does not warrant preparation of a Regulatory Evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, CLASS B, CLASS C, CLASS D AND CLASS E AIRSPACE AREAS; AIRWAYS; ROUTES; AND REPORTING POINTS

1. The authority citation for 14 CFR Part 71 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; EO 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of Federal Aviation Administration Order 7400.9E, Airspace Designations and Reporting Points, dated September 10, 1997, and effective September 16, 1997, is amended as follows:

Paragraph 6005 Class E airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ASO FL E5 Guntersville, AL [New]

Guntersville Municipal Airport, AL
(lat. 34°23′57″ N, long. 86°16′12″ W)

That airspace extending upward from 700 feet above the surface within a 6.3-mile radius of Guntersville Municipal Airport, excluding that airspace within the Albertville, AL, Class E airspace area.

* * * * *

Issued in College Park, Georgia, on November 3, 1997.

Nancy B. Shelton,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 97–30357 Filed 11–18–97; 8:45 am]

BILLING CODE 4910–13–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Animal Drugs, Feeds, and Related Products; Change of Sponsor

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 change of sponsor for 61 approved new animal drug applications (NADA's) from Mallinckrodt Veterinary, Inc., to Schering-Plough Animal Health Corp.

EFFECTIVE DATE: November 19, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Mallinckrodt Veterinary, Inc., Mundelein, IL 60060, has informed FDA that it has transferred the ownership of, and all rights and interests in the approved NADA's to Schering-Plough Animal Health Corp. The agency is amending 21 CFR 510, 520, 522, 524, and 558 to reflect the change of sponsor.

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 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 510, 520, 522, 524, 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. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entry for ''Mallinckrodt Veterinary Inc.''; and in the table in paragraph (c)(2) by removing the entry for ''011716''.

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.

§ 520.82a [Amended]

4. Section 520.82a *Aminopropazine fumarate tablets* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.82b [Amended]

5. Section 520.82b *Aminopropazine fumarate, neomycin sulfate tablets* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.222 [Amended]

6. Section 520.222 *Bunamidine hydrochloride* is amended in paragraph (c) by removing ''011716'' and adding in its place ''000061''.

§ 520.580 [Amended]

7. Section 520.580 *Dichlorophene and toluene capsules* is amended in paragraph (b)(2) by removing ''011716'' and adding in its place ''000061''.

§ 520.622c [Amended]

8. Section 520.622c *Diethylcarbamazine citrate chewable tablets* is amended in paragraph (b)(5) by removing ''011716'' and adding in its place ''000061''.

§ 520.784 [Amended]

9. Section 520.784 *Doxylamine succinate tablets* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.863 [Amended]

10. Section 520.863 *Ethylisobutrazine hydrochloride tablets* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.1120a [Amended]

11. Section 520.1120a *Haloxon drench* is amended in paragraph (c) by removing ''011716'' and adding in its place ''000061''.

§ 520.1120b [Amended]

12. Section 520.1120b *Haloxon boluses* is amended in paragraph (c) by removing ''011716'' and adding in its place ''000061''.

§ 520.1242a [Amended]

13. Section 520.1242a *Levamisole hydrochloride drench and drinking water* is amended in paragraph (c)(2) by removing ''011716'' and adding in its place ''000061''.

§ 520.1242b [Amended]

14. Section 520.1242b *Levamisole hydrochloride tablet or oblet (bolus)* is amended in paragraph (c) by removing ''011716'' and adding in its place ''000061''.

§ 520.1242g [Amended]

15. Section 520.1242g *Levamisole resinate and famphur paste* is amended in paragraph (c) by removing ''011716'' and adding in its place ''000061''.

§ 520.1320 [Amended]

16. Section 520.1320 *Mebendazole oral* is amended in paragraph (c) by removing ''011716'' and adding in its place ''000061''.

§ 520.1326a [Amended]

17. Section 520.1326a *Mebendazole and trichlorfon powder* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.1326b [Amended]

18. Section 520.1326b *Mebendazole and trichlorfon paste* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.1720a [Amended]

19. Section 520.1720a *Phenylbutazone tablets and boluses* is amended in paragraph (b)(1) by removing ''011716'' and adding in its place ''000061''.

§ 520.1720b [Amended]

20. Section 520.1720b *Phenylbutazone granules* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.1720c [Amended]

21. Section 520.1720c *Phenylbutazone paste* is amended in paragraph (b) by removing ''010797 and 011716'' and adding in its place ''000061 and 010797''.

§ 520.1805 [Amended]

22. Section 520.1805 *Piperazine phosphate with thenium closylate tablets* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.2220b [Amended]

23. Section 520.2220b *Sulfadimethoxine tablets and boluses* is amended in paragraph (b)(3) by removing ''011716'' and adding in its place ''000061''.

§ 520.2220c [Amended]

24. Section 520.2220c *Sulfadimethoxine oral suspension* is amended in paragraph (c) by removing ''000069 and 011716'' and adding in its place ''000061 and 000069''.

§ 520.2362 [Amended]

25. Section 520.2362 *Thenium closylate tablets* is amended in paragraph (c) by removing ''011716'' and adding in its place ''000061''.

