principal inspector or responsible Flight Standards Office, as appropriate. If sending information directly to the manager of the certification office, send it to the attention of the person identified in paragraph (k)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by The Boeing Company Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO Branch, FAA, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) AMOCs approved for AD 2005–05–18 are approved as AMOCs for the corresponding provisions of Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021, that are required by paragraph (g) of this AD.

(5) Except as specified by paragraph (h) of this AD: For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (j)(5)(i) and (ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. If a step or substep is labeled ''RC Exempt,'' then the RC requirement is removed from that step or substep. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(k) Related Information

(1) For more information about this AD, contact Wayne Lockett, Aerospace Engineer, Airframe Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3524; email: *wayne.lockett@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (l)(3) and (4) of this AD.

(l) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Alert Service Bulletin 737–53A1251, Revision 2, dated January 20, 2021.

(ii) [Reserved]

(3) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Contractual & Data Services (C&DS), 2600 Westminster Blvd., MC 110–SK57, Seal Beach, CA 90740–5600; telephone 562–797–1717; internet *https://www.myboeingfleet.com.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on October 8, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–24225 Filed 11–5–21; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2021–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Changes of Sponsor Address

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 April, May, and June 2021. 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 improve the accuracy and readability of the regulations.

DATES: This rule is effective November 8, 2021.

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. Approvals

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during April, May, and June 2021, 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, 240–402–7500. 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.*

FDA has verified the website addresses as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING APRIL, MAY, AND JUNE 2021

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
April 5, 2021	200–697	Accord Healthcare, Inc., 1009 Slater Rd., Suite 210–B, Durham, NC 27703.	Enrofloxacin Injectable Solution 2.27%.	Dogs	Original approval as a generic copy of NADA 140–913.	FOI Summary.

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING APRIL, MAY, AND JUNE 2021—Continued

Approval date	File No.	Sponsor	Product name	Species	Effect of the action	Public documents
April 12, 2021	141–528	Elanco US Inc., 2500 Innovation Way, Greenfield, IN 46140.	CREDELIO CAT (lotilaner) Chewable Tablets.	Cats	Supplemental approval for treatment and control of black-legged tick infestations for one month in cats and kittens.	FOI Summary.
April 23, 2021	200–702	Cronus Pharma Specialties India Private Ltd., Sy No-99/1, M/s GMR Hyderabad Aviation SEZ Ltd., Mamidipalli Village, Shamshabad Mandal, Ranga Reddy, Hyderabad, Telangana, 501218, India.	Amoxicillin and Clavulanate Potassium Tablets.	Dogs and cats	Original approval as a generic copy of NADA 055–099.	FOI Summary.
April 26, 2021	139–189	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE–GUARD (fenbendazole) Type C free-choice medicated feed blocks.	Cattle	Supplemental approval providing for a tolerance and tissue withdrawal periods in accordance with a repartitioning of the acceptable daily intake (ADI); and the addition of indications for 4th-stage larval forms of certain endoparasites.	FOI Summary.
May 18, 2021	141–452	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	SIMPARICA (sarolaner) Chewables.	Dogs	Supplemental approval for the prevention of *Borrelia burgdorferi* infection as a direct result of killing *Ixodes scapularis* vector ticks.	FOI Summary.
May 26, 2021	140–269	Do	KETOFEN (ketoprofen) Injectable Solution.	Cattle	Supplemental approval for control of pyrexia associated with bovine respiratory disease (BRD) and establishing a tolerance for residues of ketoprofen in edible tissues of cattle.	FOI Summary.
June 1, 2021	141–543	Do	DRAXXIN KP (tulathromycin and ketoprofen) Injectable Solution.	Cattle	Original approval for the treatment of bovine respiratory disease (BRD) and control of pyrexia associated with BRD in certain classes of cattle.	FOI Summary.
June 10, 2021	200–700	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.	PARASEDGE Multi for Dogs (imidacloprid and moxidectin) Topical Solution.	Dogs	Original approval as a generic copy of NADA 141–234.	FOI Summary.
June 10, 2021	200–701	Do	PARASEDGE Multi for Cats (imidacloprid and moxidectin) Topical Solution.	Cats	Original approval as a generic copy of NADA 141–254.	FOI Summary.
June 14, 2021	128–620	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE–GUARD (fenbendazole) Suspension.		Supplemental approval to establish a milk discard time in cattle and a goat tissue tolerance in accordance with repartitioning of the ADI.	FOI Summary.
June 14, 2021	200–704	Felix Pharmaceuticals PVT Ltd., 25–28 North Wall Quay, Dublin, 1, Ireland.	Deracoxib Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 141–203.	FOI Summary.
June 28, 2021	200–706	Do	Carprofen Chewable Tablets.	Dogs	Original approval as a generic copy of NADA 141–111.	FOI Summary.

