Matthew.McConnell@nrc.gov. Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Discussion

The NRC is issuing a revision in the NRC's ''Regulatory Guide'' series. This series was developed to describe methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, to explain techniques that the staff uses in evaluating specific issues or postulated events, and to describe information that the staff needs in its review of applications for permits and licenses.

Revision 2 to RG 1.89 was issued with a temporary identification of Draft Regulatory Guide, DG–1361 (ADAMS Accession No. ML20183A423).

The staff revised RG 1.89 to endorse, with clarifications, exceptions, and supplements, International Electrotechnical Commission/Institute of Electrical and Electronic Engineers Standard 60780–323, ''Nuclear Facilities—Electrical Equipment Important to Safety—Qualification,'' Edition 1, 2016–02, as this standard reflects almost 40 years of experience gained in implementing regulatory requirements and industry research and testing related to environmental qualification (EQ). Nuclear plant license renewal provides additional motivation for continuing attention to equipment qualification. This revised guide contains information specific for EQ for both older plants and newer reactors licensed under parts 50 and 52 of title 10 of the *Code of Federal Regulations* (10 CFR).

II. Additional Information

The NRC published notices of the availability of DG–1361 in the **Federal Register** on December 17, 2020 (85 FR 81958) and February 18, 2021 (86 FR 10133) for 60-day public comment periods. The public comment periods closed on February 16, 2021, and April 19, 2021, respectively. Public comments on DG–1361 and the staff responses to the public comments are available under ADAMS under Accession No. ML22272A601.

As noted in the **Federal Register** on December 9, 2022 (87 FR 75671), this document is being published in the ''Rules'' section of the **Federal Register** to comply with publication requirements under 1 CFR chapter I.

III. Congressional Review Act

This RG is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting, Forward Fitting, and Issue Finality

Issuance of RG 1.89, Revision 2, does not constitute backfitting as defined in 10 CFR 50.109, ''Backfitting,'' and as described in NRC Management Directive (MD) 8.4, ''Management of Backfitting, Forward Fitting, Issue Finality, and Information Requests''; affect the issue finality of an approval issued under 10 CFR part 52; or constitute forward fitting as defined in MD 8.4 because, as explained in this RG, licensees are not required to comply with the positions set forth in this RG.

V. Submitting Suggestions for Improvement of Regulatory Guides

A member of the public may, at any time, submit suggestions to the NRC for improvement of existing RGs or for the development of new RGs. Suggestions can be submitted on the NRC's public website at *https://www.nrc.gov/reading-rm/doc-collections/reg-guides/contactus.html.* Suggestions will be considered in future updates and enhancements to the ''Regulatory Guide'' series.

Dated: April 28, 2023.

For the Nuclear Regulatory Commission.

Meraj Rahimi,

Chief, Regulatory Guide and Programs Management Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2023–09389 Filed 5–2–23; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 516, 520, 522, 524, 526, 529, 556, and 558

[Docket No. FDA–2023–N–0002]

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

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), abbreviated new animal drug applications (ANADAs), and conditionally approved new animal drug applications (cNADAs) during January, February, and March 2023. 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 their accuracy and readability.

DATES: This rule is effective May 3, 2023.

