hour period.'' Children 5 to 9 years of age: Oral dosage is dibasic sodium phosphate 0.86 to 1.89 g and monobasic sodium phosphate 2.2 to 5.05 g (5 to 10 mL dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. ''Do not take more than 10 mL (2 teaspoonfuls) in a 24-hour period.'' Children under 5 years of age: ask a doctor.

(c) After June 22, 1998, for package size limitation and September 18, 1998, for labeling in accord with paragraph (b) of this section, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce, or any such drug product that is repackaged or relabeled after these dates regardless of the date the product was manufactured, initially introduced, or initially delivered for introduction into interstate commerce, that is not in compliance with this section is subject to regulatory action.

Dated: April 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–12053 Filed 5–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Name

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 name from Protiva, a unit of Monsanto, to Monsanto Co.

EFFECTIVE DATE: May 21, 1998.

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: Protiva, a unit of Monsanto has informed FDA of a change of sponsor name to Monsanto Co. Accordingly, FDA is amending 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

List of Subjects in 21 CFR Part 510

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

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 510 is 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 ''Protiva, A Unit of Monsanto Co.'' and by alphabetically adding a new entry for ''Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167'' and in the table in paragraph (c)(2) in the entry for ''059945'' by removing the sponsor name ''Protiva, A Division of Monsanto Co.'' and adding in its place ''Monsanto Co.''

Dated: May 8, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–13162 Filed 5–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 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 a change of sponsor for 96 new animal drug applications (NADA's) and 4 abbreviated animal drug applications (ANADA's) from Hoffmann-La Roche, Inc., to Roche Vitamins, Inc.

EFFECTIVE DATE: May 21, 1998.

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: Hoffmann-La Roche, Inc., Nutley, NJ 07110, has informed FDA that it has transferred the ownership of and all rights and interests in approved NADA's and ANADA's to Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298. Accordingly, the agency is amending the regulations in 21 CFR parts 510 and 558 to reflect the change of sponsor. The agency is also amending the regulations in § 510.600(c)(1) and (c)(2) by removing Hoffmann-La Roche, Inc., because the sponsor no longer sponsors any approved new animal drugs, and by alphabetically adding an entry for Roche Vitamins, Inc.

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, 21 CFR 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: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for ''Hoffmann-La Roche, Inc.,'' and by alphabetically adding an entry for ''Roche Vitamins, Inc.,'' and in the table in paragraph (c)(2) by removing the entry for ''000004'' and by numerically adding an entry for ''063238'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

Firm name and address	Drug labeler code
* * *	* * * *
Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298	063238
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
* * *	* * * *
063238	Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054–1298
* * *	* * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

§ 558.58 [Amended]

3. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraph (d)(1)(iii), under the ''Limitations'' column in the entries for ''Bacitracin 4 to 50'', ''Bacitracin 5 to 35 plus roxarsone 34 (0.00375%)'', and ''Bacitracin 10 to 50 plus roxarsone 15.4 to 45.4 (0.0017% to 0.005%)'' by removing ''000004 and 046573'' and adding in its place ''046573 and 063238'', and under the ''Sponsor'' column by removing ''000004'' wherever it appears and adding in its place ''063238''.

§ 558.78 [Amended]

4. Section 558.78 *Bacitracin zinc* is amended in paragraph (a)(2), in the table in paragraph (d)(1), under the ''Sponsor'' column, and in paragraph (d)(2)(ii) by removing ''000004'' wherever it appears and adding in its place ''063238''.

§ 558.95 [Amended]

5. Section 558.95 *Bambermycins* is amended in paragraph (d)(1)(xi)(*b*) and (d)(1)(xii)(*b*) by removing ''Nos. 012799 and 000004'' and adding in its place ''Nos. 012799 and 063238''.

§ 558.120 [Amended]

6. Section 558.120 *Carbarsone (not U.S.P.)* is amended in paragraph (d)(1)(iii)(*b*) by removing ''Nos. 000004 and 046573'' and adding in its place ''Nos. 046573 and 063238''.

