

among the parties. The agreement shall be made available, on request, to representatives of the Department of Transportation.

(2) The agreement shall provide that all actions necessary to ensure accessible boarding for passengers with disabilities are completed as soon as practicable, but no later than December 2, 1998, at large and medium commercial service hub airports (those with 1,200,000 or more annual enplanements); December 2, 1999, for small commercial service hub airports (those with between 250,000 and 1,199,999 annual enplanements); or December 2, 2000, for non-hub commercial service primary airports (those with between 10,000 and 249,999 annual enplanements). All air carriers and airport operators involved are jointly responsible for the timely and complete implementation of the agreement.

(3) Boarding assistance under the agreement is not required in the following situations:

(i) Access to aircraft with a capacity of fewer than 19 or more than 30 seats;

(ii) Access to float planes;

(iii) Access to the following 19-seat capacity aircraft models: the Fairchild Metro, the Jetstream 31, and the Beech 1900 (C and D models);

(iv) Access to any other 19-seat aircraft model determined by the Department of Transportation to be unsuitable for boarding assistance by lift, ramp or other suitable device on the basis of a significant risk of serious damage to the aircraft or the presence of internal barriers that preclude passengers who use a boarding or aisle chair to reach a non-exit row seat.

(4) When boarding assistance is not required to be provided under paragraph (c)(3) of this section, or cannot be provided as required by paragraphs (b) and (c) of this section (e.g., because of mechanical problems with a lift), boarding assistance shall be provided by any available means to which the passenger consents, except hand-carrying as defined in 14 CFR 382.39(a)(2).

(5) The agreement shall ensure that all lifts and other accessibility equipment

are maintained in proper working condition.

(d)(1) Each airport operator shall negotiate in good faith with each carrier serving the airport concerning the acquisition and use of boarding assistance devices for aircraft with a seating capacity of 31 or more passengers where level entry boarding is not otherwise available. The airport operator and the carrier(s) shall, by no later than March 4, 2002 sign a written agreement allocating responsibility for meeting the boarding assistance requirements of this section between or among the parties. The agreement shall be made available, on request, to representatives of the Department of Transportation.

(2) The agreement shall provide that all actions necessary to ensure accessible boarding for passengers with disabilities are completed as soon as practicable, but no later than December 4, 2002. All air carriers and airport operators involved are jointly responsible for the timely and complete implementation of the agreement.

(3) Level-entry boarding assistance under the agreement is not required with respect to float planes or with respect to any widebody aircraft determined by the Department of Transportation to be unsuitable for boarding assistance by lift, ramp, or other device on the basis that no existing boarding assistance device on the market will accommodate the aircraft without a significant risk of serious damage to the aircraft or injury to passengers or employees.

(4) When level-entry boarding assistance is not required to be provided under paragraph (d)(3) of this section, or cannot be provided as required by paragraphs (b) and (d) of this section (e.g., because of mechanical problems with a lift), boarding assistance shall be provided by any available means to which the passenger consents, except hand-carrying as defined in 14 CFR 382.39(a)(2).

(5) The agreement shall ensure that all lifts and other accessibility equipment are maintained in proper working condition.

(e) In the event that airport personnel are involved in providing boarding

assistance, the airport shall ensure that they are trained to proficiency in the use of the boarding assistance equipment used at the airport and appropriate boarding assistance procedures that safeguard the safety and dignity of passengers.

Issued this 27th day of April 2001 at Washington, DC.

Norman Y. Mineta,

Secretary of Transportation.

[FR Doc. 01-11201 Filed 5-1-01; 10:22 am]

BILLING CODE 4910-62-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; Tylosin Tartrate for Injection, etc.; Withdrawal of Approval of NADAs

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations by removing those portions that reflect approval of 13 new animal drug applications (NADAs) listed below. In a notice published elsewhere in this issue of the **Federal Register**, FDA is withdrawing approval of the NADAs.

DATES: This rule is effective May 14, 2001.

FOR FURTHER INFORMATION CONTACT:

Pamela K. Esposito, Center for Veterinary Medicine (HFV-210), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-5593.

SUPPLEMENTARY INFORMATION: The following sponsors have requested that FDA withdraw approval of the NADAs listed below because the products are no longer manufactured or marketed:

Sponsor	NADA Number Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Elanco Animal Health, A Div. of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285.	NADA 12-585 Tylan Injectable (tylosin tartrate)	522.2640b (000986)
	NADA 15-207 Hyferdex Injection (iron dextran complex).	522.1183(c) (000986)
	NADA 30-330 Tylocine Sulfa Tablets (sulfadiazine, sulfamerazine, sulfamethazine, tylosin).	not applicable

Sponsor	NADA Number Product (Drug)	21 CFR Cite Affected (Sponsor Drug Labeler Code)
Bioproducts, Inc., 320 Springside Dr., suite 300, Fairlawn, OH 44333-2435. Young's, Inc., Roaring Spring, PA 16673 Veterinary Laboratories, Inc., 12340 Santa Fe Dr., Lenexa, KS 66215. Webel Feeds, Inc., Pittsfield, IL 62363	NADA 31-962 Tylan plus Neomycin Eye Powder (neomycin sulfate, tylosin).	524.2640 (000986)
	NADA 40-123 Toptic Ointment (cephalonium, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride, polymyxin B sulfate).	524.321 (000986)
	NADA 47-092 Tribodine (ticarbodine)	520.2460a (000986)
	NADA 47-353 Ferti-Cept (chorionic gonadotropin)	522.1081(b) (000986)
	NADA 92-602 Cephalothin Discs (cephaloridine) ..	529.360 (000986)
	NADA 96-678 Tribodine Capsules (ticarbodine)	520.2460b (000986)
	NADA 93-518 Tylan® 10 Plus (tylosin phosphate)	558.625(b)(2) (051359)
	NADA 96-162 Hog Grow-R-Mix-4000, Hog Grow-R-Mix-800 (tylosin phosphate).	558.625(b)(13) (035393)
	NADA 42-889 Oxytocin Injection (oxytocin)	522.1680(b) (000857)
	NADA 116-196 Webel Tylan Premix (tylosin phosphate).	558.625(b)(73) (035098)

Following the withdrawal of approval of these NADAs, Young's, Inc., is no longer the sponsor of any approved applications. Therefore, 21 CFR 510.600(c) is amended to remove the entries for the sponsor.

Elanco Animal Health's NADA 30-330 Tylocine Sulfa Tablets is not codified in 21 CFR part 520. Therefore, an amendment to the regulations for this withdrawal is not required.

As provided below, the animal drug regulations are amended to reflect the withdrawal of approvals.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

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: 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 "Young's, Inc.", and in the table in paragraph (c)(2) by removing the entry "035393".

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.

§ 520.2460 [Removed]

4. Section 520.2460 *Ticarbodine oral dosage forms* is removed.

§ 520.2460a [Removed]

5. Section 520.2460a *Ticarbodine tablets* is removed.

§ 520.2460b [Removed]

6. Section 520.2460b *Ticarbodine capsules* is removed.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.1081 [Amended]

8. Section 522.1081 *Chorionic gonadotropin for injection; chorionic gonadotropin suspension* is amended by removing and reserving paragraph (b).

§ 522.1183 [Amended]

9. Section 522.1183 *Iron hydrogenated dextran injection* is amended by removing and reserving paragraph (c).

§ 522.1680 [Amended]

10. Section 522.1680 *Oxytocin injection* is amended in paragraph (b) by removing "000857,".

§ 522.2640b [Removed]

11. Section 522.2640b *Tylosin tartrate for injection* is removed.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 524.321 [Removed]

13. Section 524.321 *Cephalonium, polymyxin B sulfate, flumethasone, iodochlorhydroxyquin, piperocaine hydrochloride topical-otic ointment* is removed.

