DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

Food Additives Permitted for Direct Addition to Food for Human Consumption; Sucralose

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of sucralose as a general purpose sweetener for food. This action is in response to a petition filed by McNeil Specialty Products Co.

DATES: This regulation is effective August 12, 1999; written objections and requests for a hearing by September 13, 1999.

ADDRESSES: Written objections may be sent to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.


SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the Federal Register on January 11, 1999 (64 FR 1634), FDA announced that a food additive petition (FAP 8A4624) had been filed by McNeil Specialty Products, Co., 501 George St., New Brunswick, NJ 08903–2400. The petition proposed that the food additive regulations be amended at § 172.831 (21 CFR 172.831) to expand the permitted uses of sucralose to allow for use as a general purpose sweetener in food. FDA previously approved sucralose for use in 15 food categories under § 172.831 (64 FR 16417, Apr 3, 1999).

II. Identity

Sucralose is a disaccharide that is made from sucrose in a five-step process that selectively substitutes three atoms of chlorine for three hydroxyl groups in the sugar molecule. It is a free-flowing, white crystalline solid, product at an approximate purity of 98 percent, that is soluble in water and stable both in crystalline form and in most aqueous solutions. The sweetness intensity for sucrose in 320 to 1,000 times that of sucrose, depending on the food application.

Hydrolysis of sucralose may occur under conditions of prolonged storage at elevated temperatures in highly acidic aqueous food products. The hydrolysis products are the monosaccharides, 4-chloro-4-deoxy-galactose (4-CG) and 1,6-dichloro-1,6-dideoxyfructose (1,6-DCF).

III. Evaluation of Safety

In support of safety for the proposed expanded uses of sucralose, the petitioner referenced the toxicological safety data base submitted in food additive petition (FAP) 9A3987 that established the safety of the currently approved uses. Also referenced were the identity, manufacturing process, and specifications for the sweetener. In the new petition (FAP 8A4624), the petitioner submitted data concerning:

Use and typical use levels; (2) self-limiting levels; (3) proof of technical effect; (4) exposure; (5) stability; and (6) analysis in foods for both sucrose and its potential hydrolysis products.

In order to determine whether sucralose can be safely used as a general...
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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 on 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 foods generally, in
accordance with current good manufacturing practice in an amount not to exceed that reasonably required
to accomplish the intended effect.

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
particularly 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, New 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

§ 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.

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