§ 558.128 [Amended]

7. Section 558.128 *Chlortetracycline* is amended in paragraph (a)(1) by removing ''000004'' and adding in its place ''063238'', and in the table in paragraph (d)(1), under the ''Sponsors'' column, by removing ''000004'' wherever it appears and adding in its place ''063238''.

§ 558.145 [Amended]

8. Section 558.145 *Chlortetracycline, procaine penicillin, and sulfamethazine* is amended in paragraph (a)(1) by removing ''000004 and 046573'' and adding in its place ''046573 and 063238'', and in paragraph (a)(2) by removing ''000004'' and adding in its place ''063238''.

§ 558.175 [Amended]

9. Section 558.175 *Clopidol* is amended in paragraph (d)(1)(iii)(*b*) and (d)(1)(iv)(*b*) by removing ''Nos. 000004 and 046573'' and adding in its place ''Nos. 046573 and 063238''.

§ 558.195 [Amended]

10. Section 558.195 *Decoquinate* is amended in the table in paragraph (d) in the entry for ''27.2 (0.003 pct.), Roxarsone 11 to 45 (0.0012–0.005 pct.) plus Bacitracin 12 to 50'' under the ''Limitations'' column by removing ''Nos. 000004, 011716, and 046573'' and adding in its place ''Nos. 011716, 046573, and 063238''.

§ 558.305 [Amended]

11. Section 558.305 *Laidlomycin propionate potassium* is amended in paragraph (a) by removing ''000004'' and adding in its place ''063238''.

§ 558.311 [Amended]

12. Section 558.311 *Lasalocid* is amended in paragraphs (b)(2), (b)(3), (b)(4), (b)(5), (b)(6), and (b)(7) by removing ''000004'' and adding in its place ''063238''; in the table in paragraph (e)(1)(v) under the ''Limitations''column by removing ''000004'' and adding in its place ''063238'' and under the ''Sponsors'' column by removing ''000007'' and adding in its place ''063238''; and in paragraphs (e)(2)(v) and (e)(3)(v) by removing ''000004'' and adding in its place ''063238''.

§ 558.340 [Amended]

13. Section 558.340 *Maduramicin ammonium* is amended in paragraph (a) by removing ''000004'' and adding in its place ''063238''.

§ 558.342 [Amended]

14. Section 558.342 *Melengestrol acetate* is amended in paragraph (d)(3)(ii) by removing ''000004'' and adding in its place ''063238'', and in paragraph (d)(6)(ii) by removing ''Nos. 000004, 000009, and 000986'', and adding in its place ''Nos. 000009, 000986, and 063238''.

§ 558.355 [Amended]

15. Section 558.355 *Monensin* is amended in paragraphs (b)(8), (b)(9), (f)(1)(iv)(*b*), (f)(1)(v)(*b*), (f)(1)(xiv)(*b*), (f)(1)(xv)(*b*) by removing ''000004'' and adding in its place ''063238'', and in paragraph (f)(1)(xvi)(*b*) by removing ''Nos. 000004 and 046573'' and adding in its place ''Nos. 046573 and 063238''.

§ 558.515 [Amended]

16. Section 558.515 *Robenidine hydrochloride* is amended in paragraphs (a) and (d)(1)(vi)(*b*) by removing ''000004'' and adding in its place ''063238''.

§ 558.550 [Amended]

17. Section 558.550 *Salinomycin* is amended in paragraphs (a)(1), (d)(1)(vii)(*c*), (d)(1)(xv)(*c*), and (d)(1)(xvi)(*c*) by removing ''000004'' and adding in its place ''063238'', and in paragraph (d)(1)(ix)(*c*) by removing ''Nos. 000004 and 046573'' and adding in its place ''Nos. 046573 and 063238''.