II. Change of Sponsor's Address

Alexion Pharmaceuticals, Inc., 100 College St., New Haven, CT 06510 has informed FDA that it has changed its address to 121 Seaport Blvd., Boston, MA 02210.

Purina Animal Nutrition LLC, 1080 County Road F West, Shoreview, MN 55126–2910 has informed FDA that it has changed its address to 4001 Lexington Ave., North Arden Hills, MN 55126–2910.

III. Technical Amendments

FDA is making the following amendment to improve the accuracy of the animal drug regulations:

- 21 CFR 520.304 is amended to reflect the currently approved strengths of carprofen chewable tablets.
- 21 CFR part 522 is amended to organize sections for injectable pentobarbital drugs by their titles in alphabetic sequence.
- 21 CFR 558.128 is amended to add introductory text identifying the paragraph for medicated cattle feeds containing chlortetracycline.
- 21 CFR 558.355 is amended to add introductory text identifying the paragraph for medicated cattle feeds containing monensin.

IV. 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 510

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

21 CFR Parts 520, 522, and 524

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 510, 520, 522, 524, 556, 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.

■ 2. In § 510.600:

■ a. In the table in paragraph (c)(1), revise the entries for ''Alexion Pharmaceuticals, Inc.'' and ''Purina Animal Nutrition LLC;'' and

■ b. In the table in paragraph (c)(2), revise the entries for ''017800'' and ''069334''.

The revisions 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
* * * * * * *	
Alexion Pharmaceuticals, Inc., 121 Seaport Blvd., Boston, MA 02210	069334
* * * * * * *	
Purina Animal Nutrition LLC, 4001 Lexington Ave., North Arden Hills, MN 55126–2910	017800
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
017800	Purina Animal Nutrition LLC, 4001 Lexington Ave., North Arden Hills, MN 55126–2910.
* * * * * * *	
069334	Alexion Pharmaceuticals, Inc., 121 Seaport Blvd., Boston, MA 02210.
* * * * * * *	

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 § 520.88g, revise paragraph (b)(2) to read as follows:

§ 520.88g Amoxicillin trihydrate and clavulanate potassium tablets.

* * * * *

(b) * * *

(2) Nos. 026637 and 069043 for use of tablets as in paragraph (c) of this section.

* * * * *

■ 5. In § 520.304, revise paragraph (b)(2) to read as follows:

§ 520.304 Carprofen.

* * * * *

(b) * * *

(2) Nos. 058198 and 086101 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

* * * * *

■ 6. In § 520.538, remove paragraph (c) and redesignate paragraph (d) as new paragraph (c); and revise paragraph (b) to read as follows:

§ 520.538 Deracoxib.

* * * * *

(b) *Sponsors.* See Nos. 013744, 058198, and 086101 in § 510.600(c) of this chapter.

* * * * *

■ 7. In § 520.905a, revise paragraphs (e)(2), (3), and (4) to read as follows:

§ 520.905a Fenbendazole suspension.

* * * * *

(e) * * *

(2) *Beef and dairy cattle*—(i) *Amount.* Administer orally 2.3 mg/lb of body weight (5 mg/kg).

(ii) *Indications for use.* For the treatment and control of: Lungworms: Adult (*Dictyocaulus viviparus*); Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*); adult and fourth-stage larvae barberpole worms (*Haemonchus contortus* and *H. placei*); adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).

(iii) *Limitations.* Milk taken from cows during treatment and for 48 hours

after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves.

(3) *Beef cattle*—(i) *Amount.* Administer orally 4.6 mg/lb of body weight (10 mg/kg).