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, ANADAs, and cNADAs during January, February, and March 2023, 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.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
January 5, 2023	200–732	Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland.	Carprofen Tablets (carprofen tablets) Caplets.	Original approval for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs as a generic copy of NADA 141–053.	FOI Summary	520.304
January 11, 2023	200–611	Akorn Operating Company LLC, 5605 Centerpoint Ct., Suite A, Gurnee, IL 60031.	DETOMISED (detomidine hydrochloride) Injectable Solution.	Original approval as a sedative and analgesic to facilitate minor surgical and diagnostic procedures in horses as a generic copy of NADA 140–862.	FOI Summary	522.536
January 11, 2023	200–738	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009.	DECTOGARD (doramectin topical solution) Topical Solution.	Original approval for treatment and control of internal and external parasites of cattle as a generic copy of NADA 141–095.	FOI Summary	524.770
January 12, 2023	141–426	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	BRAVECTO (fluralaner) Chewable tablets.	Supplemental approval for the treatment and control of Asian long horned tick infestations for 12 weeks in dogs and puppies.	FOI Summary	520.998
January 12, 2023	200–721	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	MIDAMOX for Cats (imidacloprid and moxidectin) Topical Solution.	Supplemental approval for prevention of heartworm disease and treatment of flea infestations in ferrets as a generic copy of NADA 141–254.	FOI Summary	524.1146
January 12, 2023	200–733	Felix Pharmaceuticals Pvt. Ltd., 25–28 North Wall Quay, Dublin 1, Ireland.	Marbofloxacin Chewable Tablets (marbofloxacin).	Original approval for treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin as a generic copy of NADA 141–151.	FOI Summary	520.1310
January 12, 2023	200–734	Do	Praziquantel Tablets (praziquantel).	Original approval for removal or removal and control of certain canine tapeworms as a generic copy of NADA 111–798.	FOI Summary	520.1870
January 13, 2023	200–735	ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534.	Dexmedetomidine Hydrochloride (dexmedetomidine hydrochloride) Injectable Solution.	Original approval for use as a sedative, analgesic, and preanesthetic in dogs and cats as a generic copy of NADA 141–267.	FOI Summary	522.558
January 13, 2023	200–736	Do	Marbofloxacin Tablets (marbofloxacin).	Original approval for treatment of infections in dogs and cats associated with bacteria susceptible to marbofloxacin as a generic copy of NADA 141–151.	FOI Summary	520.1310
February 2, 2023	200–737	Do	Enrofloxacin (enrofloxacin) Flavored Antimicrobial Tablets.	Original approval for the management of diseases associated with bacteria susceptible to enrofloxacin in dogs and cats as a generic copy of NADA 140–441.	FOI Summary	520.812
February 2, 2023	200–739	Do	Carprofen (carprofen) Chewable Tablets.	Original approval for the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries in dogs as a generic copy of NADA 141–111.	FOI Summary	520.304
February 9, 2023	200–701	Chanelle Pharmaceuticals Manufacturing Ltd., Loughrea, County Galway, Ireland.	PARASEDGE Multi for Cats (imidacloprid and moxidectin) Topical Solution.	Supplemental approval for prevention of heartworm disease and treatment of flea infestations in ferrets as a generic copy of NADA 141–254.	FOI Summary	524.1146

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS, ANADAS, AND CNADAS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2023 REQUIRING EVIDENCE OF SAFETY AND/OR EFFECTIVENESS—Continued

Approval date	File No.	Sponsor	Product name	Effect of the action	Public documents	21 CFR section
February 24, 2023	200–741	Aurora Pharmaceutical, Inc., 1196 Highway 3 South, Northfield, MN 55057–3009.	EPRIGARD (eprinomectin) Topical Solution.	Original approval for treatment and control of internal and external parasites in cattle as a generic copy of NADA 141–079.	FOI Summary	524.814
March 21, 2023	200–743	Provetica LLC, 8735 Rosehill Rd., Suite 300, Lenexa, KS 66215.	MODULIS for Dogs (cyclosporine oral solution) USP MODIFIED.	Original approval for the control of atopic dermatitis in dogs as a generic copy of NADA 141–218.	FOI Summary	520.522
March 21, 2023	200–745	Parnell Technologies Pty. Ltd., Unit 4, 476 Gardeners Rd., Alexandria, New South Wales 2015, Australia.	RESPIRMYCIN 25 (tulathromycin injection) Injectable Solution.	Original approval for the treatment of respiratory disease in swine and calves as a generic copy of NADA 141–349.	FOI Summary	522.2630
March 29, 2023	200–744	Provetica LLC, 8735 Rosehill Rd., Suite 300, Lenexa, KS 66215.	MODULIS for Cats (cyclosporine oral solution) USP MODIFIED.	Original approval for the control of feline allergic dermatitis in cats as a generic copy of NADA 141–329.	FOI Summary	520.522
March 30, 2023	200–746	Norbrook Laboratories Ltd., Carnbane Industrial Estate, Newry, County Down, BT35 6QQ, United Kingdom.	TAURAMOX (moxidectin) Injectable Solution.	Original approval for treatment and control of internal and external parasites in beef and nonlactating dairy cattle as a generic copy of NADA 141–220.	FOI Summary	522.1450
March 31, 2023	200–747	ZyVet Animal Health, Inc., 73 Route 31N, Pennington, NJ 08534.	Maropitant Citrate (maropitant citrate) Tablets.	Original approval for the prevention of acute vomiting and the prevention of vomiting due to motion sickness in dogs as a generic copy of NADA 141–262.	FOI Summary	520.1315

Also, FDA is amending the animal drug regulations to reflect approval of supplemental applications, as listed in table 2, to change the marketing status of dosage form antimicrobial animal drug products from over the counter (OTC) to by veterinary prescription (Rx). These applications were submitted in voluntary compliance with the goals of the FDA Center for Veterinary Medicine's (CVM's) Judicious Use Initiative as identified by guidance for industry #263, ''Recommendations for Sponsors of Medically Important Antimicrobial Drugs Approved for Use in Animals to Voluntarily Bring Under Veterinary Oversight All Products That Continue to be Available Over-the-Counter,'' June 11, 2021 (*https://www.fda.gov/media/130610/download*).

