

Authority: 42 U.S.C. 4321–4370h, 7101–7352; E.O. 12009, 3 CFR 1978 Comp., p. 142.

§ 380.1 [Amended]

■ 47. In § 380.1, add the word “(NEPA)” after the words “the National Environmental Policy Act of 1969” in the first sentence and remove the year “(1986)” from the second sentence.

§ 380.3 [Corrected]

■ 48. In § 380.3(a)(1), correct the word “and” to read “an”.

§ 380.4 [Corrected]

■ 49. In § 380.4(a)(27), correct the word “requires” to read “require”.

§ 380.5 [Corrected]

■ 50. In § 380.5(b)(7), correct the reference “§§ 4.30(b)(27) and 4.101–4.106” to read “§§ 4.30(b)(29) and 4.101–4.108”.

§ 380.6 [Corrected]

■ 51. In § 380.6(a)(3), correct the words “right-of-way” to read “rights-of-way”.

§ 380.8 [Amended]

■ 52. In § 380.8, remove the words “Council on Environmental Quality” and add, in their place, the word “Council” and remove the telephone number “(202) 219–8700” and add, in its place, the telephone number “(202) 502–8700”.

§ 380.12 [Amended]

■ 53. In § 380.12:
 ■ a. In paragraphs (b)(1) and (b)(5), remove the period at the end of the sentence for each paragraph and add, in their place, a semi-colon.
 ■ b. In paragraph (e)(3), correct the phrase “affected acreage” to read “acreage”.

■ c. In paragraph (f) introductory text, correct the words “In order to prepare” to read “In preparing”.

■ d. In paragraph (f)(2) introductory text, change the “D” in the word “Documentation” to a lower case letter “d”.

■ e. In paragraph (i)(5), move the comma following the closing quotation mark for the phrase “Upland Erosion Control, Revegetation and Maintenance Plan” inside the closing quotation mark to read as “Upland Erosion Control, Revegetation and Maintenance Plan.”.

■ f. In paragraph (o)(12), remove the word “of” from the words “Identify of all codes”.

§ 380.14 [Corrected]

■ 54. In § 380.14(a) introductory text, correct the words “Commission take” to read “Commission to take”.

§ 380.15 [Corrected]

■ 55. In § 380.15(f)(5), correct the word “above-ground” to read “aboveground”.

PART 385—RULES OF PRACTICE AND PROCEDURE

■ 56. The authority citation for Part 385 is revised to read as follows:

Authority: 5 U.S.C. 551–557; 15 U.S.C. 717–717z, 3301–3432; 16 U.S.C. 792–828c, 2601–2645; 28 U.S.C. 2461; 31 U.S.C. 3701, 9701; 42 U.S.C. 7101–7352, 16441, 16451–16463; 49 U.S.C. 60502; 49 App. U.S.C. 1–85 (1988).

§ 385.2201 [Corrected]

■ 57. In § 385.2201(c)(1), italicize the words “Contested on-the-record proceeding”.

[FR Doc. 2012–1307 Filed 1–31–12; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2011–N–0003]

New Animal Drugs; Chloramphenicol, Diethylcarbamazine Citrate, Hygromycin B, Methoxyflurane, Neomycin Sulfate, Penicillin G, Phenylbutazone, Pyrantel Tartrate, Tylosin Phosphate, and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal of approval of 20 new animal drug applications (NADAs).

DATES: Withdrawal of approval is effective February 13, 2012.

FOR FURTHER INFORMATION CONTACT: John Bartkowiak, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9079, email: john.bartkowiak@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The sponsors of the 20 approved NADAs listed in table 1 of this document have requested that FDA withdraw approval because the products are no longer manufactured or marketed:

TABLE 1—VOLUNTARY REQUESTS FOR WITHDRAWAL OF APPROVAL (WOA) OF 20 NADAS

Application No.	Trade name (drug)	Applicant
NADA 014–485	METOPHANE Inhalation (methoxyflurane)	Medical Developments, International, Ltd., P.O. Box 21, Sandown Village, 3171 VIC Australia.
NADA 032–322	LIQUISONE F with Cerumene (hexamethyltetraacosane, prednisolone, tetracaine, neomycin sulfate).	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 044–655	NEOMYCANE Ophthalmic Ointment (neomycin sulfate).	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 045–288	OPTISON (neomycin sulfate, prednisolone acetate).	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 049–890	NORCO T–2 Pre-Pak (tylosin phosphate)	Norco Mills of Norfolk, Inc., P.O. Box 56, Norfolk, NE 68701.
NADA 055–034	CHLORASOL (chloramphenicol)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 055–052	Chlora-Tabs 100 (chloramphenicol)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 065–158	CHLORICOL (chloramphenicol)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 065–259	CHLORASONE Ophthalmic Ointment (chloramphenicol, prednisolone acetate).	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.

