§ 416.1442 Prehearing proceedings and decisions by attorney advisors.

* * * * *

(g) *Sunset provision.* The provisions of this section will no longer be effective on July 1, 1998, unless they are extended by the Commissioner of Social Security by publication of a final rule in the **Federal Register**.

[FR Doc. 97–16962 Filed 6–27–97; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, 529, 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 52 approved new animal drug applications (NADA's) from Fermenta Animal Health Co. to Boehringer Ingelheim Animal Health, Inc.

EFFECTIVE DATE: June 30, 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: Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64153, has informed FDA that it has transferred the ownership of, and all rights and interests in, the following approved NADA's to Boehringer Ingelheim Animal Health, Inc., 2621 North Belt Hwy., St. Joseph, MO 65406:

NADA No.	Product Name
011–531	DIZAN Tablets
011–674	DIZAN Soluble Powder
012–469	DIZAN Suspension
031–512	ATGARD® V (dichlorvos)/Swine Wormer (V-3)
033–803	TASK® (dichlorvos) Dog Anthelmintic
035–918	EQUIGARD® (dichlorvos) Equine Anthelmintic/Horse Wormer
038–200	OXY WS™ (oxytetracycline HCl soluble powder)
039–077	CSP™ Premixes
040–848	ATGARD® V (dichlorvos)/Swine Wormer
043–606	ATGARD® V (dichlorvos)/Swine Wormer (V-22)
045–143	OXYJECT® (5% oxytetracycline HCl)
048–237	EQUIGEL® (dichlorvos) Equine Anthelmintic
048–271	TASK® (dichlorvos) Tabs Anthelmintic for Cats & Puppies
049–032	ATGARD® C (dichlorvos) Production Efficiency Improver
065–178	FERMYCIN™ (Chlortetracycline) Soluble
065–486	CTC Bisulfate Soluble
065–491	MEDICHOL® (Chloramphenicol) Tablets
065–496	Tetracycline HCl Soluble Powder
092–837	Nemacide® (DECC) Oral Syrup
097–452	OXYJECT® 100 (10% oxytetracycline HCl)
098–569	Medacide (SDM) 10% Injection
106–772	Iron Hydrogenated Dextran Injection, 100 mg
108–963	MEDAMYCIN® (OTC–HCl) Injection, 50 mg & 100 mg
109–305	Oxytocin Injection
117–531	Acepromazine Maleate Injection, (dogs) 10 mg
117–532	Acepromazine Maleate Tablets, 10 & 25 mg
117–689	NEUROSYN™ (primidone) Tablets
125–797	Nitrofurazone Dressing
126–236	Nitrofurazone Soluble Powder
126–676	D & T Worm Capsules
127–034	DISAL® (furosemide) 5% Injection (horses only)
127–627	NEMIACIDE® (DECC) Tablets
128–069	NEMIACIDE® (DECC) Chewable Tablets
129–034	DISAL® (furosemide) Tablets, 12.5 & 50 mg
131–538	DISAL® (furosemide) 5% Injection (dogs/horses)
132–028	ANESTATAL™ (Sodium Thiamylal for Injection)
134–644	DENAGARD® (tiamulin) Soluble Antibiotic
134–708	Iron Dextran Injection, 200 mg/mL
135–771	Methylprednisolone Tablets
136–212	Methylprednisolone Acetate Sterile Suspension
137–310	Gentamicin Injection, 50 mg/mL
137–694	Triamicinolone Acetonide Tablets
138–869	Triamicinolone Acetonide Sterile Suspension
138–955	Tylosin Injection, 50 & 200 mg/mL
139–472	DENAGARD® (tiamulin) Premixes
140–270	Sulfamethazine SR Boluses
140–442	Xylazine HCl Injection (100 mg base/mL)
140–916	DENAGARD® (tiamulin) Liquid Concentrate
141–011	DENAGARD® 10 + CTC Premixes
200–023	Gentamicin Sulfate Solution, 100 mg/mL
200–029	Ketamine Hydrochloride Injection, 100 mg/mL Ketamine Base
200–165	SMD Sulfadimethoxine 12.5% Oral Solution

The agency is amending 21 CFR parts 510, 520, 522, 524, 529, and 558 to reflect the change of sponsor. The agency is amending § 510.600(c)(1) and (c)(2) to remove the sponsor name for Fermenta Animal Health Co. because the firm no longer is the holder of any approved NADA's.

List of Subjects

21 CFR Part 510

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

21 CFR Parts 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 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: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (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 ''Fermenta Animal Health Co.'' and in the table in paragraph (c)(2) by removing the entry for ''054273''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

3. 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) .

§ 520.23 [Amended]

4. Section 520.23 *Acepromazine maleate tablets* is amended in paragraph (a)(2) by removing ''054273'' and adding in its place ''000010''.

§ 520.390a [Amended]

5. Section 520.390a *Chloramphenicol tablets* is amended in paragraph (a)(2) by removing ''054273'' and adding in its place ''000010''.