TABLE 2—SUPPLEMENTAL APPLICATIONS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2023 TO CHANGE THE MARKETING STATUS OF ANTIMICROBIAL ANIMAL DRUG PRODUCTS FROM OTC TO Rx

Approval date	File No.	Sponsor	Product name	21 CFR section
January 3, 2022	200–274	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LINCOMIX (lincomycin hydrochloride) Injectable Solution.	522.1260
January 12, 2022	012–123	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	GALLIMYCIN 100 Injection (erythromycin) Injectable Solution.	522.820
January 12, 2022	130–952	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	GENTOCIN Pinkeye Spray (gentamicin) Topical Spray.	524.1044e
January 13, 2022	008–774	Huvepharma EEOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	SULMET (sodium sulfamethazine) Injectable Solution.	522.2260
February 10, 2023	065–506	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	COMBI–PEN–48 (penicillin G benzathine and penicillin G procaine) Injectable Suspension.	522.1696a
February 14, 2023	055–018	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	Chlortetracycline (chlortetracycline hydrochloride) Tablets, 25 mg.	520.443
February 15, 2023	033–157	Do	SPECTAM Scour-Halt (spectinomycin) Oral Solution.	520.2123c
February 15, 2023	040–040	Do	SPECTAM (spectinomycin) Injectable Solution.	522.2120
February 24, 2023	065–010	Do	NOROCILLIN (penicillin G procaine) Injectable Suspension.	522.1696b
March 1, 2023	200–351	Do	Lincomycin Injectable, USP	522.1260
March 1, 2023	200–368	Do	Lincomycin Injectable, USP	522.1260
March 1, 2023	130–464	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	GARACIN Pig Pump (gentamicin) Oral Solution.	520.1044b

TABLE 2—SUPPLEMENTAL APPLICATIONS APPROVED DURING JANUARY, FEBRUARY, AND MARCH 2023 TO CHANGE THE MARKETING STATUS OF ANTIMICROBIAL ANIMAL DRUG PRODUCTS FROM OTC TO Rx—Continued

Approval date	File No.	Sponsor	Product name	21 CFR section
March 9, 2023	035–456	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	GALLIMYCIN–36 (erythromycin) Intramammary Solution.	526.820
March 13, 2023	200–315	Sparhawk Laboratories, Inc., 12340 Santa Fe Trail Dr., Lenexa, KS 66215.	LINCOMYCIN 300 (lincomycin hydrochloride) Injectable Solution.	522.1260
March 16, 2023	065–505	Bimeda Animal Health Ltd., 1B The Herbert Building, The Park, Carrickmines, Dublin 18, Ireland.	PRO–PEN–G (penicillin G procaine) Injectable Suspension.	522.1696b
March 20, 2023	200–127	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	PROSPEC (spectinomycin hydrochloride) Injectable Solution.	522.2120
March 25, 2023	040–181	Huvepharma EOOD, 5th Floor, 3A Nikolay Haytov Str., 1113 Sofia, Bulgaria.	VETSULID (sulfachlorpyridazine) Oral Suspension.	520.2200
March 28, 2023	065–081	HQ Specialty Pharma Corp., 120 Rte. 17 North, Suite 130, Paramus, NJ 07652.	MASTI–CLEAR (penicillin G procaine) Suspension and GO–DRY (penicillin G procaine) Suspension.	526.1696

II. Withdrawals of Approval

Elanco US Inc. (Elanco), 2500 Innovation Way, Greenfield, IN 46140 has requested that FDA withdraw approval of conditionally approved NADA 141–527 for BAYTRIL 100–CA1 (enrofloxacin) Injectable Solution. Pursuant to Elanco's request, approval of their application was withdrawn on March 31, 2023. As provided in the regulatory text of this document, the animal drug regulations in 21 CFR 516.812 are removed to reflect this action.

Boehringer Ingelheim Animal Health USA, Inc., 3239 Satellite Blvd., Duluth, GA 30096 has requested that FDA withdraw approval of the 49 applications listed in table 3 because the products are no longer manufactured or marketed. As provided in the regulatory text of this document, the animal drug regulations are amended where appropriate to reflect this action.

