clarithromycin used conforms to the standards prescribed by § 452.50(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to complying with the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(A) The clarithromycin used in making the batch for potency, moisture, pH, residue on ignition, heavy metals, specific rotation, identity, and crystallinity.

(B) The batch for content, loss on drying, pH, and identity.

(ii) Samples, if required by the Director, Center for Drug Evaluation and Research:

(A) The clarithromycin used in making the batch: 10 packages, each containing approximately 500 milligrams.

(B) The batch: A minimum of six immediate containers.

(b) *Tests and methods of assay*—(1) *Clarithromycin content.* Proceed as directed in § 452.50(b)(1), except use a known injection volume between 10 and 60 microliters. Also, prepare the mobile phase, working standard solution, and sample solution, and use system suitability requirements and calculation as follows:

(i) *Mobile phase.* Add 600 milliliters of methanol and 400 milliliters of 0.067M potassium phosphate, monobasic, to a suitable container, mix well, and adjust the pH to 3.5 with phosphoric acid. Filter through a suitable filter capable of removing particulate matter to 0.5 micron in diameter. Degas the mobile phase just before its introduction into the chromatographic system.

(ii) *Preparation of standard solution.* Dissolve an accurately weighed portion of the clarithromycin working standard in sufficient methanol to obtain a solution having a known concentration of approximately 2.1 milligrams per milliliter of clarithromycin. Quantitatively transfer and dilute an aliquot of this solution with mobile phase and mix to obtain a solution of known concentration of approximately 415 micrograms of clarithromycin per milliliter.

(iii) *Preparation of sample solution.* Constitute as directed in the labeling. Accurately measure a representative portion of the suspension that contains about 1 to 2 grams of clarithromycin activity and, using approximately 330 milliliters of 0.067M potassium phosphate, dibasic, quantitatively transfer into a 1,000 milliliter volumetric flask containing approximately 50 milliliters of 0.067M potassium phosphate, dibasic. Shake for 30 minutes. Dilute to volume with methanol. Mix well and place in an ultrasonic bath for 30 minutes. Cool to room temperature and adjust to volume with methanol. Add a magnetic stirring bar and stir for 60 minutes. Allow excipients to settle and dilute an appropriate aliquot of the solution with mobile phase to obtain a solution containing 500 micrograms of clarithromycin activity per milliliter and mix well. Filter through a suitable filter capable of removing particulate matter 0.5 micron in diameter.

(iv) *System suitability requirements*—(A) *Tailing factor.* The tailing factor (T) is satisfactory if it is not less than 1.0 and not greater than 1.7 for the clarithromycin peak.

(B) *Efficiency of the column.* The efficiency (n) is satisfactory if it is greater than 2,100 theoretical plates for the clarithromycin peak.

(C) *Capacity factor.* The capacity factor (k') is satisfactory if it is between 2.5 and 6 for the clarithromycin peak.

(D) *Coefficient of variation (relative standard deviation).* The coefficient of variation (S_R in percent of three replicate injections) is satisfactory if it is not more than 2.0 percent.

(v) *Calculations.* Calculate the clarithromycin content as follows:

$$\text{Milligrams of clarithromycin per milliliter} = \frac{A_U \text{ X } P_S \text{ X D}}{A_S \text{ X } V}$$

where:

A_U = Area of the clarithromycin peak in the chromatogram of the sample;

A_S = Area of the clarithromycin peak in the chromatogram of the clarithromycin working standard;

P_S = Clarithromycin activity in the clarithromycin working standard solution in micrograms per milliliter;

D = Dilution factor of the sample test solution; and

V = Volume, in milliliters, of the portion of suspension taken.

(2) *Loss on drying.* Proceed as directed in § 436.200(a) of this chapter, using a sample weight of approximately 1 gram, weighing in a normal laboratory atmosphere.

(3) *pH.* Proceed as directed in § 436.202 of this chapter, using the suspension prepared as directed in the labeling. Stir the suspension for 10 minutes with the electrode immersed and record the pH.

(4) *Identity.* Using the high-performance liquid chromatographic procedure described in paragraph (b)(1) of this section, the retention times for the clarithromycin peak must be within 2 percent of the retention time for the peak of the reference standard.

Dated: June 20, 1996.

Janet Woodcock,

Director, Center for Drug Evaluation and Research.

