

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier	Mike Bell

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Sulfadimethoxine, Ormetoprim

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the new animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Roche Vitamins, Inc. The supplemental NADA provides for a change in the name of a duck pathogen. Infections of the pathogen are controlled by use of sulfadimethoxine/ormetoprim Type C medicated feed.

EFFECTIVE DATE: (*Insert date of publication in the Federal Register.*)

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7569.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298, filed a supplement to NADA 40-209 that provides for use of Rofenaid® 40 (113.5 grams per pound (g/lb) sulfadimethoxine with 68 g/lb ormetoprim) to make Type C medicated duck feeds containing 454 g per ton (/t) sulfadimethoxine with 272.4 g/t ormetoprim. The Type C medicated feeds are used as an aid in the control of bacterial infections in ducks. The supplement provides for a change of nomenclature of one pathogen from *Pasteurella anatipestifer* to *Riemerella anatipestifer* based on the results of studies obtained from DNA-rRNA hybridization analyses and determinations of DNA ratios and from analyses of protein and fatty acids. According to the published report (Ref. 1), the causative agent of the disease known as "septicemia anserum

exsudativa” constitutes a separate taxon within the *Flavobacterium-Cytophaga* rRNA homology cluster and is named *R. anatipestifer*. This organism is distributed world wide and causes septicemia in ducks, geese, and turkeys. The supplemental NADA was approved as of June 15, 1999, and the regulations are amended in 21 CFR 558.575 (d)(4)(ii)(a) to reflect the change in nomenclature.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a copy of the information submitted to support approval of this supplemental 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.

FDA 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.

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.

Reference

The following reference has been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. *International Journal of Systematic Bacteriology*, p. 768-776, October, 1993.

List of Subjects in 21 CFR Part 558

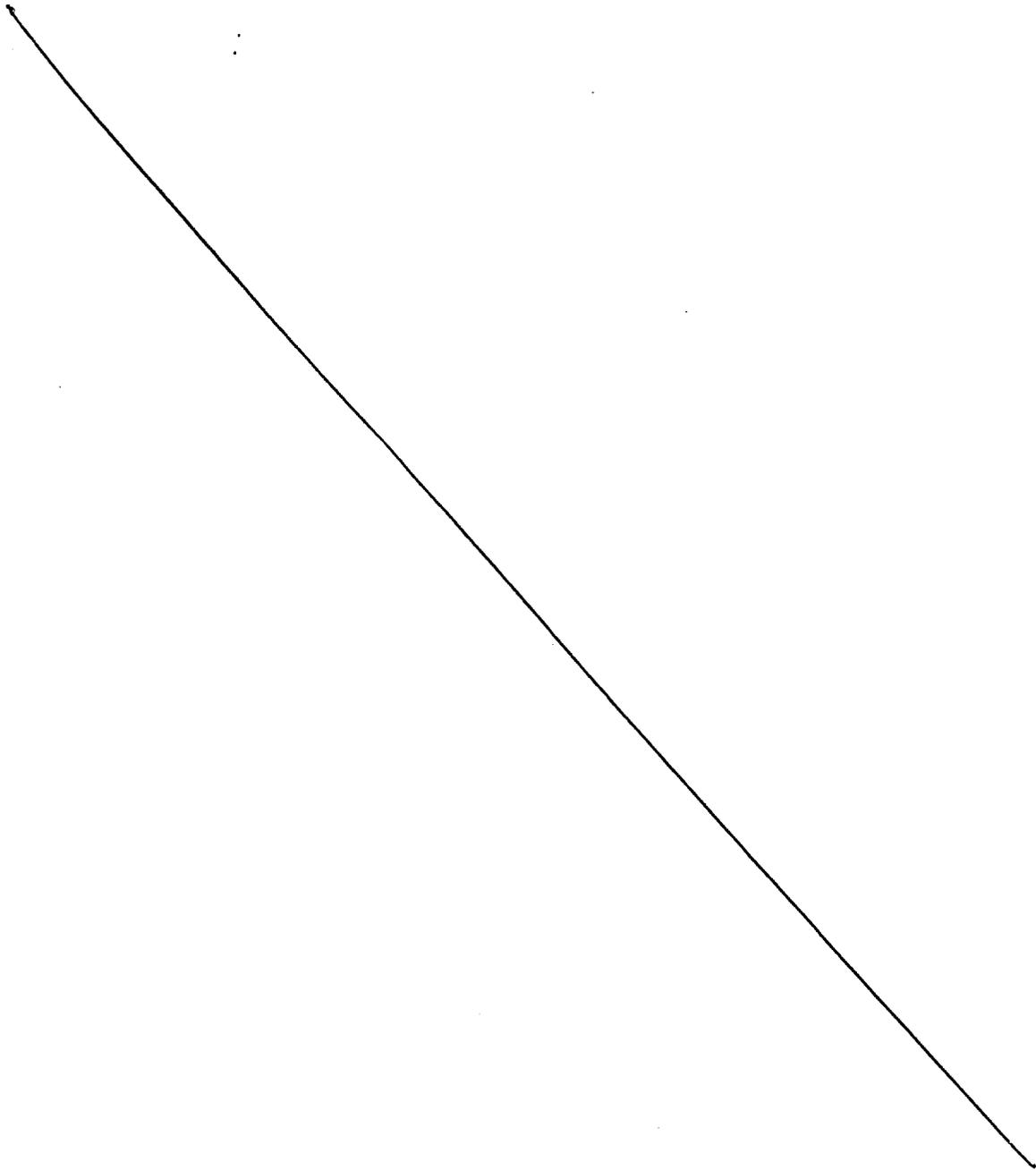
Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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.



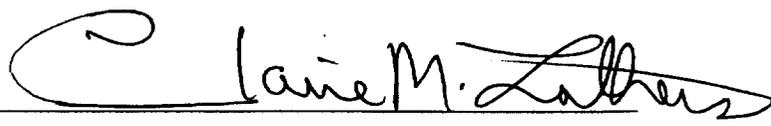
§ 558.575 [Amended]

no list

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2. Section 558.575 is amended in paragraph (d)(4)(ii)(a) by removing "P." and adding in its place "Riemerella".

Dated: 8/02/99
August 2, 1999



Clair M. Lathers
Director, Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

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Michael W. Bell