TABLE 3—APPLICATIONS FOR WHICH APPROVAL WAS VOLUNTARILY WITHDRAWN BY FDA

File No.	Product name	21 CFR cite
006–623	CAPARSOLATE (arsenamide sodium) Injectable Solution	Not codified
008–422	SELEEN (selenium disulfide) Topical Suspension	524.2101
010–424	NALLINE (nalorphine hydrochloride) Injectable Solution	522.1452
011–080	HYDELTRONE-TBA (prednisolone tertiary butylacetate) Injectable Suspension	522.1885
011–437	HYDELTRONE (neomycin sulfate and prednisolone sodium phosphate) Ointment	524.1484j
011–532	SULFABROM (sulfabromomethazine sodium) Bolus	520.2170
011–678	DIURIL (chlorothiazide) Tablets	520.420
012–734	DIURIL (chlorothiazide) Bolus	520.420
013–022	THIBENZOLE (thiabendazole) Sheep & Goat Wormer	520.2380c
013–407	EQUIZOLE (thiabendazole) Horse Wormer Top Dress	520.2380a
013–624	Triamcinolone Acetonide Tablets	520.2483
013–674	HYDROZIDE (hydrochlorothiazide) Injectable Solution	522.1150
013–954	THIBENZOLE (thiabendazole) 20% Swine Premix	558.600
014–350	OMNIZOLE (thiabendazole) Oral Liquid	520.2380b
015–123	TBZ (thiabendazole) Cattle Wormer Oral Liquid	520.2380b
015–875	TBZ 200 (thiabendazole) Medicated Feed Premix	558.600
030–103	THIBENZOLE (thiabendazole) Oral Liquid	520.2380b
032–702	PROM ACE (acepromazine maleate) Tablets	520.23
033–127	VETISULID (sulfachlorpyridazine) Bolus	520.2200
033–318	VETISULID (sulfachlorpyridazine) Injectable Solution	520.2200
033–319	VETISULID (sulfachlorpyridazine) Tablets	520.2200
034–114	EQUIZOLE (thiabendazole) Oral Liquid	520.2380b
034–879	DOPRAM-V (doxapram hydrochloride) Injectable Solution	522.775
035–631	THIBENZOLE (thiabendazole) Pig Wormer	520.2380b
037–410	EQUIZOLE A (thiabendazole and piperazine phosphate) Oral Liquid	520.2380e
043–141	THIBENZOLE 300 (thiabendazole) Medicated	558.600
044–654	EQUIZOLE (thiabendazole) Horse Wormer Pellets	520.2380a
046–146	VETALOG (triamcinolone acetonide) Cream	524.2483
047–333	EQUIZOLE A (thiabendazole and piperazine citrate) Oral Liquid	520.2380d
048–487	TBZ (thiabendazole) Wormer Paste 50%	520.2380b
049–461	TBZ (thiabendazole) Wormer Paste 43%	520.2380b
055–021	HETACIN K (hetacillin potassium) Capsules Vet	520.1130
055–022	HETACIN K (hetacillin potassium) Tablets	520.1130
055–048	HETACIN K (hetacillin potassium) Oral Liquid	520.1130
065–275	Penicillin VK (penicillin V potassium) Filmtab Tablets 250 mg	520.1696c
065–276	VEESYN (penicillin V potassium) Granules for Oral Solution	520.1696b
093–600	VOREN (dexamethasone-21-isonicotinate) Suspension	522.542

TABLE 3—APPLICATIONS FOR WHICH APPROVAL WAS VOLUNTARILY WITHDRAWN BY FDA—Continued

File No.	Product name	21 CFR cite
094–642	CAMVET (cambendazole) Suspension Horse Wormer	520.284a
095–642	OXY-TET (oxytetracycline hydrochloride) Injectable Solution	522.1662a
096–506	CAMVET (cambendazole) Horse Wormer Pellets	520.284b
096–731	CAMVET (cambendazole) Horse Wormer Paste 45%	520.284c
098–689	EQUIZOLE (thiabendazole) 50% Wormer Paste	520.2380b
099–388	VETALOG (triamcinolone acetonide) Oral Powder	520.2483
117–531	Acepromazine Maleate Injection	522.23
127–443	EQVALAN (ivermectin) Injectable Solution	522.1192
140–439	EQVALAN (ivermectin) Oral Liquid For Horses	522.1195
141–180	TORPEX (albuterol sulfate)	529.40
200–361	Acepromazine Maleate Injection	522.23
200–564	Ivermectin Paste 1.87%	520.1192

III. Technical Amendments

FDA is making the following amendments to improve the accuracy of the animal drug regulations.

- 21 CFR 520.48 is amended to reflect the sponsors of products containing altrenogest for use in horses and swine.
- 21 CFR 520.2380 is removed and 21 CFR 558.600 revised to characterize a free-choice block containing thiabendazole as a new animal drug for use in cattle feed.
- 21 CFR 522.1077 is amended to reflect indications for use of gonadorelin in cattle.
- 21 CFR 522.1222 is amended to reflect sponsors of approved applications for use of ketamine in cats and subhuman primates.
- 21 CFR 556.620 is removed because there are no longer any approved products containing sulfabromomethazine for use in food-producing animals.
- 21 CFR 556.730 is revised to reflect the removal of products containing thiabendazole for use in food-producing animals other than cattle.
- 21 CFR 558.311 is amended to reflect approved classes of pasture cattle for use of lasalocid medicated feeds.
- 21 CFR 558.455 is amended to reflect the approved conditions of use of medicated feeds containing oxytetracycline and neomycin in sheep.

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 Part 516

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, 524, 526, and 529

Animal drugs.

21 CFR Part 556

Animal drugs, Dairy products, Foods, Meat and meat products.

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, 516, 520, 522, 524, 526, 529, 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 paragraph (c)(1), amend the table by adding an entry for ''Provetica LLC''; and

■ b. In paragraph (c)(2), amend the table by adding add an entry for ''086097''.

The 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
* * * * * * *	
Provetica LLC, 8735 Rosehill Rd., Suite 300, Lenexa, KS 66215	086097
* * * * * * *	

(2) * * *

Drug labeler code	Firm name and address
* * * * * * *	
086097	Provetica LLC, 8735 Rosehill Rd., Suite 300, Lenexa, KS 66215.
* * * * * * *	

PART 516—NEW ANIMAL DRUGS FOR MINOR USE AND MINOR SPECIES

■ 3. The authority citation for part 516 continues to read as follows:

Authority: 21 U.S.C. 360ccc–1, 360ccc–2, 371.

§ 516.812 [Removed]

■ 4. Remove § 516.812.

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.

■ 6. In § 520.48, revise paragraph (b) to read as follows:

§ 520.48 Altrenogest.

* * * * *

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

(1) Nos. 000061 and 051072 for use as in paragraph (d) of this section.

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

(3) No. 013744 for use as in paragraph (d)(2) of this section.

* * * * *

§§ 520.284, 520.284a, 520.284b, and 520.284c [Removed]

■ 7. Remove §§ 520.284, 520.284a, 520.284b, and 520.284c.

■ 8. In § 520.304, revise paragraphs (b)(1) and (2) to read as follows:

§ 520.304 Carprofen.

* * * * *

(b) * * *

(1) Nos. 017033, 054771, 055529, 062250, and 086101 for use of products described in paragraph (a)(1) and (2) of this section as in paragraph (c) of this section.

(2) Nos. 058198 and 086117 for use of product described in paragraph (a)(2) as in paragraph (c) of this section.

* * * * *

§§ 520.420 [Removed]

■ 9. Remove § 520.420.

■ 10. In § 520.443, amend paragraph (d)(2)(ii) by adding a sentence at the end of the paragraph to read as follows:

§ 520.443 Chlortetracycline tablets and boluses.

* * * * *

(d) * * *

(2) * * *

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

* * * * *

■ 11. In § 520.522, add paragraph (b)(4) and revise (d)(2)(ii) to read as follows:

§ 520.522 Cyclosporine.

* * * * *

(b) * * *

(4) No. 086097 for use of product described in paragraph (a)(2) as in paragraph (d) of this section.

* * * * *

(d) * * *

(2) * * *

(ii) *Indications for use.* For the control of feline allergic dermatitis as manifested by excoriations (including facial and neck), miliary dermatitis, eosinophilic plaques, and self-induced alopecia in cats at least 6 months of age and at least 3 lbs (1.4 kg) in body weight.

* * * * *

§ 520.812 [Amended]

■ 12. Amend § 520.812 by:

■ a. In paragraph (b)(2), removing ''No. 017033'' and in its place adding ''Nos. 017033 and 086117''; and

■ b. Removing paragraph (b)(4).

■ 13. In § 520.998, revise paragraph (c)(2)(i) to read as follows:

§ 520.998 Fluralaner.

* * * * *

(c) * * *

(2) * * *

(i) *Chewable tablets described in paragraph (a)(1) of this section.* 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), *Rhipicephalus sanguineus* (brown dog tick), and *Haemaphysalis longicornis* (Asian longhorned tick)) for 12 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lbs or greater; and for the treatment and control of *Amblyomma americanum* (lone star tick) infestations for 8 weeks in dogs and puppies 6 months of age and older, and weighing 4.4 lbs or greater.

* * * * *

■ 14. Amend § 520.1044b by adding a sentence at the end of paragraph (d)(3) to read as follows:

§ 520.1044b [Amended]

* * * * *

(d) * * *

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

§ 520.1130 [Removed]

■ 15. Remove §§ 520.1130.

§ 520.1195 [Amended]

■ 16. In § 520.1195, in paragraph (b)(1), remove ''000010,''.

■ 17. In § 520.1310, revise paragraphs (a) and (b) to read as follows:

§ 520.1310 Marbofloxacin.

(a) *Specifications.* Each tablet or chewable tablet contains 25, 50, 100, or 200 milligrams (mg) marbofloxacin.

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section:

(1) Nos. 017033, 054771, and 086117 for use of tablets.

(2) No. 086101 for use of chewable tablets.

* * * * *

■ 18. In § 520.1315, revise paragraph (b) to read as follows:

§ 520.1315 Maropitant.

* * * * *

(b) *Sponsors.* See Nos. 054771 and 086117 in § 510.600(c) of this chapter.

* * * * *

§ 520.1696b [Removed]

■ 19. Remove § 520.1696b.

■ 20. In § 520.1696c, revise paragraph (b) to read as follows:

§ 520.1696c Penicillin V tablets.

* * * * *

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

* * * * *

§ 520.1870 [Amended]

■ 21. In § 520.1870, in paragraph (b)(2), remove ''No. 069043'' and in its place add ''Nos. 069043 and 086101''.

■ 22. In § 520.2200, revise paragraph (a)(2), remove paragraph (a)(3), revise paragraphs (d)(1)(i) and (d)(2)(i), and remove (d)(3) to read as follows:

§ 520.2200 Sulfachlorpyridazine.

(a) * * *

(2) Each milliliter (mL) of suspension contains 50 milligrams (mg) of sodium sulfachlorpyridazine.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* Administer 30 to 45 mg sulfachlorpyridazine powder per pound (/lb) of body weight per day in milk or milk replacer in divided doses twice daily for 1 to 5 days.

* * * * *

(2) * * *

(i) *Amount.* Administer 20 to 35 mg/lb body weight per day in divided doses twice daily for 1 to 5 days in drinking water or an oral suspension containing 50 mg per mL.

* * * * *

§§ 520.1696b, 520.2170, 520.2380, 520.2380a, 520.2380b, 520.2380c, 520.2380d and 520.2380e [Removed]

■ 23. Remove §§ 520.1696b, 520.2170, 520.2380, 520.2380a, 520.2380b, 520.2380c, 520.2380d and 520.2380e.

§ 520.2380f [Redesignated]

■ 24. Redesignate § 520.2380f as § 520.2382.

§ 520.2483 [Removed]

■ 25. Remove § 520.2483.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.536 [Amended]

■ 27. In § 522.536, in paragraph (b), remove ''Nos. 015914 and 052483'' and in its place add ''Nos. 015914, 052483, and 059399''.

§ 522.542 [Removed]

■ 28. Remove § 522.542.

§ 522.558 [Amended]

■ 29. In § 522.558, in paragraph (b)(1), remove ''Nos. 017033 and 059399'' and in its place add ''Nos. 017033, 059399, and 086117''.

§ 522.775 [Removed]

■ 30. Remove § 522.775.

■ 31. Amend § 522.820 by adding a sentence at the end of paragraph (d)(3)(iii) to read as follows:

§ 522.820 Erythromycin.

* * * * *

(d) * * *

(3) * * *

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

■ 32. In § 522.1077, revise paragraphs (b)(2), (d)(1)(iv), and (e)(1)(i) to read as follows:

§ 522.1077 Gonadorelin.

* * * * *

(b) * * *

(2) No. 068504 for use of the 100-µg/mL product described in paragraph (a)(2) as in paragraphs (d)(1)(i) and (iv) of this section.

* * * * *

(d) * * *

(1) * * *

(iv) Dinoprost injection for use as in paragraph (e)(1)(vi) of this section as provided by No. 054771 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(1) * * *

(i) For the treatment of ovarian follicular cysts in dairy cattle: Administer 86 µg gonadorelin (No. 000061), or 100 µg gonadorelin diacetate tetrahydrate (Nos. 000010 and 061133), or 100 µg gonadorelin (as gonadorelin acetate; No. 068504) by intramuscular or intravenous injection.

* * * * *

§ 522.1150 [Removed]

■ 33. Remove § 522.1150.

■ 34. In § 522.1192, remove and reserve paragraph (a)(1), and revise paragraphs (b)(1) and (2), remove and reserve paragraph (e)(1), and revise paragraph (e)(2)(i) to read as follows:

§ 522.1192 Ivermectin.

* * * * *

(b) * * *

(1) Nos. 000010, 016592, 055529, 058005, and 061133 for use of the product described in paragraph (a)(2) of this section as in paragraphs (e)(2) through (e)(5) of this section; and

(2) No. 000010 for use of the product described in paragraph (a)(3) of this section as in paragraphs (e)(3) and (e)(6) of this section.

* * * * *

(e) * * *

(2) * * *

(i) *Amount.* 200 micrograms per kilogram (µg/kg) of body weight by subcutaneous injection.

* * * * *

§ 522.1222 [Amended]

■ 35. In § 522.1222, revise paragraph (b) by adding, in numeric sequence, ''00010,''.

■ 36. In § 522.1450, revise paragraphs (a), (b), and (e) to read as follows:

§ 522.1450 Moxidectin solution.

(a) *Specifications.* Each milliliter (mL) of solution contains 10 milligrams (mg) moxidectin.

(b) *Sponsors.* See Nos. 055529 and 058198 in § 510.600(c) of this chapter.

* * * * *

(e) *Conditions of use in cattle—(1) Amount.* Administer by subcutaneous injection 1 mL for each 110 pounds (lb) (50 kilograms (kg)) body weight to provide 0.2 mg moxidectin/2.2 lb (0.2 mg/kg) body weight.

(2) *Indications for use.* Beef and nonlactating dairy cattle: For treatment and control of Gastrointestinal roundworms: *Ostertagia ostertagi* (adults, fourth-stage larvae, and inhibited larvae), *Haemonchus placei* (adults), *Trichostrongylus axei* (adults and fourth-stage larvae), *Trichostrongylus colubriformis* (adults and fourth-stage larvae), *Cooperia oncophora* (adults), *Cooperia pectinata* (adults), *Cooperia punctata* (adults and fourth-stage larvae), *Cooperia spatulata* (adults), *Cooperia surnabada* (adults

and fourth-stage larvae), *Nematodirus helvetianus* (adults), *Oesophagostomum radiatum* (adults and fourth-stage larvae), *Trichuris* spp. (adults); Lungworms: *Dictyocaulus viviparus* (adults and fourth-stage larvae); Cattle grubs: *Hypoderma bovis* and *Hypoderma lineatum;* Mites: *Psoroptes ovis* (*Psoroptes communis* var. *bovis*); Lice: *Linognathus vituli* and *Solenopotes capillatus.* For protection from reinfection with *Dictyocaulus viviparus* and *Oesophagostomum radiatum* for 42 days after treatment, with *Haemonchus placei* for 35 days after treatment, and with *Ostertagia ostertagi* and *Trichostrongylus axei* for 14 days after treatment.

(3) *Limitations.* Cattle must not be slaughtered for human consumption within 21 days of treatment. 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. A withdrawal period has not been established for preruminating calves. Do not use in calves to be processed for veal.

§ 522.1696b [Amended]

■ 37. In § 522.1696b, amend paragraph (d)(2)(iii)(C), by removing ''For Nos. 054771 and 055529:''.

§ 522.1885 [Removed]

■ 38. Remove § 522.1885.

■ 39. Amend § 522.2120 by adding a sentence at the end of paragraph (d)(1)(ii) to read follows:

§ 522.2120 Spectinomycin hydrochloride.

* * * * *

(d) * * *

(1) * * *

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

* * * * *

§ 522.2200 [Removed]

■ 40. Remove § 522.2200.

■ 41. In 522.2630, revise paragraph (b)(2) to read as follows:

§ 522.2630 Tulathromycin.

* * * * *

(b) * * *

(2) Nos. 013744, 051311, 054771, 058198, and 068504 for use of product described in paragraph (a)(2) as in paragraphs (d)(1)(i), (d)(1)(ii)(B), (d)(1)(iii)(B), and (d)(2) of this section.

* * * * *

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 43. In § 524.770, revise paragraph (b) to read as follows:

§ 524.770 Doramectin.

* * * * *

(b) *Sponsors.* See Nos. 051072 and 054771 in § 510.600(c) of this chapter.

* * * * *

■ 44. In § 524.814, revise paragraphs (b) and (e)(1) to read as follows:

§ 524.814 Eprinomectin.

* * * * *

(b) *Sponsors.* See Nos. 000010, 051072, and 055529 in § 510.600(c) of this chapter.

* * * * *

(e) * * *

(1) *Amount.* Apply 5 mg (1 mL) per 10 kilograms (kg) of body weight (500 micrograms/kg) topically along backbone from withers to tailhead.

* * * * *

§ 524.1044e [Amended]

■ 45. Amend § 524.1044e by adding a sentence at the end of paragraph (d)(3) to read as follows:

§ 524.1044e Gentamicin spray.

* * * * *

(d) * * *

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

§ 524.1146 [Amended]

■ 46. In § 524.1146, in paragraph (b)(3), remove ''Nos. 051072 and 058198'' and in its place add ''Nos. 051072, 055529, 058198, and 061651''.

§ 524.1484j [Removed]

■ 47. Remove § 524.1484j.

§ 524.2101 [Amended]

■ 48. In § 524.2101, in paragraph (b), remove ''000010, 000061,'' and in its place add ''000061''.

§ 524.2483 [Amended]

■ 49. In § 524.2483, in paragraph (b), remove ''Nos. 000010 and 054925'' and in its place add ''No. 054925''.

