DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

Animal Drugs, Feeds, and Related Products; Oxytetracycline Hydrochloride Soluble Powder

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 Rhone Merieux Canada, Inc. The ANADA provides for the use of a generic oxytetracycline hydrochloride soluble powder administered orally in drinking water for the control of certain diseases of chickens and turkeys and the treatment and control of certain diseases of swine, all susceptible to oxytetracycline.

EFFECTIVE DATE: August 9, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643. **SUPPLEMENTARY INFORMATION: Rhone** Merieux Canada, Inc., 345 Boul. Labbe Blvd., North Victoriaville, QC, G6P 1B1, Canada, filed ANADA 200-144 which provides for use of oxytetracycline hydrochloride soluble powder in drinking water of chickens, turkeys, and swine. The medicated drinking water is used as follows: (1) Chickens for control of infectious synovitis caused by Mycoplasma synoviae susceptible to oxytetracycline; control of chronic respiratory disease (CRD) and air sac infections caused by M. gallisepticum and Escherichia coli susceptible to oxytetracycline; control of fowl cholera caused by Pasteurella multocida susceptible to oxytetracycline; (2) turkeys for control of hexamitiasis

caused by Hexamita meleagridis susceptible to oxytetracycline; infectious synovitis caused by M. synoviae susceptible to oxytetracycline; and control of complicating bacterial organisms associated with blue comb (transmissible enteritis; coronaviral enteritis) susceptible to oxytetracycline; (3) swine for control and treatment of bacterial enteritis caused by E. coli and Salmonella choleraesuis and bacterial pneumonia caused by P. multocida susceptible to oxytetracycline; and (4) breeding swine for control and treatment of leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by Leptospira pomona susceptible to oxytetracycline.

Approval of ANADA 200–144 for oxytetracycline soluble powder is a generic copy of I. D. Russell's NADA 130–435 (Oxytet Soluble). The ANADA is approved as of June 26, 1995, and the regulations in § 520.1660d (21 CFR 520.1660d) are amended to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, Rhone Merieux Canada, Inc., has not been previously listed in 21 CFR 510.600(c) as sponsor of an approved application. That section is amended to add entries for the firm.

In addition, the regulation contains an outdated paragraph citing the National Academy of Sciences/National Research Council (NAS/NRC) status of these products. The Generic Animal Drug and Patent Term Restoration Act of 1988 changed that status, therefore, § 520.1660d(c)(2) is removed and reserved.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 510

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

21 CFR Part 520

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 parts 510 and 520 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. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for "Rhone Merieux Canada, Inc.," and in the table in paragraph (c)(2) by numerically adding a new entry for "047015" to read as follows:

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

*	*			*	*	*
	(c) *	*	*			
	(1) *					

	Firm		Drug labeler code			
*	*	*	*	*	*	*
Rhone Merieux (Canada, Inc., 345 Bou	1	047015			
*	*	*	*	*	*	*

(2) * * *