§ 520.445b [Amended]

6. Section 520.445b *Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate)* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 520.580 [Amended]

7. Section 520.580 *Dichlorophene and toluene capsules* is amended in paragraph (b)(2) by removing ''011716, 038782, and 054273'' and adding in its place ''000010, 011716, and 038782''.

§ 520.600 [Amended]

8. Section 520.600 *Dichlorvos* is amended in paragraph (c) by removing ''054273'' and adding in its place ''000010''.

§ 520.622a [Amended]

9. Section 520.622a *Diethylcarbamazine citrate tablets* is amended in paragraph (a)(6) by removing ''054273'' and adding in its place ''000010''.

§ 520.622b [Amended]

10. Section 520.622b *Diethylcarbamazine citrate syrup* is amended in paragraph (c)(2) by removing ''054273'' and adding in its place ''000010''.

§ 520.622c [Amended]

11. Section 520.622c *Diethylcarbamazine citrate chewable tablets* is amended in paragraph (a)(6) by removing ''054273'' and adding in its place ''000010''.

§ 520.763a [Amended]

12. Section 520.763a *Dithiazanine iodide tablets* is amended in paragraph (c) by removing ''054273'' and adding in its place ''000010''.

§ 520.763b [Amended]

13. Section 520.763b *Dithiazanine iodide powder* is amended in paragraph (c) by removing ''054273'' and adding in its place ''000010''.

§ 520.763c [Amended]

14. Section 520.763c *Dithiazanine iodide and piperazine citrate suspension* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 520.1010a [Amended]

15. Section 520.1010a *Furosemide tablets or boluses* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 520.1408 [Amended]

16. Section 520.1408 *Methylprednisolone tablets* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 520.1660d [Amended]

17. Section 520.1660d *Oxytetracycline hydrochloride soluble powder* is amended in paragraphs (b)(3), (e)(1)(ii)(A)(*3*), (e)(1)(ii)(B)(*3*), and (e)(1)(ii)(C)(*3*) by removing ''054273'' and adding in its place ''000010''.

§ 520.1900 [Amended]

18. Section 520.1900 *Primidone tablets* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 520.2220a [Amended]

19. Section 520.2220a *Sulfadimethoxine oral solution and soluble powder* is amended in paragraph (b) by removing ''000069, 054273, and 057561'' and adding in its place ''000010, 000069, and 057561''.

§ 520.2260b [Amended]

20. Section 520.2260b *Sulfamethazine sustained-release boluses* is amended in paragraphs (f)(1) and (h)(1) by removing ''054273'' and adding in its place ''000010''.

§ 520.2345d [Amended]

21. Section 520.2345d *Tetracycline hydrochloride soluble powder* is amended in paragraphs (a)(1), (d)(1)(iii), and (d)(2)(iii) by removing ''054273'' and adding in its place ''000010''.

§ 520.2455 [Amended]

22. Section 520.2455 *Tiamulin soluble powder* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 520.2456 [Amended]

23. Section 520.2456 *Tiamulin liquid concentrate* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 520.2481 [Amended]

24. Section 520.2481 *Triamcinolone acetonide tablets* is amended in paragraph (b) by removing ''053501 and 054273'' and adding in its place ''000010 and 053501''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

25. 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).

§ 522.23 [Amended]

26. Section 522.23 *Acepromazine maleate injection* is amended in paragraph (c) by removing ''054273'' and adding in its place ''000010''.

§ 522.1010 [Amended]

27. Section 522.1010 *Furosemide injection* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 522.1044 [Amended]

28. Section 522.1044 *Gentamicin sulfate injection* is amended in paragraph (b)(3) by removing ''054273'' and adding in its place ''000010''.

§ 522.1182 [Amended]

29. Section 522.1182 *Iron dextran complex injection* is amended in paragraph (b)(2)(i) by removing ''054273'' and adding in its place ''000010''.

§ 522.1183 [Amended]

30. Section 522.1183 *Iron hydrogenated dextran injection* is amended in paragraph (e)(1) by removing ''017287, 050604, and 054273'' and adding in its place ''000010, 017287, and 050604''.

§ 522.1222a [Amended]

31. Section 522.1222a *Ketamine hydrochloride injection* is amended in paragraph (c) by removing ''000856, 045984, 054273, and 059130'' and adding in its place ''000010, 000856, 045984, and 059130''.

§ 522.1410 [Amended]

32. Section 522.1410 *Sterile methylprednisolone acetate suspension* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 522.1662a [Amended]

33. Section 522.1662a *Oxytetracycline hydrochloride injection* is amended in paragraphs (a)(2), (g)(2), and (h)(2) by removing ''054273'' and adding in its place ''000010''.

§ 522.1680 [Amended]

34. Section 522.1680 *Oxytocin injection* is amended in paragraph (b) by removing ''054273,''and numerically adding ''000010,''.

§ 522.2220 [Amended]

35. Section 522.2220 *Sulfadimethoxine injection* is amended in paragraph (c)(2) by removing ''054273'' and adding in its place ''000010''.

§ 522.2424 [Amended]

36. Section 522.2424 *Sodium thiamylal for injection* is amended in

paragraph (b) by removing '', 000856, and 054273'' and adding in its place ''and 000856''.

§ 522.2483 [Amended]

37. Section 522.2483 *Sterile triamcinolone acetonide suspension* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

§ 522.2640a [Amended]

38. Section 522.2640a *Tylosin injection* is amended in paragraph (b)(2) by removing ''054273'' and adding in its place ''000010''.

§ 522.2662 [Amended]

39. Section 522.2662 *Xylazine hydrochloride injection* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.1580b [Amended]

41. Section 524.1580b *Nitrofurazone ointment* is amended in paragraph (b) by removing ''000857, 000864, 000069, 050749, 023851, 051259, and 054273'' and adding in its place ''000010, 000857, 000864, 000069, 050749, 023851, and 051259''.

§ 524.1580c [Amended]

42. Section 524.1580c *Nitrofurazone soluble powder* is amended in paragraph (b) by removing ''000069, 050749, and 054273'' and adding in its place ''000010, 000069, and 050749''.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.1044a [Amended]

44. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing ''054273'' and adding in its place ''000010''.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

45. 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).

§ 558.155 [Amended]

46. Section 558.155 *Chlortetracycline, sulfathiazole, penicillin* is amended in paragraphs (a)(1) and (a)(2) by removing ''054273'' and adding in its place ''000010''.

§ 558.205 [Amended]

47. Section 558.205 *Dichlorvos* is amended in paragraph (a) by removing ''054273'' and adding in its place ''000010''.

§ 558.600 [Amended]

48. Section 558.600 *Tiamulin* is amended in paragraph (a) by removing ''054273'' and adding in its place ''000010''.

Dated: June 9, 1997.

Robert C. Livingston,

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

[FR Doc. 97–16967 Filed 6–27–97; 8:45 am]

BILLING CODE 4160–01–F

OFFICE OF NAVAJO AND HOPI INDIAN RELOCATION

25 CFR Part 700

Protection of Archaeological Resources

AGENCY: Office of Navajo and Hopi Indian Relocation.

ACTION: Final rule.

SUMMARY: This final rule establishes procedures for implementing provisions of the Archaeological Resources Protection Act of 1979 (16 U.S.C. 470–aa–11) for the lands which are administered by the O.N.H.I.R. which have been acquired pursuant to Pub. L. 96–305 (25 U.S.C. 640–d(h). The rule is necessary and its intended effect is to allow the Federal Land Manager to protect archaeological resources on lands being developed for resettlement purposes.

EFFECTIVE DATE: June 30, 1997.

FOR FURTHER INFORMATION CONTACT: Paul Tessler (Legal Counsel), Office of Navajo and Hopi Indian Relocation at 520–779–8953.

SUPPLEMENTARY INFORMATION: On July 8, 1996, the O.N.H.I.R. published its Interim Final Rule with comment period for establishing procedures for implementing provisions of the Archaeological Resources Protection Act of 1979, (16 U.S.C. 470–aa–11) for lands which are administered by the O.N.H.I.R. The O.N.H.I.R. received written comments on the Interim Final Rule from the President of the Navajo National and the Historic Preservation Department of the Navajo Nation. In reviewing the comments received, the O.N.H.I.R. considered both comments to be those of the Navajo Nation. The O.N.H.I.R. has considered all comments received and responds to these comments as stated below:

Section 700.805(a)(3)(i). Comment was received that this section should be changed to include shrines and offering sites. This comment was not accepted because this section is considered to already include shrines and offering sites

Section 700.805(a)(5). Comment was received that this section should be amended to include a provision that requires notification of the Navajo Nation and an opportunity to object, before the Federal Lands Manager makes a determination allowing materials to be excluded from protection. This section was amended to require that the Federal Land Manager consult with the Navajo Nation to obtain concurrence before making a determination allowing material remains to be excluded from protection. Comment was also received that this section specifies that material remains otherwise meeting the definition of archaeological resources can be determined not be archaeological resources ''under special circumstances.'' The comment further indicated that these special circumstances are not delineated in the regulation. This comment was adopted by adding § 700.841, *Determination of Loss or Absence of Archaeological Interest.*

Section 805(e). Comment was received that the definition of ''New Lands'' and ''public lands'' are inconsistent. This comment was adopted and in all instances the ''New Lands'' have been defined consistently. The O.N.H.I.R. also made it clear that the consent of the Navajo is required for all permits.

Section 700.815. Comment was received, without citing a specific section, suggesting that the Navajo Nation should be informed of all requests for permits and be allowed to deny these permits. This comment was already covered in § 700.815(a)(5) which requires the consent of the Navajo Nation prior to issuance of a permit.

Section 700.827(a). Comment was received, without citing a specific section, from the Navajo Nation that the regulations should require all archaeological resources removed from the New Lands be properly stored and safe guarded and that such resources be returned to the Navajo Nation upon request, once the Navajo Nation has established its own museum or