PART 526—INTRAMAMMARY DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 51. Amend § 526.1696 by adding a sentence at the end of paragraph (d)(3) and paragraph (e)(3) to read as follows:

§ 526.1696 Penicillin G procaine.

* * * * *

(d) * * *

(3) * * * For No. 042791: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(e)

(3) * * * For No. 042791: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.40 [Removed]

■ 53. Remove § 529.40.

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

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

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

§ 556.620 [Removed]

■ 55. Remove § 556.620.

■ 56. Revise § 556.730 to read as follows:

§ 556.730 Thiabendazole.

(a) [Reserved]

(b) *Tolerances.* The tolerances for thiabendazole are:

(1) *Cattle*—(i) Edible tissues (excluding milk): 0.1 ppm.

(ii) Milk: 0.05 ppm.

(2) [Reserved]

(c) *Related conditions of use.* See § 558.600.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 58. In § 558.311, revise paragraph (e)(3)(iii) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(3) * * *

Lasalocid amount	Indications for use	Limitations	Sponsor
* *	* *	* * *	*
(iii) Not less than 60 mg or more than 300 mg of lasalocid per head per day.	Pasture cattle (slaughter, stocker, feeder cattle, and beef replacement heifers): For increased rate of weight gain.	Feed continuously at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day when on pasture. The drug must be contained in at least 1 pound of feed. Daily intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.	054771
* *	* *	* * *	*

* * * * *

■ 50. In § 558.455, revise paragraph (e)(5) to read as follows:

§ 558.455 Oxytetracycline and neomycin.

* * * * *

(e) * * *

(5) *Sheep.* It is used in feed as follows:

Oxytetracycline and neomycin sulfate amount	Indications for use	Limitations	Sponsors
(i) To provide 10 mg/lb of body weight daily.	Sheep: For treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to oxytetracycline; treatment and control of colibacillosis (bacterial enteritis) caused by *E. coli* susceptible to neomycin.	Feed continuously for 7 to 14 days. Treatment should continue 24 to 48 hours beyond remission of clinical signs of disease. Withdraw 5 days before slaughter.	066104 069254

(ii) [Reserved]

■ 59. Revise § 558.600 to read as follows:

§ 558.600 Thiabendazole.

(a) *Specifications.* Mineral protein block containing 3.3 percent thiabendazole.

(b) *Sponsor.* See No. 012286 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.730 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use in cattle*—(1) *Amount.* Provide free-choice to cattle on pasture or range accustomed to mineral protein block feeding for 3 days. Cattle should consume at a recommended level of 0.11 pound per 100 pounds of body weight per day. Animals maintained under conditions of constant worm exposure may require retreatment within 2 to 3 weeks.

(2) *Indications for use.* For control of infections of gastrointestinal roundworms (*Trichostrongylus, Haemonchus, Ostertagia,* and *Cooperia*).

(3) *Limitations.* Milk taken from animals during treatment and within 96 hours (8 milkings) after the latest treatment must not be used for food. Do not treat cattle within 3 days of slaughter.

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 230427–0115]

RIN 0648–BL89

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Resources of the Gulf of Mexico; Temporary Measures To Reduce Overfishing of Gag

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final temporary rule.

SUMMARY: This final temporary rule implements interim measures to reduce overfishing of gag in Federal waters of the Gulf of Mexico (Gulf). This final temporary rule reduces the 2023 commercial and recreational sector harvest levels for gag and changes the 2023 recreational fishing season for gag in Federal waters of the Gulf. This temporary rule is effective for 180 days, but NMFS may extend the interim measures for a maximum of an additional 186 days. The purpose of this temporary rule is to reduce overfishing of gag while the long-term management measures are developed.

DATES: This final temporary rule is effective from May 3, 2023, until October 30, 2023.

ADDRESSES: An electronic copy of the environmental assessment (EA) supporting these interim measures may be obtained from the Southeast Regional Office website at *https://www.fisheries.noaa.gov/action/interim-action-reduce-overfishing-gag-gulf-mexico.* The EA includes a regulatory impact review and a Regulatory Flexibility Act (RFA) analysis.

FOR FURTHER INFORMATION CONTACT: Dan Luers, NMFS Southeast Regional Office, telephone: 727–824–5305, or email: *daniel.luers@noaa.gov.*

SUPPLEMENTARY INFORMATION: The reef fish fishery in the Gulf is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP) and includes gag and 30 other managed reef fish species. The FMP was prepared by the Gulf of Mexico Fishery Management Council (Council) and is implemented by NMFS through regulations at 50 CFR part 622 under authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act).

On February 3, 2023, NMFS published a proposed temporary rule in the **Federal Register** and requested public comment (88 FR 7388). The proposed temporary rule and EA outline the rationale for the actions contained in this final temporary rule, and the EA is available from NMFS (see **ADDRESSES**