§ 520.2610 [Amended]

26. Section 520.2610 *Trimethoprim and sulfadiazine tablets* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.2611 [Amended]

27. Section 520.2611 *Trimethoprim and sulfadiazine oral paste* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 520.2612 [Amended]

28. Section 520.2612 *Trimethoprim and sulfadiazine oral suspension* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.82 [Amended]

30. Section 522.82 *Aminopropazine fumarate sterile solution injection* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 522.150 [Amended]

31. Section 522.150 *Azaperone injection* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 522.784 [Amended]

32. Section 522.784 *Doxylamine succinate injection* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 522.863 [Amended]

33. Section 522.863 *Ethylisobutrazine hydrochloride injection* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 522.1155 [Amended]

34. Section 522.1155 *Imidocarb dipropionate sterile powder* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 522.1244 [Amended]

35. Section 522.1244 *Levamisole phosphate injection* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 522.1503 [Amended]

36. Section 522.1503 *Neostigmine methylsulfate injection* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 522.1704 [Amended]

37. Section 522.1704 *Sodium pentobarbital injection* is amended in paragraph (a)(2) by removing ''011716'' and adding in its place ''000061''.

§ 522.1720 [Amended]

38. Section 522.1720 *Phenylbutazone injection* is amended in paragraph (b)(1) by removing ''011716'' and adding in its place ''000061''.

§ 522.2005 [Amended]

39. Section 522.2005 *Propofol injection* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 522.2610 [Amended]

40. Section 522.2610 *Trimethoprim and sulfadiazine sterile suspension* is amended in paragraph (a)(2) by removing ''000856 and 011716'' and adding in its place ''000061 and 000856''.

§ 522.2680 [Amended]

41. Section 522.2680 *Zeranol* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.154 [Amended]

43. Section 524.154 *Bacitracin or bacitracin zinc-neomycin sulfate-polymyxin B sulfate ophthalmic ointment* is amended in paragraph (a)(2) by removing ''011716'' and adding in its place ''000061''.

§ 524.155 [Amended]

44. Section 524.155 *Bacitracin zinc-polymyxin B sulfate-neomycin sulfate-hydrocortisone or hydrocortisone acetate ophthalmic ointment* is amended in paragraph (a)(1) by removing ''011716'' and adding in its place ''000061''.

§ 524.900 [Amended]

45. Section 524.900 *Famphur* is amended in paragraph (c) by removing ''011716'' and adding in its place ''000061''.

§ 524.1240 [Amended]

46. Section 524.1240 *Levamisole* is amended in paragraph (b) by removing ''010042 and 011716'' and adding in its place ''000061 and 010042''.

§ 524.1443 [Amended]

47. Section 524.1443 *Miconazole nitrate cream; miconazole nitrate lotion; miconazole nitrate spray* is amended in paragraph (b) by removing ''011716'' and adding in its place ''000061''.

§ 524.1742 [Amended]

48. Section 524.1742 *N-(Mercaptomethyl) phthalimide S-(O,O-dimethyl phosphorodithioate) emulsifiable liquid* is amended in paragraph (b) by removing ''011536 and 011716'' and adding in its place ''000061 and 011536''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.175 [Amended]

50. Section 558.175 *Clopidol* is amended in paragraph (c)(1)(iii)(*b*) and (c)(1)(iv)(*b*) by removing ''011716'' and adding in its place ''000061''.

§ 558.195 [Amended]

51. Section 558.195 *Decoquinate* is amended in the table in paragraph (d), under the ''Limitations'' column by removing ''011716'' wherever it appears and adding in its place ''000061''.

§ 558.254 [Amended]

52. Section 558.254 *Famphur* is amended in paragraph (a) by removing ''011716'' and adding in its place ''000061''.

§ 558.311 [Amended]

53. Section 558.311 *Lasalocid* is amended in the table in paragraph (e)(1)(ii), under the ''Limitations'' column, 5th paragraph, by removing ''011716'' and adding in its place ''000061''.

§ 558.515 [Amended]

54. Section 558.515 *Robenidine hydrochloride* is amended in paragraph (d)(1)(vi)(*b*) by removing ''011716'' and adding in its place ''000061''.

Dated: November 3, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 97–30337 Filed 11–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Oral Dosage Form New Animal Drugs; Orbifloxacin Tablets

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health. The supplemental NADA provides for veterinary prescription use of orbifloxacin tablets for management of diseases in cats associated with bacteria susceptible to orbifloxacin.

EFFECTIVE DATE: NOVEMBER 19, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph J. Bertone, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1692.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, is sponsor of NADA 141–081 Orbax™ (orbifloxacin) tablets that provide for veterinary prescription use in dogs for management of diseases associated with bacteria susceptible to orbifloxacin. The sponsor filed a supplemental NADA providing for veterinary prescription use of orbifloxacin tablets for management of diseases in cats associated with bacteria susceptible to orbifloxacin. The supplemental NADA is approved as of September 18, 1997, and the regulations are amended in 21 CFR 520.1616 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Furthermore, certain limitations, although required in the labeling, are not required in the regulation. Those limitations are removed from the regulation at this time.

Also, the sponsor's address has been changed. At this time, the address in the list of sponsors of approved applications in 21 CFR 510.600(c)(1) and (c)(2) is amended to reflect the new address.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning September 18, 1997, because the supplemental application contains substantial evidence of the effectiveness of the drug involved or studies of target animal safety required for approval and conducted or sponsored by the applicant. Three years marketing exclusivity is limited to use of orbifloxacin tablets for cats.

FDA has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects

21 CFR Part 510

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

21 CFR Part 520

Animal drugs.

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 510 and 520 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. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) in the entry for