[FR Doc. 96–16977 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Parts 520, 522, 529, and 558

Animal Drugs, Feeds, and Related Products; 29 Various New Animal Drug Products and Type A Medicated Articles

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions reflecting approval of 29 new animal drug applications (NADA's) held by Bayer Corp., Agriculture Division, Animal Health (formerly Miles, Inc., Agriculture Division, Animal Health Products), Hubbard Milling Co., Hoffmann-LaRoche, Inc., and Ohmeda, Inc. The NADA's provide for the use of 29 various new animal drug products and Type A medicated articles used to manufacture finished medicated animal feeds. In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: July 15, 1996.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV–216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0159.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the Federal Register, FDA is withdrawing approval of the following NADA's:

NADA No.	Drug name	Sponsor name and address
6–462	Diethylcarbamazine tablets	Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201.
10–540	Calcium disodium edetate injection	Do.
11–380	Diethylcarbamazine powder	Do.
12–054	Protokylol hydrochloride tablets and injection	Do.
12–103	Triamcinolone tablets	Do.
12–392	Triamcinolone injection	Do.
12–598	Disophenol sodium injection	Do.
15–161	Trichlorfon powder	Do.
15–965	Coumaphos Type A medicated article	Do.
30–045	Triamcinolone/neomycin sulfate ointment	Do.
34–394	Niclosamide tablets	Do.
35–263	Styrylpyridinium chloride, diethylcarbamazine (as base) oral liquid.	Do.
45–287	Coumaphos crumbles	Do.
48–645	Tylosin Type A medicated articles (5, 10, 20, and 40 grams per pound).	Hubbard Milling Co., 424 North Riverfront Dr., P.O. Box 8500, Mankato, MN 56002–8500.
49–555	Styrylpyridinium chloride, diethylcarbamazine control diet HRH/MSD.	Bayer Corp.
91–628	Diethylcarbamazine citrate syrup	Do.
93–372	Chlortetracycline calcium complex Type A medicated articles.	Hoffmann-LaRoche, Inc., Nutley, NJ 07110.
94–402	Tylosin and sulfamethazine Type A medicated articles	Hubbard Milling Co.
95–078	Trichlorfon oral liquid	Bayer Corp.
96–031	Styrylpyridinium chloride, diethylcarbamazine citrate tablets.	Do.
100–201	Trichlorfon paste	Do.
100–356	Styrylpyridinium chloride, diethylcarbamazine control diet HRH.	Do.
100–670	Niclosamide Type A medicated article	Do.
101–078	Dichlorophene and toluene capsules	Do.
120–327	Diethylcarbamazine chewable tablets	Do.
120–670	Styrylpyridinium, diethylcarbamazine edible tablets	Do.
121–291	Enflurane liquid (anesthetic)	Ohmeda, Inc., Pharmaceutical Products Division, P.O. Box 804, Liberty Corner, NJ 07938–0804.
121–813	Styrylpyridinium, diethylcarbamazine film-coated tablets	Bayer Corp.
133–509	Pyrantel tartrate Type A medicated articles	Hubbard Milling Co.

The sponsors requested withdrawal of approval of the NADA's. This final rule removes 21 CFR 520.500, 520.620a, 520.620b, 520.1520, 520.2022, 520.2160a, 520.2160b, 520.2160c, 520.2160d, 520.2480, 520.2520c, 520.2520d, 522.281, 522.740, 522.2022, 522.2480, 529.810, 558.367, and 558.565, and amends 21 CFR 520.580, 520.622a, 520.622b, 520.2520a, 558.185, 558.485, 558.625, and 558.630.

List of Subjects

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 authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520, 522, 529, and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.500 [Removed]

2. Section 520.500 *Coumaphos crumbles* is removed.

§ 520.580 [Amended]

3. Section 520.580 *Dichlorophene and toluene capsules* is amended in paragraph (b)(2) by removing ''000859,''.

§ 520.620a [Removed]

4. Section 520.620a *Diethylcarbamazine* is removed.

§ 520.620b [Removed]

5. Section 520.620b *Diethylcarbamazine chewable tablets* is removed.

§ 520.622a [Amended]

6. Section 520.622a *Diethylcarbamazine citrate tablets* is amended in paragraph (a) by removing ''000859 and''.

7. Section 520.622b is amended by revising paragraph (b)(2) to read as follows:

§ 520.622b Diethylcarbamazine citrate syrup.

* * * * *

(b)(1) * * *

(2) *Sponsors.* See No. 017030 for use as in paragraphs (b)(3)(ii)(*a*) and (b)(3)(ii)(*c*) of this section.