§ 524.2640 [Removed]

14. Section 524.2640 *Tylosin, neomycin eye powder* is removed.

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 529.360 [Removed]

16. Section 529.360 *Cephalothin discs* is removed.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.625 [Amended]

18. Section 558.625 *Tylosin* is amended by removing and reserving paragraphs (b)(2), (b)(13), and (b)(73).

Dated: April 23, 2001.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 01-11070 Filed 5-2-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 522, and 558

Animal Drugs, Feeds, and Related Products; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to reflect changes to previously approved new animal drug applications (NADAs). Several sponsors currently listed as sponsors of approved applications and specified in the animal drug approval regulations are incorrect. This action is being taken to improve the accuracy of the regulations.

DATES: This rule is effective May 3, 2001.

FOR FURTHER INFORMATION CONTACT:

George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567.

SUPPLEMENTARY INFORMATION: FDA has found several errors in the agency's regulations concerning approval of animal drugs, feeds, and related products including the list of sponsors of approved applications. To correct those errors, FDA is amending 21 CFR 510.600(c)(1) and (c)(2) to remove 28 sponsor names and their corresponding drug labeler codes (DLCs) because the firms are no longer the holders of any approved NADAs. This document is also amending the animal drug approval regulations by correcting nonsubstantive DLC errors in 21 CFR 522.2120, 558.274, 558.625, and 558.630.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). Notice and public procedure are unnecessary because FDA is merely correcting nonsubstantive errors.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the

congressional review requirements in 5 U.S.C. 801-808.

List of Subjects

21 CFR Part 510

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

21 CFR Part 522

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, 522, 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 entries for "Albion Laboratories, Inc.," "Balfour Guthrie & Co.," "Diamond Shamrock Corp.," "DuPont Merck Pharmaceutical Co.," "Farmers Feed & Supply Co.," "Franklin Laboratories, Inc.," "Gland-O-Lac Co.," "Michael Gordon, Inc.," "Henwood Feed Additives," "Heska Corp.," "Hubbard Milling Co.," "Lemmon Co.," "Mattox & Moore, Inc.," "McClellan Laboratories, Inc.," "Nixon and Co.," "Osborn Laboratories, Inc.," "Peter Hand Foundation," "Premier Malt Products, Inc.," "Protein Blenders, Inc.," "The Rath Packing Co.," "Rhône Merieux Canada, Inc.," "Shell Chemical Co.," "Square Deal Fortification Co.," "Sterling Winthrop, Inc.," "Syntex Animal Health, Inc.," "V.P.O., Inc.," "Vet-A-Mix, Inc.," and "Westchester Veterinary Products, Inc.," and in the table in paragraph (c)(2) by removing the entries for "000033, 000056, 000693, 000934, 010290, 010290, 011461, 011485, 011789, 012190, 012487, 025001 026186, 027863, 028260, 032707, 033999, 036108, 043728, 043729, 043732, 043735, 043737, 043738, 043743, 043744, 047015, 049047, and 063604".

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.2120 [Amended]

4. Section 522.2120 *Spectinomycin dihydrochloride injection* is amended in paragraph (b) by removing "Nos. 000033 and 059130" and adding in its place "No. 059130".

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.274 [Amended]

6. Section 558.274 *Hygromycin B* is amended by removing and reserving paragraph (a)(5); by removing "011790 and" in paragraph (a)(7); and by removing "026186," from the "Sponsor" column in the table in paragraphs (c)(1)(i) and (c)(1)(ii).

§ 558.625 [Amended]

7. Section 558.625 *Tylosin* is amended by removing and reserving paragraphs (b)(16), (b)(19), and (b)(34), and in paragraph (b)(79) by removing "012286" and adding in its place "017519".

§ 558.630 [Amended]

8. Section 558.630 *Tylosin and sulfamethazine* is amended in paragraph (b)(8) by removing "026186".

Dated: April 23, 2001.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 01-11158 Filed 5-2-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 11

RIN 1076-AE15

Law and Order on Indian Reservations

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Temporary final rule and request for comments.

SUMMARY: The Bureau of Indian Affairs (BIA) is amending its regulations contained in 25 CFR Part 11 to add the