(ii) *Indications for use.* For the treatment and control of stomach worms (fourth-stage inhibited larvae/type II ostertagiasis), *Ostertagia ostertagi,* and tapeworms, *Moniezia benedeni.*

(iii) *Limitations.* Cattle must not be slaughtered for human consumption within 8 days following last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in preruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Goats*—(i) *Amount.* Administer orally 2.3 mg/lb of body weight (5 mg/kg).

(ii) *Indications for use.* For the treatment and control of stomach worms (adults) *Haemonchus contortus* and *Teladorsagia circumcincta.*

(iii) *Limitations.* Goats must not be slaughtered for human consumption within 6 days following last treatment with this drug product. Because a milk discard time has not been established, do not use in lactating goats.

* * * * *

§ 520.905e [Removed]

■ 8. Remove § 520.905e.

■ 9. In § 520.1286, revise paragraph (c)(2)(ii) to read as follows:

§ 520.1286 Lotilaner.

* * * * *

(c) * * *

(2) * * *

(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 and older, and weighing 2.0 pounds or greater; and for the treatment and control of *Ixodes scapularis* (black-legged tick) for 1 month in cats and kittens 6 months of age and older, and weighing 2.0 pounds or greater.

* * * * *

■ 10. In § 520.2086, in paragraph (c)(2), add a sentence at the end of the paragraph to read as follows:

§ 520.2086 Sarolaner.

* * * * *

(c) * * *

(2) * * * For the prevention of *Borrelia burgdorferi* infections as a direct result of killing *Ixodes scapularis* vector ticks.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 12. In § 522.812, revise paragraphs (b)(1) and (e)(1)(i) to read as follows:

§ 522.812 Enrofloxacin.

* * * * *

(b) * * *

(1) Nos. 016729, 017033, 055529, and 058198 for use of product described in paragraph (a)(1) of this section as in paragraph (e)(1) of this section; and

* * * * *

(e) * * *

(1) * * *

(i) *Amount.* 2.5 mg per kilogram (/kg) of body weight (1.13 mg per pound) as a single, intramuscular, initial dose followed by use of tablets twice daily for 2 to 3 days beyond cessation of clinical signs to a maximum of 30 days.

* * * * *

■ 13. Revise § 522.1225 to read as follows:

§ 522.1225 Ketoprofen.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) ketoprofen.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter.

(1) No. 054771 for use as in paragraphs (d)(1) and (d)(2) of this section.

(2) No. 061133 for use as in paragraph (d)(1) of this section.

(c) *Related tolerances.* See § 556.345 of this chapter.

(d) *Conditions of use*—(1) *Horses—(i) Amount.* Administer by intravenous injection 1.0 mg per pound (/lb) of body weight once daily for up to 5 days.

(ii) *Indications for use.* For alleviation of inflammation and pain associated with musculoskeletal disorders in horses.

(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.

(2) *Cattle—(i) Amount.* Administer by subcutaneous injection 3 mg per kilogram (1.36 mg/lb) of body weight once daily for up to 3 days.

(ii) *Indications for use.* For the control of pyrexia associated with bovine respiratory disease (BRD) in beef heifers, beef steers, beef calves 2 months of age and older, beef bulls, replacement dairy heifers, and dairy bulls.

(iii) *Limitations.* Not for use in reproducing animals over 1 year of age. Cattle must not be slaughtered for human consumption within 48 hours following last treatment with this drug product. Not for use in female dairy cattle 1 year 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 or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

§§ 522.1697, 522.1698, and 522.1704 [Redesignated]

■ 14. Redesignate §§ 522.1697, 522.1698, and 522.1704 as §§ 522.1700, 522.1702, and 522.1703.

■ 15. Add § 522.2632 to read as follows:

§ 522.2632 Tulathromycin and ketoprofen.

(a) *Specifications.* Each milliliter of solution contains 100 milligrams (mg) tulathromycin and 120 milligrams (mg) ketoprofen.

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

(c) *Related tolerances.* See §§ 556.345 and 556.745 of this chapter.

(d) *Conditions of use*—(1) *Cattle—(i) Amount.* Administer as a single subcutaneous injection 2.5 mg tulathromycin and 3 mg ketoprofen per kilogram (1.1 mL/100 lb) of body weight.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Mannheimia haemolytica, Pasteurella multocida, Histophilus somni,* and *Mycoplasma bovis,* and control of pyrexia associated with BRD in beef steers, beef heifers, beef calves 2 months of age and older, beef bulls, dairy bulls, and replacement dairy heifers.