§ 558.575 [Amended]

18. Section 558.575 *Sulfadimethoxine, ormetoprim* is amended in paragraphs (a)(1) and (a)(2) by removing ''000004'' and adding in its place ''063238''.

§ 558.582 [Amended]

19. Section 558.582 *Sulfamerazine* is amended in paragraph (a) by removing ''000004'' and adding in its place ''063238''.

§ 558.600 [Amended]

20. Section 558.600 *Tiamulin* is amended in paragraph (c)(4)(ii) by removing ''000004 and 046573'' and adding in its place ''046573 and 063238''.

Dated: May 8, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98–13161 Filed 5–20–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 537

Burmese Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.

SUMMARY: The Office of Foreign Assets Control of the U.S. Department of the Treasury is issuing the Burmese Sanctions Regulations to implement Executive Order 13047 of May 20, 1997, ''Prohibiting New Investment in Burma.''

EFFECTIVE DATE: May 21, 1998.

FOR FURTHER INFORMATION CONTACT: Steven I. Pinter, Chief of Licensing, tel.: 202/622–2480, or William B. Hoffman, Chief Counsel, tel.: 202/622–2410, Office of Foreign Assets Control, Department of the Treasury, Washington, DC 20220.

SUPPLEMENTARY INFORMATION:

Electronic Availability

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Background

On May 20, 1997, the President issued Executive Order 13047 (the ''Order''), effective at 12:01 a.m. EDT on May 21, 1997, certifying to Congress under section 570(b) of the Foreign Operations, Export Financing, and Related Programs Appropriations Act, 1997, (Public Law 104–208) (the ''Act'') that the Government of Burma has committed large–scale repression of the Democratic opposition in Burma after September 30, 1996, thereby invoking the prohibition on new investment in Burma by U.S. persons, contained in that section. The President also declared a national emergency to deal with the threat posed to the national security and foreign policy of the United States by the actions and policies of the Government of Burma, invoking the authority, *inter alia*, of the International Emergency Economic Powers Act (50 U.S.C. 1701–1706). The Order authorizes the Secretary of the Treasury, in consultation with the Secretary of State, to take such actions, including the promulgation of rules and regulations, as may be necessary to carry out the purposes of the Order. In implementation of the Order, the Treasury Department is issuing the Burmese Sanctions Regulations, 31 CFR part 537 (the ''Regulations'').

Section 537.201 of the Regulations implements section 1 of the Order, and prohibits new investment in Burma by U.S. persons. The term *new investment*, defined in section 4(d) of the Order, means any of the following activities, if such an activity is undertaken pursuant to an agreement, or pursuant to the exercise of rights under such an agreement, that is entered into with the Government of Burma or a nongovernmental entity in Burma on or after May 21, 1997:

(1) the entry into a contract that includes the economic development of resources located in Burma;

(2) the entry into a contract providing for the general supervision and guarantee of another person's performance of a contract that includes the economic development of resources located in Burma;

(3) the purchase of a share of ownership, including an equity interest, in the economic development of resources located in Burma; or

(4) the entry into a contract providing for the participation in royalties, earnings, or profits in the economic development of resources located in Burma, without regard to the form of the participation.

Section 537.202 of the Regulations implements section 2(a) of the Order and prohibits any approval or other facilitation by a United States person, wherever located, of a transaction by a foreign person where the transaction would constitute prohibited new investment in Burma if engaged in by a United States person or within the United States.

Section 537.203 of the Regulations implements section 2(b) of the Order and prohibits any transaction by a U.S. person or within the United States that evades or avoids, or that has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in the Order.

The prohibitions contained in these sections are subject to the exemption contained in section 3 of the Order, implemented in § 537.204 of the Regulations, which excludes from the new investment and facilitation prohibitions the entry into or performance or financing of a contract to sell or purchase goods, services, or technology. This exemption, however, does not apply where the entry into such a contract on or after the effective date of the Order is for the general supervision and guarantee of another person's performance of a contract for the economic development of resources located in Burma; or where such