its place add ''Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200''.

§ 184.1595 [Amended]

■ 37. In § 184.1595, in paragraph (b), remove ''Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740'' and in its place add ''Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200''.

§ 184.1866 [Amended]

■ 38. In § 184.1866, in paragraph (b), remove ''Office of Premarket Approval, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740'' and in its place add ''Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200''.

§ 184.1914 [Amended]

■ 39. In § 184.1914, in paragraph (b), remove ''Office of Premarket Approval (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740'' and in its place add ''Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200''.

§ 184.1985 [Amended]

■ 40. In § 184.1985, in paragraph (b), remove ''Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., Suite 1200, Washington, DC'' and in its place add ''Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200''.

PART 189—SUBSTANCES PROHIBITED FROM USE IN HUMAN FOOD

■ 41. The authority citation for 21 CFR part 189 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371, 381.

§ 189.110 [Amended]

■ 42. In § 189.110, in paragraph (c), remove ''Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740'' and in its place add ''Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200''.

§ 189.180 [Amended]

■ 43. In § 189.180, in paragraph (c), remove ''Division of Food and Color Additives, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740'' and in its place add ''Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200''.

Dated: February 1, 2013.

Susan M. Bernard,

Director, Office of Regulations, Policy and Social Sciences, Center for Food Safety and Applied Nutrition.

[FR Doc. 2013–04701 Filed 3–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

[Docket No. FDA–2012–N–1167]

New Animal Drug Applications; Alfaprostol; Bicyclohexylammonium Fumagillin; *N*-Butyl Chloride; Competitive Exclusion Culture; Dichlorophene and Toluene; Flurogestone Acetate; Isoflurane; Pyrantel; Tylosin; Tylosin and Sulfamethazine

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the withdrawal approval of 19 new animal drug applications (NADAs) and one abbreviated new animal drug application (ANADA). The applications are being withdrawn for lack of compliance with the reporting requirements in an FDA regulation.

DATES: This rule is effective March 18, 2013.

FOR FURTHER INFORMATION CONTACT: David Alterman, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855; 240–453–6843; *david.alterman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of the 19 NADAs and one ANADA listed in table 1, and all supplements and amendments thereto, is withdrawn, effective March 18, 2013, for lack of compliance with reporting requirements in 21 CFR 514.80. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect withdrawal of approval of the following applications and a current format. Withdrawal of approval of some applications did not require amending the regulations.

TABLE 1—NADAS AND ANADA FOR WHICH APPROVAL IS WITHDRAWN

Application No.	Trade name (drug)	Applicant	Citation in 21 CFR
NADA 009–252	FUMIDIL B (bicyclohexylammonium fumagillin)	Mid-Continent Agrimarketing, Inc., 8833 Quivira Rd., Overland Park, KS 66214	520.182
NADA 034–601	SYNCHRO–MATE (flurogestone acetate)	G. D. Searle LLC, Pharmacia Corp., 4901 Searle Pkwy., Skokie, IL 60077	529.1003

TABLE 1—NADAS AND ANADA FOR WHICH APPROVAL IS WITHDRAWN—Continued

Application No.	Trade name (drug)	Applicant	Citation in 21 CFR
NADA 039–284	Swisher Super Broiler 300–108 (amprolium, ethopabate, bacitracin zinc, and roxarsone).	Swisher Feed Division, William Davies Co., Inc., P.O. Box 578, Danville, IL 61832	558.58
NADA 040–920	Chick Grower Developer Fortified (amprolium)	Honeggers and Co., Inc., 201 W. Locust St., Fairbury, IL 61739	Not codified
NADA 094–223	Canine Worm Caps (*n*-butyl chloride)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214	520.260
NADA 098–429	Medic-Meal-T Premix (tylosin phosphate)	J. C. Feed Mills, 1050 Sheffield, P.O. Box 224, Waterloo, IA 50704	558.625
NADA 098–639	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	Bioproducts, Inc., 320 Springside Dr., suite 300, Fairlawn, OH 44333–2435	558.630
NADA 106–507	TYLAN 10 (tylosin phosphate)	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501	558.625
NADA 110–044	PRO–TONE Plus Pak GF T–1 (tylosin phosphate).	Peavey Co., 730 Second Ave. South, Minneapolis, MN 55402	558.625
NADA 117–688	Dichlorophene and Toluene Capsules	Texas Vitamin Co., P.O. Box 18417, 10695 Aledo St., Dallas, TX 57218	520.580
NADA 120–614	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	Webel Feeds, Inc., R.R. 3, Pittsfield, IL 62363	558.630
NADA 120–671	Pet-Worm-Caps (dichlorophene and toluene)	K. C. Pharmacal, Inc., 8345 Melrose Dr., Lenexa, KS 66214	520.580
NADA 121–147	Nutra-Mix TYLAN (tylosin phosphate)	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	558.625
NADA 122–522	TYLAN Sulfa-G (tylosin phosphate and sulfamethazine).	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501	558.630
NADA 124–391	Nutra-Mix TYLAN-Sulfa Premixes (tylosin phosphate and sulfamethazine).	Ag-Mark, Inc., P.O. Box 127, Teachey, NC 28464	558.630
NADA 127–195	TYLAN 10 (tylosin phosphate)	I.M.S. Inc., 13619 Industrial Rd., Omaha, NE 68137	558.625
NADA 129–415	Custom Ban Wormer 9.6 Banminth (pyrantel tartrate).	Custom Feed Blenders Corp., 540 Hawkeye Ave., Fort Dodge, IA 50501	558.485
NADA 130–092	ALFAVET (alfaprostol)	Vetem, S.p.A., Viale E. Bezzi 24, 20146 Milano, Italy	522.46
NADA 141–101	PREEMPT (competitive exclusion culture)	Bioscience Division, of Milk Specialties Co., 1902 Tennyson Lane, Madison, WI 53704	529.469
ANADA 200–187	Isoflurane, USP	Marsam Pharmaceuticals, LLC, Bldg. 31, 24 Olney Ave., Cherry Hill, NJ 08034	529.1186

Following these withdrawals of approval, Ag-Mark, Inc.; Bioproducts, Inc.; Bioscience Division of Milk Specialties Co.; Custom Feed Blenders Corp.; G. D. Searle LLC; I.M.S. Inc.; J. C. Feed Mills; K. C. Pharmacal, Inc.; Marsam Pharmaceuticals, LLC; Mid-Continent Agrimarketing, Inc.; Peavey Co.; Texas Vitamin Co.; Vetem, S.p.A.; and Webel Feeds, 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. In addition, the entries for Wyeth Laboratories, Division American Home Products Corp. are being removed because that firm is not the sponsor of an approved NADA.

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

List of Subjects

21 CFR Part 510

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

21 CFR Parts 520, 522, 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, 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 ''Ag-Mark, Inc.'', ''Bioproducts, Inc.'', ''Bioscience Division of Milk Specialties Co.'', ''Custom Feed Blenders Corp.'', ''G. D. Searle LLC'', ''I.M.S. Inc.'', ''J. C. Feed Mills'', ''K. C. Pharmacal, Inc.'', ''Marsam Pharmaceuticals, LLC'', ''Mid-Continent Agrimarketing, Inc.'', ''Peavey Co.'', ''Texas Vitamin Co.'', ''Vetem, S.p.A.'', ''Webel Feeds, Inc.'', and ''Wyeth Laboratories, Division American Home Products Corp.''; and in the table in paragraph (c)(2), remove the entries for ''000008'', ''000014'', ''000209'', ''000842'', ''024174'', ''028459'', ''032761'', ''035098'', ''038782'', ''039741'', ''046987'', ''050639'', ''051359'', ''055882'', and ''059620''.

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.

§ 520.182 [Removed]

■ 4. Remove § 520.182.

■ 5. In § 520.260, revise the section heading and add paragraphs (b)(1) through (3) to read as follows:

§ 520.260 n-Butyl chloride.

* * * * *

(b) * * *

(1) *Specifications.* Each capsule contains 221, 272, 442, 816, 884, 1,768 milligrams, or 4.42 grams of *n*-butyl chloride.

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

(i) No. 000069 for use of 221-milligram capsules.

(ii) No. 021091 for use of 272- or 816-milligram capsules.

(iii) No. 023851 for use of 221-, 442-, 884-, or 1,768-milligram, or 4.42-gram capsules.