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§ 520.1520 [Removed]

8. Section 520.1520 *Niclosamide tablets* is removed.

§ 520.2022 [Removed]

9. Section 520.2022 *Protokylol hydrochloride tablets* is removed.

§ 520.2160a [Removed]

10. Section 520.2160a *Styrylpyridinium, diethylcarbamazine tablets* is removed.

§ 520.2160b [Removed]

11. Section 520.2160b *Styrylpyridinium chloride, diethylcarbamazine (as base)* is removed.

§ 520.2160c [Removed]

12. Section 520.2160c *Styrylpyridinium, diethylcarbamazine edible tablets* is removed.

§ 520.2160d [Removed]

13. Section 520.2160d *Styrylpyridinium, diethylcarbamazine film-coated tablets* is removed.

§ 520.2480 [Removed]

14. Section 520.2480 *Triamcinolone tablets* is removed.

§ 520.2520a [Amended]

15. Section 520.2520a *Trichlorfon oral* is amended in paragraph (b) by removing the phrase ''Nos. 017800 and 000859'' and adding in its place ''No. 017800''.

§ 520.2520c [Removed]

16. Section 520.2520c *Trichlorfon oral liquid* is removed.

§ 520.2520d [Removed]

17. Section 520.2520d *Trichlorfon paste* is removed.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 522.281 [Removed]

19. Section 522.281 *Calcium disodium edetate injection* is removed.

§ 522.740 [Removed]

20. Section 522.740 *Disophenol sodium injection* is removed.

§ 522.2022 [Removed]

21. Section 522.2022 *Protokylol hydrochloride injection* is removed.

§ 522.2480 [Removed]

22. Section 522.2480 *Triamcinolone injection* is removed.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 529.810 [Removed]

24. Section 529.810 *Enflurane* is removed.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

Authority: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

§ 558.185 [Amended]

26. Section 558.185 *Coumaphos* is amended by removing and reserving paragraph (a)(1).

§ 558.367 [Removed]

27. Section 558.367 *Niclosamide* is removed.

§ 558.485 [Amended]

28. Section 558.485 *Pyrantel tartrate* is amended by removing and reserving paragraph (a)(16).

§ 558.565 [Removed]

29. Section 558.565 *Styrylpyridinium chloride, diethylcarbamazine* is removed.

§ 558.625 [Amended]

30. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(72).

§ 558.630 [Amended]

31. Section 558.630 *Tylosin and sulfamethazine* is amended in paragraph (b)(10) by removing ''012190,''.

Dated: June 3, 1996.

Michael J. Blackwell,

Acting Director, Center for Veterinary Medicine.

[FR Doc. 96–16886 Filed 7–2–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF JUSTICE

28 CFR Part 42

[A.G. Order No. 2037–96]

Equal Employment Opportunity

AGENCY: Department of Justice

ACTION: Final Rule

SUMMARY: This document revises the Department of Justice policy with regard to the nondiscrimination in employment to include sexual orientation as a prohibited basis for discrimination. This revised rule also makes clear that retaliation for opposing a prohibited practice or participating in a related proceeding is prohibited. This action promotes the equitable treatment of employees and applicants for employment

EFFECTIVE DATE: June 26, 1996.

FOR FURTHER INFORMATION CONTACT:

Ted McBurrows, Director, Equal Employment Opportunity Staff, Room 1246, 10th & Pennsylvania Ave., NW, Washington, DC 20530, (202) 616–4800.

SUPPLEMENTARY INFORMATION: In 1994, pursuant to 5 U.S.C. 301, the Attorney General issued several policy statements prohibiting discrimination on the basis of sexual orientation and affirmatively promoting the principles of equal employment opportunity. The Attorney General is revising 28 CFR 42.1 to reflect this policy. This policy affects agency operation and procedures, and therefore is exempt from the notice requirement of 5 U.S.C. 553(b) and is effective upon issuance.

This rule has been drafted and reviewed in accordance with section 1(b) of Executive Order 12866. This rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866. Accordingly, this rule has not been reviewed by the Office of Management and Budget. In accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), the Attorney General certifies that this rule will not have a significant economic impact on a substantial number of small entities.

This rule will not have a substantial direct impact upon the states, on the relationships between the national government and the states, or on distribution of power and responsibilities among the various levels of government. Therefore, this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment in accordance with Executive order 12612.

List of Subjects in 28 CFR Part 42

Administrative practice and procedure, Aged, Civil rights, Equal employment opportunity, Grant programs, Individuals with disabilities, Reporting and recordkeeping, Sex discrimination.

Accordingly, for reasons set out in the preamble, 28 CFR Part 42 is amended as set forth below.

PART 42—EQUAL EMPLOYMENT OPPORTUNITY WITHIN THE DEPARTMENT OF JUSTICE

1. The authority citation for Part 42 Subpart A is revised to read as follows:

Authority: 5 U.S.C. 301, 28 U.S.C. 509, 510; E.O. 11246, 3 CFR 1964–1965 Comp., p. 339; E.O. 11478, 3 CFR 1966–1970 Comp., p. 803.

2. Section 42.1 is revised to read as follows: