in the use of [phthalocyaninato(2-)] copper in contact lenses.

FDA gave interested persons until November 28, 1986, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA had concluded that the final rule published in the **Federal Register** of October 28, 1986, should be confirmed.

List of Subjects in 21 CFR Part 74

Color additives, Cosmetics, Drugs, Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055–1056 as amended, 74 Stat. 399–407 as amended (21 U.S.C. 371, 376)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), notice is given that no objections or requests for a hearing were filed in response to the October 28, 1986, final rule. Accordingly, the amendments promulgated thereby became effective November 28, 1986.

Dated: March 6, 1987.

Richard J. Ronk,

Acting Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 87–5446 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Parts 331, 332, and 357

[Docket No. 82N–0154]

Labeling of Drug Products for Over-The-Counter Human Use; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that changed its "exclusivity" policy for labeling of over-the-counter (OTC) drug products. This document indicates that specific paragraphs in 21 CFR 331.130(b), 332.30(a), and 357.250(b) where other statements describing indications for use are located. By indicating these specific paragraphs, FDA will eliminate the ambiguity associated with the use of the term "above".

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug and Biologics (HFN–210), Food and Drugs Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–9720, appearing on page 16258 in the issue of Thursday, May 1, 1986, the following corrections are made:

§ 331.30 [Corrected]

1. On page 16266, in the third column under § 331.30 *Labeling of antacid products*, paragraph (b), 14th line, "above" is corrected to read "in this paragraph (b)".

§ 332.30 [Corrected]

2. On page 16266, in the third column under § 332.30 *Labeling of antiflatulent products*, paragraph (a), 9th line, "above" is corrected to read "in this paragraph (a)".

§ 357.250 [Corrected]

3. On page 16267, in the second column under § 357.250 *Labeling of cholecystokinetic drug products*, paragraph (b), 9th line "above" is corrected to read "in this paragaph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5382 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 341

[Docket No. 75N–052B]

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Final Monograph for OTC Bronchodilator Drug Products; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that established conditions under which over-the-counter (OTC) bronchodilator drug products (drug products used in the symptomatic treatment of wheezing and shortness of breath of asthma) are generally recognized as safe and effective and not misbranded. This document indicates the specific paragraph in 21 CFR 341.76(b) where other statements describing indications for use are located. By indicating this specific paragraph, FDA will eliminate the ambiguity associated with the use of the term "below."

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–22151, appearing on page 35326 in the issue of Thursday, October 2, 1986, the following correction is made on page 35339: In the third column under § 341.76 *Labeling of bronchodilator drug products*, paragraph (b), 8th line, "below" is corrected to read "in this paragraph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5380 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 344

[Docket No. 77N–0334]

Topical Otic Drug Products for Over-the-Counter Human Use; Final Monograph; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that established conditions under which over-the-counter (OTC) topical otic drug products (drug products for the ear) are generally recognized as safe and effective and not misbranded. This document indicates the specific paragraph in 21 CFR 344.50(b) where other statements describing indications for use are located. By indicating this specific paragraph, FDA will eliminate the ambiguity associated with the use of the term "above."

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–17854, appearing on page 28656 in the issue of Friday, August 8, 1986, the following correction is made on page 28661: In the second column under § 344.50 *Labeling of topical otic drug products*, paragraph (b), 10th line, "above" is corrected to read "in this paragraph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5381 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

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21 CFR Part 357

[Docket No. 79N–0378]

Anthelmintic Drug Products for Over-The-Counter Human Use; Final Monograph; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting the final rule that established conditions under which over-the-counter (OTC) anthelmintic drug products (products that destroy pinworms) are generally recognized as safe and effective and not misbranded. This document indicates the specific paragraph in 21 CFR 357.150(b) where other statements describing indications for use are located. By indicating this specific paragraph, FDA will eliminate the ambiguity associated with the use of the term "above."

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drugs and Biologics (HFN–210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–295–8000.

SUPPLEMENTARY INFORMATION: In FR Doc. 86–17180, appearing on page 27756 in the issue of Friday, August 1, 1986, the following correction is made on page 27759: In the second column under § 357.150 *Labeling of anthelmintic drug products,* paragraph (b), 8th line, "above" is corrected to read "in this paragraph (b)".

Dated: March 5, 1987.

John M. Taylor,

Associate Commissioner for Regulatory Affairs.

[FR Doc. 87–5379 Filed 3–12–87; 8:45 am]

BILLING CODE 4160–01–M

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

Animal Drugs, Feeds, and Related Products; Change of Sponsor; Labeler Code; Correction

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect (1) a change of sponsor of several new animal drug applications (NADA's) from Burns-Biotec Laboratories, Inc., to Schering Corp. and (2) a change of sponsor of an NADA to Summit Hill Laboratories from Burns-Biotec Laboratories, Inc. The regulations are also amended to designate the correct drug labeler code assigned to Shering Corp. for its veterinary drug products.

EFFECTIVE DATE: March 13, 1987.

FOR FURTHER INFORMATION CONTACT: John W. Borders, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6243.

SUPPLEMENTARY INFORMATION: Burns-Biotec Laboratories, Inc., 8530–8536 K St., P.O. Box 3113, Omaha, NE 68103, has informed FDA of a change of sponsor for NADA 48–854, glyceryl guaiacolate injection for horses, to Summit Hill Laboratories, P.O. Box 535, Navesink, NJ 07752. The NADA provides for the intravenous use of glyceryl quaiacolate as a muscle relaxant in horses. Summit Hill Laboratories (drug labeler code 037990) has confirmed the change of sponsor. Summit Hill has also filed a supplemental NADA containing updated manufacturing facilities, methods, and controls information

Schering Corp., Galloping Hill, Rd., Kenilworth, NJ 07933, filed several supplemental NADA's providing for a change of sponsor from its subsidiary, Burns-Biotec Laboratories, Inc. The NADA's affected are:

NADA	Product	Ingredient
9–167	P.L.H. (cattle, horses, swine, sheep, dogs).	Pituitary luteninizing hormone for injection.
9–505	F.S.H.-P. (cattle, horses, swine, sheep, dogs).	Follicle stimulating hormone-pituitary for injection.
10–793	Nonemic (swine)	Iron dextran injection.
12–635	BO-SE and L-SE (calves, lambs, ewes, sows).	Sodium selenite, vitamin E injection.
30–313	Selotoc Caps and Minicaps (dogs).	Sodium selenite, vitamin E.
30–314	MU-SE (cattle, calves, swine)	Sodium selenite, vitamin E injection.
30–315	E-SE (equine)	Sodium selenite, vitamin E injection.
30–316	Selectoc Injection (horses, dogs).	Sodium selenite vitamin E injection.
31–971	Cuprate (cattle)	Cupric glycinate injection.
40–322	Kymar (intment Improved (horses, dogs, cats).	Neomycin pamitate, hydrocortisone acetate.
46–288	Histavet-P (horses)	Pyrilamine maleate injection.
119–807	Beuthanasia-D Special (dogs)	Euthanasia solution.

The change of sponsor to Schering Corp. does not involve any changes in current manufacturing facilities, equipment, procedures, or production personnel. FDA is amending the regulations to reflect the change of sponsor.

FDA is amending 21 CFR 510.600(c) (1) and (2) and the sponsor paragraphs of 21 CFR 520.540a, 520.540b, 520.970a, 520.970b, 520.1044a, 520.1044b, 520.1044c, 520.1100, 520.1341, 520.2100, 520.2473a, 522.161, 522.163, 522.518, 522.540, 522.900, 522.970, 522.1044, 522.1060b, 522.1182, 522.1820, 522.1822, 522.1890, 522.2063, 522.2100, 524.1044a, 524.1044b, 524.1044c, 524.1044d, 524.1044e, 524.1044f, 524.2350, 529.1044a, and 529.1044b providing for use of the veterinary drug products currently sponsored by Schering; this action is required to change the drug labeler code currently used in those regulations from 000085 to 000061. Schering has been assigned drug labeler code 000085 for human drug products and 000061 for veterinary drug products. Therefore, the regulations are amended to insert the correct labeler code.

FDA is also amending 21 CFR 510.600(c)(1) and (2) to remove Burns-Biotec Laboratories, Inc. because it is no longer the sponsor 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.

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, Parts 510, 520, 524, and 529 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. 512, 701(a), 52 Stat. 1055, 82 Stat. 343–351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10 and 5.83.

§ 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 Schering Corp. by revising the drug labeler code to read "000061" and by removing the entry for Burns-Biotec Laboratories, Inc., and in paragraph (c)(2) by revising the entry for "000085" to read "000061" and numerically inserting it in proper sequence, and by removing the entry for "000845".

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

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

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

§ 520.540a [Amended]

4. Section 520.540a *Dexamethasone powder* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 520.540b [Amended]

5. Section 520.540b *Dexamethasone tablets and boluses* is amended in paragraphs (a)(2) and (b)(2) by removing "000085" and inserting in its place "000061."

§ 520.970a [Amended]

6. Section 520.970a *Flunixin meglumine granules* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 520.970b [Amended]

7. Section 520.970b *Flunixin meglumine paste* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 520.1044a [Amended]

8. Section 520.1044a *Gentamicin sulfate oral solution* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 520.1044b [Amended]

9. Section 520.1044b *Gentamicin sulfate pig pump oral solution* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 520.1044c [Amended]

10. Section 520.1044c *Gentamicin sulfate soluble powder* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 520.1100 [Amended]

11. Section 520.1100 *Griseofulvin* is amended in paragraph (c)(1) by removing "000085" and inserting in its place "000061."

§ 520.1341 [Amended]

12. Section 520.1341 *Megestrol acetate tablets* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 520.2100 [Amended]

13. Section 520.2100 *Selenium, vitamin E capsules* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 520.2473a [Amended]

14. Section 520.2473a *Tioxidazole granules* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

15. The authority citation for 21 CFR Part 522 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

§ 522.161 [Amended]

16. Section 522.161 *Betamethasone acetate and betamethasone disodium phosphate aqueous suspension* is amended in paragraph (c) by removing "000085" and inserting in its place "000061."

§ 522.163 [Amended]

17. Section 522.163 *Betamethasone dipropionate and betamethasone sodium phosphate aqueous suspension* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 522.518 [Amended]

18. Section 522.518 *Cupric glycinate injection* is amended in paragraph (b) by removing "000845" and inserting in its place "000061."

§ 522.540 [Amended]

19. Section 522.540 *Dexamethasone injection* is amended in paragraph (a)(2) by removing "000085" and inserting in its place "000061."

§ 522.900 [Amended]

20. Section 522.900 *Euthanasia solution* is amended in paragraph (b)(2) by removing "000845" and inserting in its place "000061."

§ 522.970 [Amended]

21. Section 522.970 *Flunixin meglumine solution* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 522.1044 [Amended]

22. Section 522.1044 *Gentamicin sulfate injection* is amended in paragraph (b)(1) by removing "000085" and inserting in its place "000061."

§ 522.1060b [Amended]

23. Section 522.1060b *Glyceryl guaiacolate injection* is amended in paragraph (b) by removing "000845" and inserting in its place "037990."

§ 522.1182 [Amended]

24. Section 522.1182 *Iron dextran complex injection* is amended in paragraph (a)(4)(i) by removing "000845" and inserting in its place "000061."

§ 522.1820 [Amended]

25. Section 522.1820 *Pituitary luteinizing hormone for injection* is amended in paragraph (b) by removing "000845" and inserting in its place "000061."

§ 522.1822 [Amended]

26. Section 522.1822 *Follicle stimulating hormone-pituitary for injection* is amended in paragraph (b) by removing "000845" and inserting in its place "000061."

§ 522.1890 [Amended]

27. Section 522.1890 *Sterile prednisone suspension* is amended in paragraph (b)(2) by removing "000085" and inserting in its place "000061."

§ 522.2063 [Amended]

28. Section 522.2063 *Pyrilamine maleate injection* is amended in paragraph (b) by removing "000845" and inserting in its place "000061."

§ 522.2100 [Amended]

29. Section 522.2100 *Selenium, vitamin E injection* is amended in paragraphs (a)(2) and (b)(2) by removing "000845" and inserting in its place "000061."

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

30. The authority citation for 21 CFR Part 524 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

§ 524.1044a [Amended]

31. Section 524.1044a *Gentamicin ophthalmic solution* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 524.1044b [Amended]

32. Section 524.1044b *Gentamicin sulfate, betamethasone valerate otic solution* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 524.1044c [Amended]

33. Section 524.1044c *Gentamicin ophthalmic ointment* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 524.1044d [Amended]

34. Section 524.1044d *Gentamicin sulfate, betamethasone valerate ointment* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§ 524.1044e [Amended]

35. Section 524.1044e *Gentamicin sulfate spray* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§524.1044f [Amended]

36. Section 524.1044f *Gentamicin sulfate, betamethasone valerate topical spray* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§524.2350 [Amended]

37. Section 524.2350 *Tolnaftate cream* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

38. The authority citation for 21 CFR Part 529 continues to read as follows:

Authority: Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)); 21 CFR 5.10 and 5.83.

§529.1044a [Amended]

39. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

§529.1044b [Amended]

40. Section 529.1044b *Gentamicin sulfate solution* is amended in paragraph (b) by removing "000085" and inserting in its place "000061."

Dated: March 5, 1987.

Richard A. Carnevale,

Acting Associate Director for Scientific Evaluation, Center for Veterinary Medicine.

[FR Doc. 87-5378 Filed 3-12-87; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Tylosin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove those portions of the regulations reflecting approval of two new animal drug applications (NADA's) held by De Kalb Feeds, Inc. One NADA provides for the use of a 0.8-gram-per-pound tylosin Type A article to make Type C swine feed and the other provides for use of a 10-gram-per-pound tylosin Type A article to make Type C swine, beef cattle, and chicken feeds. FDA is also amending the regulations to remove the firm from the list of sponsors of approved NADA's. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADA's.

EFFECTIVE DATE: March 23, 1987.

FOR FURTHER INFORMATION CONTACT: Mohammad I. Sharar, Center for Veterinary Medicine (HFV-214), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3184.

SUPPLEMENTARY INFORMATION: In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of De Kalb Feed's, Inc., NADA's 133-382 and 133-383. NADA 133-382 provides for use of a 10-gram-per-pound tylosin Type A article to make Type C swine, beef cattle, and chicken feeds. NADA 133-383 provides for use of a 0.8-gram-per-pound tylosin (as tylosin phosphate) Type A article for making a Type C swine feed. This document removes and reserves 21 CFR 558.625(b)(81) that reflected approval of the NADA's. Additionally, because the firm is no longer sponsor of any approved NADA's, 21 CFR 510.600(c) (1) and (2) is amended to remove the firm from the list of sponsors of approved NADA's.

List of Subjects

21 CFR Part 510

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

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, Parts 510 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. 512, 701(a), 52 Stat. 1055, 82 Stat. 343-351 (21 U.S.C. 360b, 371(a)); 21 CFR 5.10, 5.83.

§510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) by removing the entry for "De Kalb Feeds, Inc.," and in paragraph (c)(2) by removing the entry for "024857."

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR Part 558 continues to read as follows:

Authority: Sec. 512, 82 Stat. 343-351 (21 U.S.C. 360b); 21 CFR 5.10, 5.83.

§558.625 [Amended]

4. Section 558.625 *Tylosin* is amended by removing and reserving paragraph (b)(81).

Dated: March 9, 1987.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 87-5447 Filed 3-12-87; 8:45 am]

BILLING CODE 4160-01-M

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21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Oxytetracycline Hydrochloride Injection

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental NADA filed by Pfizer, Inc., providing a specification revision to correctly express the amount of drug activity as 100 milligrams of oxytetracycline hydrochloride per millimeter of drug product. The drug product is used to treat bacterial infections in beef cattle, nonlactating dairy cattle, and swine.

EFFECTIVE DATE: March 13, 1987.

FOR FURTHER INFORMATION CONTACT: John R. Markus, Center for Veterinary Medicine (HFV-142), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3442.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, is the sponsor of NADA 94-114 which provides for use of Liquamycin 100/Terramycin 100 Injections (100 milligrams of oxytetracycline hydrochloride per milliliter) in the treatment of beef cattle, nonlactating dairy cattle, and swine. Provisions for use of the drug are in 21 CFR 522.1662a(e). The specifications paragraph of that regulation currently expresses drug activity in terms of an equivalent amount of oxytetracycline base. Pfizer has filed a supplemental NADA providing for changing the activity statement from the oxytetracycline base equivalency to the amount of oxytetracycline hydrochloride. The supplement is approved and 21 CFR 522.1662a(e)(1) is amended to reflect the approval.

Approval of this supplement is an administrative action that did not require generation of new effectiveness or safety data. Therefore, a freedom of information summary (pursuant to 21 CFR 514.11(e)(2)(ii)) is not required.