(3) *Conditions of use in dogs*—(i) *Amount.* Administered capsules orally. Capsules containing 221 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage of 1 capsule per 1¼ pounds of body weight. Capsules containing 442 milligrams of *n*-butyl chloride are administered to dogs weighing under 5 pounds at a dosage of 1 capsule per 2½ pounds body weight. Capsules containing 884 milligrams of *n*-butyl chloride are administered to dogs as follows: Weighing under 5 pounds, 1 capsule; weighing 5 to 10 pounds, 2 capsules; weighing 10 to 20 pounds, 3 capsules; weighing 20 to 40 pounds, 4 capsules; over 40 pounds, 5 capsules. Capsules containing 1,768 milligrams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 5 to 10 pounds. Capsules containing 4.42 grams of *n*-butyl chloride are administered at a dosage level of 1 capsule per dog weighing 40 pounds or over.

(ii) *Indications for use.* For the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum, Ancylostoma braziliense,* and *Uncinaria stenocephala*).

(iii) *Limitations.* Dogs should not be fed for 18 to 24 hours before being given the drug. Administration of the drug should be followed in ½ to 1 hour with a mild cathartic. Normal feeding may be resumed 4 to 8 hours after treatment. Animals subject to reinfection may be retreated in 2 weeks. A veterinarian should be consulted before using in severely debilitated dogs.

■ 6. In § 520.580, revise the section heading and paragraphs (a), (b), and (d)(1) and (2) to read as follows:

§ 520.580 Dichlorophene and toluene.

(a) *Specifications.* Each capsule contains 50 milligrams (mg) of dichlorophene and 60 mg of toluene, or multiples thereof.

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

(1) Nos. 017135, 023851, 051311, and 058670 for use only as a single dose.

(2) Nos. 000010 and 000061 for use in a single dose or divided-dosage regimen.

* * * * *

(d) * * *

(1) *Amount.* Administer as follows:

(i) Single dose: Administer 100 mg of dicholorophene and 120 mg of toluene per pound of body weight.

(ii) Divided dose: Administer 100 mg of dichlorophene and 120 mg of toluene per 5 pounds of body weight (20 and 24 mg per pound) daily for 6 days.

(2) *Indications for use.* For the removal of ascarids (*Toxocara canis* and *Toxascaris leonina*) and hookworms (*Ancylostoma caninum* and *Uncinaria stenocephala*); and as an aid in removing tapeworms (*Taenia pisiformis, Dipylidium caninum,* and *Echinococcus granulosus*) from dogs and cats.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.46 [Removed]

■ 8. Remove § 522.46.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.469 [Removed]

■ 10. Remove § 529.469.

§ 529.1003 [Removed]

■ 11. Remove § 529.1003.

§ 529.1186 [Amended]

■ 12. In paragraph (b) of § 529.1186, remove ''000209,''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.485 [Amended]

■ 14. In § 558.485, in paragraph (b)(6), remove ''Nos. 034936 and 046987'' and add in its place ''No. 034936''.

§ 558.625 [Amended]

■ 15. In § 558.625, remove and reserve paragraphs (b)(35), (b)(63), (b)(66), and (b)(77).

■ 16. In § 558.630, add paragraph (b)(5) to read as follows:

§ 558.630 Tylosin and sulfamethazine.

* * * * *

(b) * * *

(5) Nos. 000986, 012286, 034936, and 046573: 5, 10, 20, or 40 grams per pound each for use as in paragraph (e)(2)(ii) of this section.

* * * * *

Dated: February 27, 2013.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2013–04999 Filed 3–6–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[CPCLO Order No. 002–2013]

Privacy Act of 1974; Implementation

AGENCY: Drug Enforcement Administration, United States Department of Justice.

ACTION: Final rule.

SUMMARY: The Department of Justice (DOJ or Department), Drug Enforcement Administration (DEA) is issuing a final rule for the recently modified system of records titled ''Investigative Reporting and Filing System'' (IRFS), JUSTICE/DEA–008. This system, which has already been exempted from particular subsections of the Privacy Act of 1974, is now being exempted further. Information in this system relates to law enforcement and intelligence matters, and for the reasons set forth in the rule these exemptions are necessary to avoid interference with the law enforcement, counterterrorism, and national security functions and responsibilities of the DEA.

DATES: Effective March 7, 2013.

FOR FURTHER INFORMATION CONTACT: DEA Headquarters, Attn: Bettie E. Goldman, Assistant Deputy Chief Counsel (CV), 8701 Morrissette Drive, Springfield, VA 22152, telephone 202–307–8040.

SUPPLEMENTARY INFORMATION:

Background

On April 11, 2012, the Department published an updated Privacy Act