin as in § 558.635.

(ii) [Reserved]

■ 58. In § 558.76, revise paragraphs (e)(2)(vii), (viii), and (xi) to read as follows:

§ 558.76 Bacitracin methylenedisalicylate.

* * * * *

(e) * * *

(2) * * *

(vii) Fenbendazole as in § 558.258.

(viii) Halofuginone as in § 558.265.

* * * * *

(xi) Monensin as in § 558.355.

* * * * *

§ 558.185 [Removed]

■ 59. Remove § 558.185.

■ 60. In § 558.195, revise paragraph (e)(2)(ii) to read as follows:

§ 558.195 Decoquinate.

* * * * *

(e) * * *

(2) * * *

Decoquinate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(ii) 12.9 to 90.8 ..	Monensin, 5 to 30	Cattle fed in confinement for slaughter: For prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii;* and for improved feed efficiency.	Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb of body weight per day and 50 to 360 mg of monensin per head per day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. Also see paragraph (d)(1) of this section and § 558.355(d)(9)(i). Monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592, 054771.
*	*	*	*	*

* * * * *

■ 61. In § 558.342, revise paragraph (e)(1)(iv) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(1) * * *

Melengestrol acetate in mg/head/day	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(iv) 0.25 to 0.5 ...	Monensin, 10 to 40	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat); and for the prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*..	Add at the rate of 0.5 to 2 lb/head/day a medicated feed (liquid or dry) containing 0.125 to 1 mg melengestrol acetate/lb to a feed containing 10 to 40 g of monensin per ton to provide 0.25 to 0.5 mg melengestrol acetate/head/day and 0.14 to 0.42 mg monensin/lb body weight, depending on severity of coccidiosis challenge, up to 480 mg monensin/head/day. See § 558.355(d). Monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592, 054771, 058198
*	*	*	*	*

* * * * *

■ 62. In § 558.355, remove and reserve paragraph (e) and revise paragraph (f)(4)(iv) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(4) * * *

Monensin amount	Indications for use	Limitations	Sponsor
*	*	*	*
(iv) 400 mg per pound of block (0.088%).	Pasture cattle (slaughter, stocker, feeder, and dairy and beef replacement heifers): For increased rate of weight gain.	Provide 50 to 200 mg of monensin (2 to 8 ounces of block) per head per day, at least 1 block per 5 head of cattle. Feed blocks continuously. Do not feed salt or mineral supplements in addition to the blocks. Ingestion by cattle of monensin at levels of 600 mg per head per day and higher has been fatal. The effectiveness of this block in cull cows and bulls has not been established. See paragraph (d)(10)(i) of this section.	086113
*	*	*	*	*

* * * * *

■ 63. In § 558.500, revise paragraph (e)(2) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

(2) *Cattle.*

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 8.2 to 24.6	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed.	054771 058198
(ii) 8.2 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day..	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Feed continuously as sole ration during the last 28 to 42 days on feed. See paragraph § 558.355(d). Ractopamine as provided by No. 058198 or 054771; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(iii) 9.8 to 24.6	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding.	054771 058198
(iv) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See paragraph § 558.355(d). Ractopamine as provided by No. 058198 or 054771; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(v) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day.	Heifers fed in confinement for slaughter: For increased rate of weight gain, improved feed efficiency, and increased carcass leanness during the last 28 to 42 days on feed, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii,* and for suppression of estrus (heat).	Feed continuously as sole ration during the last 28 to 42 days on feed. Not for animals intended for breeding. See §§ 558.342(d) and 558.355(d). Melengestrol acetate as provided by No. 058198 or 054771; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198
(vi) Not to exceed 800; to provide 70 to 400 mg/head/day.	.....	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed.	Top dress in a minimum of 1 lb of medicated feed.	054771 058198
(vii) Not to exceed 800; to provide 70 to 400 mg/head/day.	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day.	Cattle fed in confinement for slaughter: For increased rate of weight gain and improved feed efficiency during the last 28 to 42 days on feed, and for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*.	Top dress ractopamine in a minimum of 1 lb of medicated feed during the last 28 to 42 days on feed. Not for animals intended for breeding. See § 558.355(d). Ractopamine as provided by No. 058198 or 054771; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 054771 058198

* * * * *

■ 64. In § 558.618, revise paragraphs (e)(2)(ii) and (iii) to read as follows:

§ 558.618 Tilmicosin.

