

purpose sweetener, the agency reevaluated the currently established acceptable daily intake (ADI) for sucralose, 5 milligrams per kilogram body weight per day (mg/kg bw/d) (Ref. 1) and determined that this ADI is still appropriate (Ref. 2). FDA also estimated new daily intakes (EDI) for the 90th percentile consumer of sucralose to include the expanded uses. The new EDI was derived from projections based on the amount of sucralose that may be used in the currently regulated food categories, the proposed food categories, and on data regarding the consumption levels of these particular foods. Based upon the data in the petition and other information, the agency established a no effect level (NOEL) for the hydrolysis products of sucralose at 30 mg/kg bw/d (Ref. 2).

To aid in the establishment of new exposure estimates for sucralose and its hydrolysis products, the petitioner submitted a Market Research Corporation of America (MRCA) report that addresses foods in which sucralose may be used and an updated report on the potential exposure for the hydrolysis products. From this information, the agency has determined that based on the expanded uses, the cumulative exposure to sucralose could increase to 2.4 mg/kg bw/d and the cumulative exposure to its hydrolysis products to 0.007 mg/kg bw/d (Ref. 3). The agency concludes: Exposure to sucralose will remain below the previously established ADI of 5.0 mg/kg bw/d for sucralose, and exposure to the hydrolysis products will remain far below the no effect level of 30 mg/kg bw/d (Refs. 2 and 3).

#### IV. Conclusions

From the review of all the information available on sucralose and its hydrolysis products, the agency concludes that sucralose may be safely used as a sweetener in food generally (Refs. 2 and 3).

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

#### V. Environmental

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.

#### VI. Paperwork Reduction Act 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

#### VII. Objections

Any person who will be adversely affected by this regulation may at any time on or before September 13, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

#### VIII. References

The following references have 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. Addendum memorandum from Whiteside, Scientific Support Branch, FDA, to Anderson, Novel Ingredients Branch, FDA, November 13, 1997.

2. Memorandum from Whiteside, Division of Health Effects Evaluation,

FDA, to Anderson, Regulatory Policy Branch, February 25, 1999.

3. Memorandum from DiNovi, Division Product Manufacture and Use, FDA, to Anderson, Division of Product Policy, FDA, October 22, 1998.

#### List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 172 is amended as follows:

#### PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

**Authority:** 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.831 is amended by removing the introductory paragraph and by revising paragraph (c) to read as follows:

#### § 172.831 Sucralose.

\* \* \* \* \*

(c) The additive may be used as a sweetener in foods generally, in accordance with current good manufacturing practice in an amount not to exceed that reasonably required to accomplish the intended effect.

\* \* \* \* \*

Dated: August 5, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

#### 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:** August 12, 1999.

**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]

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

Dated: August 2, 1999

**Clair M. Lathers,**

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine  
[FR Doc. 99-20844 Filed 8-11-99; 8:45 am]  
BILLING CODE 4160-01-F

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Part 1

[TS 8835]

RIN 1545-AX27

#### Furnishing Identifying Number of Income Tax Return Preparer

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Temporary and final regulations.

**SUMMARY:** This document contains temporary and final regulations that allow income tax return preparers to elect an alternative to their social security number (SSN) for purposes of identifying themselves on returns they prepare. The regulations are needed to implement changes made to the applicable law by the Internal Revenue Service Restructuring and Reform Act of 1998. The regulations affect individual preparers who elect to identify themselves using a number other than

their SSN. The text of the temporary regulations also serves as the text of the proposed regulations set forth in the notice of proposed rulemaking on this subject in the Proposed Rules section in this issue of the **Federal Register**.

**DATES:** *Effective Date:* These regulations are effective August 12, 1999.

*Applicability Date:* For dates of applicability of these regulation, see §§ 1.6109-2(d) and 1.609-2T(d).

**FOR FURTHER INFORMATION CONTACT:** Andrew J. Keyso, (202) 622-4910 (not a toll-free call).

#### SUPPLEMENTARY INFORMATION:

#### Background

Section 6109(a)(4) of the Internal Revenue Code provides that any return or claim for refund prepared by an income tax return preparer must bear the identifying number of the preparer as required by regulations prescribed by the Secretary. Prior to its amendment by the Internal Revenue Service Restructuring and Reform Act of 1998 (Public Law 105-206, 112 Stat. 685 (RRA '98)), section 6109(a) provided that the identifying number of an individual preparer was that preparer's social security number (SSN).

Section 3710 of RRA '98 amended section 6109(a) by removing the requirement that an individual preparer's identifying number be the preparer's SSN. Instead, the Secretary may prescribe alternatives to the SSN for purposes of identifying individual preparers.

#### Explanation of Provisions

On December 21, 1998, the IRS published Notice 98-63, 1998-51 IRB 15, to inform preparers of the IRS's intention to develop a system of alternative identifying numbers. This document contains amendments to the Income Tax Regulations (26 CFR part 1) to allow individual preparers to either use their SSN or elect an alternative identifying number for purposes of identifying themselves on returns they prepare. The IRS will develop a form on which preparers may apply for an alternative identifying number.

#### Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the