TABLE 1—VOLUNTARY REQUESTS FOR WITHDRAWAL OF APPROVAL (WOA) OF 20 NADAs—Continued

Application No.	Trade name (drug)	Applicant
NADA 065-488	BENZA-PEN (penicillin G benzathine, penicillin G procaine).	Walco International, Inc., 15 West Putnam, Porterville, CA 93257.
NADA 095-953	MOORMABOOST TY 4000 Medicated (tylosin phosphate).	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 100-689	DIFIL Syrup (diethylcarbamazine citrate)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 100-690	DIFIL Tablets (diethylcarbamazine citrate)	Evsco Pharmaceuticals, an Affiliate of IGI, Inc., Box 209, Harding Hwy., Buena, NJ 08310.
NADA 107-957	TYLAN 20 Sulfa-G (tylosin phosphate and sulfamethazine).	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 111-069	TYLAN 40 Sulfa-G (tylosin phosphate and sulfamethazine).	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 131-956	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 131-957	TYLAN 40 (tylosin phosphate)	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 133-490	Ban-D-Wormer II BANMINTH (pyrantel tartrate) ..	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 140-842	HYGROMIX 2.4 Premix (hygromycin B)	ADM Alliance Nutrition, Inc., 1000 North 30th St., Quincy, IL 62305-3115.
NADA 140-958	EQUIPHEN Paste (phenylbutazone) 520.1720c ..	Luitpold Pharmaceuticals, Inc., Animal Health Division, Shirley, NY 11967.

In a notice published elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADAs 014-485, 032-322, 044-655, 045-288, 049-890, 055-034, 055-052, 065-158, 065-259, 065-488, 095-953, 100-689, 100-690, 107-957, 111-069, 131-956, 131-957, 133-490, 140-842, and 140-958, and all supplements and amendments thereto, is withdrawn, effective February 13, 2012. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these withdrawals of approval and a current format.

Following these withdrawals of approval, Evsco Pharmaceuticals, an Affiliate of IGI, Inc.; Medical Developments International, Ltd.; and Norco Mills of Norfolk, Inc., are no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for these firms.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

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

21 CFR Part 520, 522, 524, and 529

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, 529, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

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

§ 510.600 [Amended]

■ 2. In § 510.600, in the table in paragraph (c)(1), remove the entries for “Evsco Pharmaceuticals, An Affiliate of IGI, Inc.,” “Medical Developments International, Ltd.,” and “Norco Mills of Norfolk, Inc.”; and in the table in paragraph (c)(2), remove the entries for “017030”, “025245”, and “027190”.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 4. Revise § 520.390a to read as follows:

§ 520.390a Chloramphenicol tablets.

(a) *Specifications.* Each tablet contains 50, 100, 250, or 500 milligrams (mg); 1 or 2.5 grams (g) of chloramphenicol.

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

(1) For use as in paragraphs (c)(1), (c)(2)(i), and (c)(3) of this section:

(i) No. 000010 for 100-, 250-, and 500-mg; and 1- and 2.5-g tablets;

(ii) No. 000856 for 100-, 250-, and 500-mg tablets;

(iii) No. 000069 for 250-mg tablets.

(2) For use as in paragraphs (c)(1), (c)(2)(ii), and (c)(3) of this section:

(i) No. 061623 for 50-, 100-, 250-, and 500-mg; and 1-g tablets;

(ii) [Reserved]

(c) *Conditions of use in dogs—(1) Amount.* Administer 25 mg per pound of body weight by mouth every 6 hours.

(2) *Indications for use—(i)* For the treatment of bacterial pulmonary infections, bacterial infections of the urinary tract, bacterial enteritis, and bacterial infections associated with canine distemper caused by susceptible organisms.

(ii) For the treatment of bacterial gastroenteritis associated with bacterial diarrhea, bacterial pulmonary infections, and bacterial infections of the urinary tract caused by susceptible organisms.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this drug in food-producing animals.

§ 520.622a [Amended]

■ 5. In § 520.622a, remove and reserve paragraph (a)(4).

§ 520.622b [Amended]

■ 6. In § 520.622b, remove and reserve paragraph (b).

§ 520.1720c [Amended]

■ 7. In § 520.1720c, in paragraph (b)(1), remove “Nos. 000061 and 010797” and in its place add “No. 000061”.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 9. In § 522.1696a, revise paragraphs (b)(1), (b)(3), (d)(1)(iii), and (d)(2)(iii) to read as follows:

§ 522.1696a Penicillin G benzathine and penicillin G procaine suspension.

* * * * *

(b) * * *

(1) Nos. 000856, 055529, and 061623 for use as in paragraph (d)(1) of this section.

* * * * *

(3) No. 000856 for use as in paragraphs (d)(2)(i), (d)(2)(ii)(B), and (d)(2)(iii) of this section.

* * * * *

(d) * * *

(1) * * *

(iii) *Limitations.* Not for use in beef cattle within 30 days of slaughter. 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) * * *

(iii) *Limitations.* Not for use within 30 days of slaughter. For Nos. 055529, 059130, and 061623: A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 10. The authority citation for 21 CFR part 524 continues to read as follows:

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

■ 11. Revise § 524.390 to read as follows:

§ 524.390 Chloramphenicol ophthalmic ointment.

(a) *Specifications.* Each gram contains 10 milligrams chloramphenicol.

(b) *Sponsors.* See Nos. 000856 and 025463 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs and cats—(1) Amount.* Apply every 3 hours around the clock for 48 hours, after

which night instillations may be omitted.

(2) *Indications for use.* For treatment of bacterial conjunctivitis caused by pathogens susceptible to chloramphenicol.

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

§§ 524.390a, 524.390b, and 524.390d [Removed]

■ 12. Remove §§ 524.390a, 524.390b, and 524.390d.

§§ 524.1484a, 524.1484j, and 524.1484k [Removed]

■ 13. Remove 524.1484a, 524.1484j, and 524.1484k.

§§ 524.1880 [Removed]

■ 14. Remove 524.1880.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 15. The authority citation for 21 CFR part 529 continues to read as follows:

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

§ 529.1455 [Removed]

■ 16. Remove 529.1455.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 17. The authority citation for 21 CFR part 558 continues to read as follows:

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

§ 558.274 [Amended]

■ 18. In § 558.274, remove and reserve paragraph (a)(7); and in the table in paragraphs (c)(1)(i) and (c)(1)(ii), in the “Sponsor” column, remove “012286”.

§ 558.485 [Amended]

■ 19. In paragraph (b)(3) of § 558.485, remove “012286”.

§ 558.625 [Amended]

■ 20. In § 558.625, remove and reserve paragraphs (b)(10), (b)(12), and (b)(67).

§ 558.630 [Amended]

■ 21. In § 558.630, remove and reserve paragraph (b)(2) and in paragraph (b)(5), remove “012286”.

Dated: January 26, 2012.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2012-2103 Filed 1-31-12; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[Docket No. USCG-2012-0010]

RIN 1625-AA00

Safety Zone; M/V Del Monte Live-Fire Gun Exercise, James River, Isle of Wight, VA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the navigable waters of the James River in Isle of Wight, VA. This action is necessary to provide for the safety of life on navigable waters during the live-fire gun exercises on the M/V Del Monte. This action is intended to restrict vessel traffic movement to protect mariners from the hazards associated with the live-fire gun exercise.

DATES: This rule is effective in the CFR on February 1, 2012 through February 3, 2012. This rule is effective with actual notice for purposes of enforcement at 11 a.m. on January 30, 2012. This rule will remain in effect through 9 a.m. on February 3, 2012.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2012-0010 and are available online by going to <http://www.regulations.gov>, inserting USCG-2012-0010 in the “Keyword” box, and then clicking “Search.” They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or email LCDR Christopher A. O’Neal, Waterways Management Division Chief, Sector Hampton Roads, Coast Guard; telephone 757-668-5581, email Christopher.A.ONeal@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:**Regulatory Information**

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act