(iii) *Limitations.* Not for use in reproducing animals over 1 year of age. Cattle must not be slaughtered for human consumption within 18 days following last treatment with this drug product. Not for use in female dairy cattle 1 year 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 or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been

established for this product in pre-ruminating calves. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 17. In § 524.1146, revise paragraphs (b)(1) and (2) to read as follows:

§ 524.1146 Imidacloprid and moxidectin.

* * * * *

(b) * * *

(1) Nos. 017030, 058198, and 061651 for use of product described in paragraph (a)(1) of this section as in paragraph (d)(1) of this section.

(2) Nos. 017030, 058198, and 061651 for use of product described in paragraph (a)(2) of this section as in paragraph (d)(2) of this section.

* * * * *

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

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

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

■ 19. In § 556.275, revise paragraph (c) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(c) *Related conditions of use.* See §§ 520.905a, 520.905b, 520.905c, 520.905d, and 558.258 of this chapter.

■ 20. Add § 556.345 to read as follows:

§ 556.345 Ketoprofen.

(a) *Acceptable daily intake (ADI).* The ADI for total residue of ketoprofen is 5 µg/kg of body weight per day.

(b) *Tolerances.* The tolerances for ketoprofen (marker residue) are:

(1) *Cattle.* (i) Kidney (target tissue): 0.36 ppm.

(ii) [Reserved]

(c) *Related conditions of use.* See §§ 522.1225 and 522.2632 of this chapter.

■ 21. In § 556.745, revise paragraph (c) to read as follows:

§ 556.745 Tulathromycin.

* * * * *

(c) *Related conditions of use.* See §§ 522.2630 and 522.2632 of this chapter.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 23. In § 558.128, revise paragraph (e)(4) introductory text to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(4) *Cattle.* It is used as follows:

* * * * *

■ 24. In § 558.258, revise paragraph (e)(3)(iii) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(e) * * *

(3) * * *

(iii) *Free-choice medicated feeds*—(A) *Proprietary formulas (§ 510.455(e)(2) of this chapter).* The following feeds can be manufactured only per an approved proprietary formula and specifications:

Amount fenbendazole	Indications for use	Limitations	Sponsor
(*1*) 750 mg/lb of protein block (to provide 5 mg/kg body weight (2.27 mg/lb)).	Beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed free choice at a rate of 0.1 pound of block per 100 pounds of body weight per day for 3 days to deliver a total of 2.27 mg fenbendazole per pound of body weight. Cattle must not be slaughtered for human consumption within 16 days following last treatment with this drug product. Not 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 or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061
(*2*) 750 mg/lb of molasses block (to provide 5 mg/kg body weight (2.27 mg/lb)).	Beef cattle: For the treatment and control of: Lungworms: adult (*Dictyocaulus viviparus*); Stomach worms: Adult brown stomach worms (*Ostertagia ostertagi*), adult and fourth-stage larvae barberpole worms (*Haemonchus contortus*), fourth-stage larvae barberpole worms (*H. placei*), and adult and fourth-stage larvae small stomach worms (*Trichostrongylus axei*); Intestinal worms (adult and fourth-stage larvae): Hookworms (*Bunostomum phlebotomum*), thread-necked intestinal worms (*Nematodirus helvetianus*), small intestinal worms (*Cooperia punctata* and *C. oncophora*), bankrupt worms (*Trichostrongylus colubriformis*), and nodular worms (*Oesophagostomum radiatum*).	Feed free choice at a rate of 0.1 pound of block per 100 pounds of body weight per day for 3 days to deliver a total of 2.27 mg fenbendazole per pound of body weight. Cattle must not be slaughtered for human consumption within 11 days following last treatment with this drug product. Not 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 or heifers. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.	000061

(B) *Published formulas (§ 510.455(e)(1) of this chapter).* The following feeds can be manufactured only per one of the formulas and specifications published below:

(1) Amount. 5 mg/kg body weight (2.27 mg/lb), including the following formulations:

Ingredient [1]	Percent	International feed No.
(*i*) Free-choice, dry Type C feed:		

Ingredient [1]	Percent	International feed No.
Salt (sodium chloride)	59.00	6–04–152
Monosodium phosphate	31.16	6–04–288
Dried cane molasses	3.12	4–04–695
Zinc sulfate	0.76	6–05–556
Copper sulfate	0.45	6–01–720
Fenbendazole 20% Type A article	5.51	n/a
(*ii*) Free-choice, dry Type C feed:		
Salt (sodium chloride)	35.93	6–04–152
Dicalcium phosphate (18.5% P)	32.44	6–00–080
Calcium carbonate (38% Ca)	15.93	6–01–069
Magnesium oxide (56% Mg)	10.14	6–02–756
Zinc sulfate	1.47	6–05–556
Mineral oil	1.00	8–03–123
Dried cane molasses (46% sugars)	0.98	4–04–695
Potassium iodide	0.01	6–03–759
Fenbendazole 20% Type A article	2.10	n/a
(*iii*) Free-choice, liquid Type C feed:		
Cane molasses [2]	80.902	4–13–251
Water	9.36	n/a
Urea solution, 55%	7.05	5–05–707
Phosphoric acid 75% (feed grade)	2.00	6–03–707
Xantham gum	0.20	8–15–818
Trace minerals	0.20	n/a
Vitamin premix	0.01	n/a
Fenbendazole 20% Type A article	0.278	n/a

[1] The content of any added vitamin and trace mineral may be varied; however, they should be comparable to those used by the manufacturer for other free-choice cattle feeds. Formulation modifications require FDA approval prior to marketing. Selenium is not approved for the free-choice formulations described in paragraph (e)(3)(iii) of this section. Free-choice cattle feeds containing selenium must comply with published regulations (see 21 CFR 573.920).

[2] The percentage of cane molasses and water in the formulation may be adjusted as needed in order to bring the brix value of the molasses to the industry standard of 79.5 brix.

(*2*) *Indications for use.* As in paragraph (e)(3)(i) of this section.

(*3*) *Limitations.* Feed a total of 5 mg of fenbendazole per kg (2.27 mg/lb) of body weight to cattle over a 3- to 6-day period. Retreatment may be needed after 4 to 6 weeks. Cattle must not be slaughtered within 13 days following last treatment. For dairy cattle the milk discard time is zero hours. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

* * * * *

■ 25. In § 558.355, add a heading to paragraph (f)(3) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) *Cattle*—

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Dated: October 28, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–24075 Filed 11–5–21; 8:45 am]

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DEPARTMENT OF JUSTICE

28 CFR Part 16

[CPCLO Order No. 010–2021]

Privacy Act of 1974; Implementation

AGENCY: United States Department of Justice.

ACTION: Final rule.

SUMMARY: The United States Department of Justice (DOJ or Department) is finalizing without changes its Privacy Act exemption regulations for the system of records titled, Department of Justice Information Technology, Information System, and Network Activity and Access Records, JUSTICE/DOJ–002, which were published as a notice of proposed rulemaking (NPRM) (July 22, 2021). Specifically, the Department's regulations will exempt the records maintained in JUSTICE/DOJ–002 from one or more provisions of the Privacy Act. The exemptions are necessary to avoid interference with the efforts of DOJ and others to prevent the unauthorized access, use, disclosure, disruption, modification, or destruction of DOJ information and information systems, and to protect information on DOJ classified networks. The Department received no comments during the notice-and-comment period and is finalizing the rule without change.

DATES: This final rule is effective December 8, 2021.

FOR FURTHER INFORMATION CONTACT: Nickolous Ward, DOJ Chief Information Security Officer, (202) 514–3101, 145 N Street NE, Washington, DC 20530.

SUPPLEMENTARY INFORMATION: In accordance with the Federal Information Security Modernization Act of 2014, among other authorities, DOJ is responsible for complying with information security policies and procedures requiring information security protections commensurate with the risk and magnitude of harm resulting from the unauthorized access, use, disclosure, disruption, modification, or destruction of DOJ information and information systems. *See, e.g.,* 44 U.S.C. 3554 (2018). Consistent with these requirements, DOJ must ensure that it maintains accurate audit and activity records of the observable occurrences on its information systems and networks (also referred to as ''events'') that are significant and relevant to the security of DOJ information and information systems. These audit and activity records may include, but are not limited to, information that establishes what type of event occurred, when the event occurred, where the event occurred, the