Dated: April 23, 2001.

Linda Tollefson,

Deputy Director, Center for Veterinary Medicine.

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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.'', ''Rhone 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.

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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