

**APPENDIX A7 TO PART 305—REFRIGERATOR-FREEZERS WITH AUTOMATIC DEFROST WITH TOP-MOUNTED FREEZER WITH THROUGH-THE-DOOR ICE SERVICE**

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 10.5 .....	(*)	(*)
10.5 to 12.4 .....	(*)	(*)
12.5 to 14.4 .....	(*)	(*)
14.5 to 16.4 .....	(*)	(*)
16.5 to 18.4 .....	(*)	(*)
18.5 to 20.4 .....	(*)	(*)
20.5 to 22.4 .....	840	840
22.5 to 24.4 .....	(*)	(*)
24.5 to 26.4 .....	905	905
26.5 to 28.4 .....	(*)	(*)
28.5 and over .....	(*)	(*)

\*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

9. Appendix A8 to Part 305 is revised to read as follows:

**APPENDIX A8 TO PART 305—REFRIGERATOR-FREEZERS WITH AUTOMATIC DEFROST WITH SIDE-MOUNTED FREEZER WITH THROUGH-THE-DOOR ICE SERVICE**

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 10.5 .....	(*)	(*)
10.5 to 12.4 .....	(*)	(*)
12.5 to 14.4 .....	(*)	(*)
14.5 to 16.4 .....	(*)	(*)
16.5 to 18.4 .....	(*)	(*)
18.5 to 20.4 .....	734	934
20.5 to 22.4 .....	714	967
22.5 to 24.4 .....	685	1000
24.5 to 26.4 .....	760	1042
26.5 to 28.4 .....	735	1080
28.5 and over .....	765	1144

\*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

10. Appendix B1 to Part 305 is revised to read as follows:

**APPENDIX B1 TO PART 305—UPRIGHT FREEZERS WITH MANUAL DEFROST**

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/yr.)	
	Low	High
Less than 5.5 .....	250	349
5.5 to 7.4 .....	(*)	(*)
7.5 to 9.4 .....	373	416
9.5 to 11.4 .....	448	456
11.5 to 13.4 .....	468	474
13.5 to 15.4 .....	509	534
15.5 to 17.4 .....	562	565
17.5 to 19.4 .....	(*)	(*)
19.5 to 21.4 .....	615	627
21.5 to 23.4 .....	(*)	(*)
23.5 to 25.4 .....	(*)	(*)
25.5 to 27.4 .....	(*)	(*)
27.5 to 29.4 .....	(*)	(*)
29.5 and over .....	685	685

(\*)No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

11. Appendix B2 To Part 305 is revised to read as follows:

**APPENDIX B2 TO PART 305—UPRIGHT FREEZERS WITH AUTOMATIC DEFROST**

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh/hr.)	
	Low	High
Less than 5.5 .....	504	516
5.5 to 7.4 .....	(*)	(*)
7.5 to 9.4 .....	(*)	(*)
9.5 to 11.4 .....	(*)	(*)
11.5 to 13.4 .....	(*)	(*)
13.5 to 15.4 .....	728	774
15.5 to 17.4 .....	784	821
17.5 to 19.4 .....	876	878
19.5 to 21.4 .....	800	896
21.5 to 23.4 .....	(*)	(*)
23.5 to 25.4 .....	(*)	(*)
25.5 to 27.4 .....	(*)	(*)
27.5 to 29.4 .....	(*)	(*)
29.5 and over .....	687	687

\*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

12. Appendix B3 to Part 305 is revised to read as follows:

**APPENDIX B3 TO PART 305—CHEST FREEZERS AND ALL OTHER FREEZERS**

[Range Information]

Manufacturer's rated total refrigerated volume in cubic feet	Range of estimated annual energy consumption (kWh.yr.)	
	Low	High
Less than 5.5 .....	212	260
5.5 to 7.4 .....	291	293
7.5 to 9.4 .....	322	322
9.5 to 11.4 .....	347	349
11.5 to 13.4 .....	391	399
13.5 to 15.4 .....	434	441
15.5 to 17.4 .....	(*)	(*)
17.5 to 19.4 .....	493	493
19.5 to 21.4 .....	529	529
21.5 to 23.4 .....	552	588
23.5 to 15.4 .....	620	629
25.5 to 27.4 .....	(*)	(*)
27.5 to 29.4 .....	(*)	(*)
29.5 and over .....	(*)	(*)

\*No data submitted for units meeting Federal Energy Conservation Standards effective January 1, 1993.

**Appendix H—[Amended]**

13. In section 2 of Appendix H or Part 305, the text and formulas are amended by removing the figure "8.31c" wherever it appears and by adding, in its place, the figure "8.42c". In addition, the text and formulas are amended by removing the figure "12.47c" wherever it appears and by adding, in its place, the figure "112.64c".

**Appendix I—[Amended]**

14. In section 2 of Appendix I of Part 305, the text and formulas are amended by removing the figure "8.31c" wherever it appears and by adding, in its place, the figure "8.42c". In addition, the text and formulas are amended by removing the figure "12.47c" wherever it appears and by adding, in its place, the figure "12.64c".

By direction of the Commission.

**Donald S. Clark,**

*Secretary.*

[FR Doc. 98-32079 Filed 12-1-98; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 522**

**Implantation or Injectable Dosage Form New Animal Drugs; Butorphanol Tartrate**

**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 an abbreviated new animal drug application (ANADA) filed by Intervet, Inc. The ANADA provides for use of butorphanol tartrate injection for horses for the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

**EFFECTIVE DATE:** December 2, 1998.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

**SUPPLEMENTARY INFORMATION:** Intervet, Inc., 405 State St., P.O. Box 318, Millsboro, DE 19966-0318, filed ANADA 200-239 that provides for veterinary prescription use of Dolorex® (butorphanol tartrate) injection intravenously for horses for the relief of pain associated with colic and postpartum pain in adult horses and yearlings.

ANADA 200-239 is approved as a generic copy of Fort Dodge Animal Health's NADA 135-780 for Torbugesic® for horses. The ANADA is approved as of September 28, 1998, and the regulations are amended in 21 CFR 522.246(b) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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 the application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency 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 in 21 CFR Part 522**

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 part 522 is amended as follows:

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

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

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

2. Section 522.246 is amended by revising paragraph (b) to read as follows:

**§ 522.246 Butorphanol tartrate injection.**

\* \* \* \* \*

(b) *Sponsors.* Approval to firms identified in § 510.600(c) of this chapter for use as indicated:

(1) See No. 057926 for use as in paragraph (c)(2) of this section.

(2) See No. 000856 for use as in paragraphs (c)(1), (c)(2), and (c)(3) of this section.

\* \* \* \* \*

Dated: November 5, 1998.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 98-32022 Filed 12-1-98; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs For Use In Animal Feeds; Chlortetracycline and Salinomycin**

**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 two abbreviated new animal drug applications (ANADA's) filed by Alpharma Inc. The ANADA's provide for using approved chlortetracycline and salinomycin Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis and as an aid in the reduction of mortality due to *E. coli* infections.

**EFFECTIVE DATE:** December 2, 1998.

**FOR FURTHER INFORMATION CONTACT:** Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20852, 301-827-0209.

**SUPPLEMENTARY INFORMATION:** Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA's 200-261 and 200-262 that provide for combining approved ChlorMax™ (50, 65, or 70 grams per

pound (g/lb) chlortetracycline) and Sacox® or Bio-Cox® (30 or 60 g/lb salinomycin sodium) Type A medicated articles to make Type C medicated broiler feeds containing chlortetracycline 500 grams per ton (g/t) and salinomycin 40 to 60 g/t. The Type C medicated feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and as an aid in the reduction of mortality due to *E. coli* infections susceptible to such treatment.

Alpharma Inc.'s ANADA 200-261 is approved as a generic copy of Roche Vitamins, Inc.'s NADA 140-859. Alpharma Inc.'s ANADA 200-262 is approved as a generic copy of Hoechst Roussel's ANADA 200-095. Alpharma Inc.'s ANADA's 200-261 and 200-262 are approved as of September 21, 1998, and 21 CFR 558.550(a)(3) is amended to reflect the approvals. The basis for approval is discussed in the freedom of information summaries.

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 these applications may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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 in 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 part 558 is amended as follows:

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

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

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

2. Section 558.550 is amended by revising paragraph (a)(3) to read as follows:

**§ 558.550 Salinomycin.**

(a) \* \* \*