* * * * *

(e) * * *

(2) * * *

Tilmicosin phosphate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
(ii) 568 to 757	Monensin, 5 to 40	Cattle fed in confinement for slaughter: For improved feed efficiency; and for the control of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See § 558.355(d). Tilmicosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 058198
(iii) 568 to 757	Monensin, 10 to 40	Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for the control of BRD associated with *Mannheimia haemolytica, Pasteurella multocida,* and *Histophilus somni* in groups of cattle fed in confinement for slaughter, where active BRD has been diagnosed in at least 10 percent of the animals in the group.	Feed continuously for 14 days to provide 12.5 mg tilmicosin/kg of bodyweight/day. The safety of tilmicosin has not been established in cattle intended for breeding purposes. This drug product is not approved for use in female dairy cattle 20 months of age or older. Use in these cattle may cause drug residues in milk. This drug product is not approved for use in calves intended to be processed for veal. A withdrawal period has not been established in pre-ruminating calves. Cattle intended for human consumption must not be slaughtered within 28 days of the last treatment with this drug product. See § 558.355(d). Tilmicosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198 in § 510.600(c) of this chapter.	016592 058198

■ 65. In § 558.625, revise paragraphs (e)(2)(vi) and (ix) to read as follows:

§ 558.625 Tylosin.

* * * * *

(e) * * *

(2) * * *

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
(vi) 8 to 10 ..	Monensin, 5 to 30 plus decoquinate, 13.6 to 22.7.	Cattle fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium pyogenes*; for the prevention of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for improved feed efficiency.	Feed continuously as the sole ration to provide 22.7 mg of decoquinate per 100 lb body weight per day, 50 to 360 mg of monensin/head/day, and 60 to 90 mg of tylosin/head/day. Feed at least 28 days during period of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to animals producing milk for food. Do not feed to lactating dairy cattle. A withdrawal time has not been established for pre-ruminating calves. Do not use in calves to be processed for veal. Tylosin as provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; decoquinate as provided by No. 058198 in § 510.600(c) of this chapter. See §§ 558.311(d) and 558.355(d).	016592 054771

Tylosin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
(ix) 8 to 10 ..	Monensin, 10 to 40 plus melengestrol, 0.25 to 2.0.	Heifers fed in confinement for slaughter: For reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium* (*Actinomyces*) *pyogenes*; for prevention and control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*; and for increased rate of weight gain, improved feed efficiency, and suppression of estrus (heat).	Feed continuously as sole ration to heifers at a rate of 0.5 to 2 pounds per head per day to provide 0.25 to 0.5 mg/head/day melengestrol acetate and 0.14 to 0.42 mg monensin/lb body weight per day, depending on the severity of the coccidiosis challenge, up to 480 mg/head/day and 60 to 90 mg/head/day tylosin. The melengestrol acetate portion of this Type C medicated feed must be mixed into the complete feed containing 10 to 40 g/ton monensin and 8 to 10 g/ton tylosin at feeding into the amount of complete feed consumed by an animal per day. A withdrawal time has not been established for preruminating calves. Do not use in calves to be processed for veal. Tylosin provided by No. 016592 or 058198; monensin as provided by No. 016592 or 058198; melengestrol provided by No. 054771 or 058198 in § 510.600(c) of this chapter. See §§ 558.342(d) and 558.355(d).	016592 054771 058198
*	*	* *	* *	*

■ 66. In § 558.635, revise paragraph (e)(1)(iv) to read as follows:

§ 558.635 Virginiamycin.

* * * * *

(e) * * *

(1) * * *

Virginiamycin grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
*	*	* *	* *	*
(iv) 20	Diclazuril, 0.91	Broiler chickens: For prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin; and for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mitis* (*mivati),* and *E. maxima*. Because diclazuril is effective against *E. maxima* late in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesions scores and improve performance and health of birds challenged with *E. maxima*.	Feed continuously as the sole ration. Do not use in hens producing eggs for human food. Diclazuril as provided by No. 058198 in § 510.600(c) of this chapter.	058198
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Dated: March 25, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–06688 Filed 3–30–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, and 526

[Docket No. FDA–2019–N–0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of eight new animal drug applications (NADAs) at the sponsor's request because the products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective March 30, 2020

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug