4. Gilbert, Linda, contributing ed., ''Leisure Cooking Still Popular,'' *Food R & D*, February 1985.

5. Greenfield, H., J. Maples, and R. B. H. Wills, ''Salting of Food—A Function of Hole Size and Location of Shakers,'' *Nature*, 301:331, 1983.

6. Letter from Marlene L. McKone, McCormick & Company, Inc., to Ellen M. Anderson, CFSAN, FDA, September 26, 1997.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, 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 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.12 is amended in paragraph (b), in Table 2, under the ''Product category'' column, under the ''Miscellaneous Category'' by revising the entry for ''Salt, salt substitutes, seasoning salts (e.g., garlic salt)'' to read as follows:

§ 101.12 Reference amounts customarily consumed per eating occasion.

* * * * *

(b) * * *

TABLE 2.—REFERENCE AMOUNTS CUSTOMARILY CONSUMED PER EATING OCCASION: GENERAL FOOD SUPPLY[1, 2, 3, 4]

Product category	Reference amount	Label statement[5]
* * *	* *	* *
Miscellaneous category:		
* * *	* *	* *
Salt, salt substitutes, seasoning salts (e.g., garlic salt).	1/4 tsp	1/4 tsp (____ g); ____ piece(s) (____ g) for discrete pieces (e.g., individually packaged products).
* * *	* *	* *

[1] These values represent the amount (edible portion) of food customarily consumed per eating occasion and were primarily derived from the 1977–1978 and the 1987–1988 Nationwide Food Consumption Surveys conducted by the U.S. Department of Agriculture.

[2] Unless otherwise noted in the Reference Amount column, the reference amounts are for the ready-to-serve or almost ready-to-serve form of the product (i.e, heat and serve, brown and serve). If not listed separately, the reference amount for the unprepared form (e.g., dry mixes; concentrates; dough; batter; fresh and frozen pasta) is the amount required to make the reference amount of the prepared form. Prepared means prepared for consumption (e.g., cooked).

[3] Manufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using the procedures in 21 CFR 101.9(b).

[4] Copies of the list of products for each product category are available from the Office of Food Labeling (HFS–150), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

[5] The label statements are meant to provide guidance to manufacturers on the presentation of serving size information on the label, but they are not required. The term ''piece'' is used as a generic description of a discrete unit. Manufacturers should use the description of a unit that is most appropriate for the specific product (e.g., sandwich for sandwiches, cookie for cookies, and bar for ice cream bars). The guidance provided is for the label statement of products in ready-to-serve or almost ready-to-serve form. The guidance does not apply to the products which require further preparation for consumption (e.g., dry mixes, concentrates) unless specifically stated in the product category, reference amount, or label statement column that it is for these forms of the product. For products that require further preparation, manufacturers must determine the label statement following the rules in § 101.9(b) using the reference amount determined according to § 101.12(c).

* * * * *

Dated: November 20, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–31462 Filed 12–1–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 97P–0206]

Food Labeling: Health Claims; Dietary Sugar Alcohols and Dental Caries

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing its decision to amend the regulation that authorizes a health claim on sugar alcohols and dental caries to include the sugar alcohol erythritol among the substances that may be the subject of the claim. Based on its review of evidence submitted with a comment on the proposal, and the evidence described in the proposal, the agency has concluded that there is significant scientific agreement that erythritol does not promote dental caries. Therefore, FDA has decided to amend the sugar alcohol and dental caries health claim to include erythritol. FDA is announcing this action in response to a petition filed by the Cerestar Holding B.V., Mitsubishi Chemical Corp., and Nikken Chemicals Co. (the petitioners).

EFFECTIVE DATE: December 2, 1997.

FOR FURTHER INFORMATION CONTACT: Joyce J. Saltsman, Center for Food Safety and Applied Nutrition (HFS–165), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5483.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 9, 1997 (62 FR 36749), the agency proposed to amend the regulation that authorizes a health claim on sugar alcohols and dental caries (§ 101.80 (21 CFR 101.80)) to include the sugar alcohol erythritol among the substances that may be the subject of the claim. FDA issued the proposed rule in response to a petition filed under section 403(r)(3)(B)(i) and (r)(4) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i) and (r)(4))). Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (and, by delegation, FDA) shall issue regulations authorizing health claims only if he or she determines, based on the totality of publicly available scientific evidence (including evidence

from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence (see also § 101.14(c) (21 CFR 101.14(c))). Section 403(r)(4) of the act sets out the procedures that FDA is to follow in health claim rulemakings.

Section 101.80(c)(2)(ii) sets out the circumstances in which a sugar alcohol is eligible to be the subject of a health claim. Section 101.80(c)(2)(ii)(A) states that the food must meet the requirement for a sugar free food set out in 21 CFR 101.60(c)(1)(i). Section 101.80(c)(2)(ii)(B) lists the sugar alcohols that are eligible to bear the claim, xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, or a combination of these. Section 101.80(c)(2)(ii)(C) states that:

> When fermentable carbohydrates are present in the sugar alcohol-containing food, the food shall not lower plaque pH below 5.7 by bacterial fermentation either during consumption or up to 30 minutes after consumption as measured by the indwelling plaque pH test found in ''Identification of Low Caries Risk Dietary Components,'' * * * which is incorporated by reference * * * .

At the time that it adopted § 101.80, the agency stated that for other sugar alcohols to be included in § 101.80(c)(2)(ii)(B), a petitioner must show how the substance conforms to the requirements of §§ 101.14(b) and 101.80 (61 FR 43433 at 43442, August 23, 1996). FDA stated ''For those substances that are to be consumed at other than decreased dietary levels, the petitioner must demonstrate to FDA's satisfaction that the substance is safe and lawful under the applicable food safety provisions of the act (§ 101.14(b)(3)(ii)).'' Likewise, the petitioner would need to provide evidence that the sugar alcohol will not lower plaque pH below 5.7. Therefore, before a claim can be made for a new sugar alcohol, it must be shown to meet the requirements for § 101.80. When this is demonstrated, FDA will take action to add the substance to the list in this regulation, which has been renumbered as § 101.80(c)(2)(ii)(B) (61 FR 43433 at 43442).

FDA considered the relevant scientific studies and data presented in the petition as part of its review of the scientific literature on erythritol and dental caries. The agency summarized this evidence in the proposed rule (62 FR 36749).

Based on the available evidence, FDA tentatively concluded that the use of erythritol in food is safe and lawful, and that this substance meets the plaque pH and other requirements of § 101.80. Consequently, FDA proposed to amend § 101.80(c)(2)(ii)(B) to include erythritol as one of the sugar alcohols that is eligible to bear the sugar alcohol and dental caries health claim. FDA did not propose to make any other changes to § 101.80.

In response to the proposal, the agency received one comment from a manufacturer. The comment supported the proposed amendment to § 101.80 to include erythritol.

Given the absence of any evidence to the contrary, FDA is confirming the tentative conclusions that it reached in the proposal. Based on these conclusions, FDA is amending § 101.80 to add erythritol to the substances listed in § 101.80(c)(2)(ii)(B) that may be the subject of the claim.

II. Environmental Impact

The agency has previously considered the environmental effects of this rule as announced in the proposed rule (62 FR 36749). The proposed rule incorrectly cited a claim of categorical exclusion under previous 21 CFR 25.24(a)(11). The agency reviewed the information submitted by the petitioner in an environmental assessment prepared under 21 CFR 25.31a(b)(5). Based on this information, the agency determined that there is no significant impact on the human environment and that an environmental impact statement is not required. No new information or comments have been received that would affect the agency's previous determination. 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.

III. Executive Order 12866 Analysis

FDA has examined the impacts of the final rule under Executive Order 12866. Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select the regulatory approach that maximizes net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). Executive Order 12866 classifies a rule as significant if it meets any one of a number of specified conditions, including having an annual effect on the economy of $100 million or adversely affecting in a material way a sector of the economy, competition, or jobs, or if it raises novel legal or policy issues. FDA finds that this rule is not a significant rule as defined by Executive Order 12866.

The authorization of health claims about the relationship between erythritol and dental caries results in either costs or benefits only to the extent that food manufacturers elect to take advantage of the opportunity to use the claim. This rule will not require that any labels be redesigned, or that any product be reformulated.

This final health claim will allow manufacturers to highlight the benefits of the sugar alcohol erythritol in addition to other sugar alcohols for which FDA has already approved a health claim. The benefit of establishing this health claim is to provide for new information in the market regarding the relationship of erythritol and dental caries and to provide consumers with the assurance that this information is truthful, not misleading, and scientifically valid.

IV. Small Entity Analysis

FDA has examined the impacts of the final rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize the economic impact of that rule on small entities.

Small entities will incur costs only if they opt to take advantage of the marketing opportunity presented by this regulation. FDA cannot predict the number of small entities that will choose to use the claim. However, no firm, including small entities, will choose to bear the cost of redesigning labels unless they believe that the claim will result in increased sales of their product. Therefore, this rule will not result in either a decrease in revenues or a significant increase in costs to any small entity. Accordingly, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), the agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

V. Paperwork Reduction Act

This final rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*)

VI. References

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. Cerestar Holding B. V., Mitsubishi Chemical Corp., and Nikken Chemicals Co., ''Petition to amend the regulation for 21 CFR 101.80 to authorize a noncariogenicity dental health claim for the sugar alcohol erythritol (1,2,3,4-butanetetrol),'' April 4, 1997, [CP1].

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, 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 101 is amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371.

2. Section 101.80 is amended by revising paragraph (c)(2)(ii)(B) to read as follows:

§ 101.80 Health claims: dietary sugar alcohols and dental caries.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(B) The sugar alcohol in the food shall be xylitol, sorbitol, mannitol, maltitol, isomalt, lactitol, hydrogenated starch hydrolysates, hydrogenated glucose syrups, erythritol, or a combination of these.

* * * * *

Dated: November 21, 1997.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 97–31587 Filed 12–1–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

23 CFR Part 1327

[Docket No. NHTSA–97–3155]

RIN 2127–AG21

Procedures for Participating in and Receiving Data From the National Driver Register Problem Driver Point System

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Interim final rule; request for comments.

SUMMARY: This interim final rule amends the agency's National Driver Register (NDR) regulations to implement a recent amendment to the National Driver Register Act of 1982, as amended. The amendment authorizes the Commandant of the Coast Guard to request and receive information from the National Driver Register (NDR) regarding the motor vehicle driving records of any officer, chief warrant officer, or enlisted member of the Coast Guard or Coast Guard Reserve (including a cadet or an applicant for appointment or enlistment of any of the foregoing, and any member of a uniformed service who is assigned to the Coast Guard). This interim final rule establishes the procedures for such individuals to request, and for the Commandant to receive, NDR information.

DATES: This interim final rule becomes effective on December 2, 1997. Comments on this interim final rule are due no later than February 2, 1998.

ADDRESSES: Written comments should refer to the docket number and be submitted (preferably in ten copies) to: Department of Transportation—Dockets, Room PL–401, Nassif Building, 400 Seventh Street, S.W., Washington, DC 20590. (Docket hours are from 10:00 a.m. to 5:00 p.m.)

FOR FURTHER INFORMATION CONTACT: Mr. William Holden, Chief, Traffic Records and Driver Register Division, NTS–32. National Highway Traffic Safety Administration, 400 Seventh Street, S.W., Washington, DC 20590; telephone (202) 366–4800 or Ms. Heidi L. Coleman, Assistant Chief Counsel for General Law, NCC–30, National Highway Traffic Safety Administration, 400 Seventh Street, S.W., Washington, DC 20590; telephone (202) 366–1834.

SUPPLEMENTARY INFORMATION: The National Driver Register (NDR) is a central file of information on individuals whose licenses to operate a motor vehicle have been denied, revoked, suspended, or canceled, for cause, or who have been convicted of certain serious traffic-related violations, such as racing on the highways or driving while impaired by alcohol or other drugs.

As provided in the NDR Act of 1982, as amended, 49 U.S.C. 30301, *et seq.*, State chief driver licensing officials are authorized to request and receive information from the NDR for driver licensing and driver improvement purposes. When an individual applies for a driver's license, for example, these State officials are authorized to request and receive NDR information to determine whether the applicant's driver's license has been withdrawn for cause in any other State. Because the NDR is a nationwide index, chief driver licensing officials need to submit only a single inquiry to obtain this information.

State chief driver licensing officials also are authorized under the Act to request NDR information on behalf of other authorized NDR users for transportation safety purposes. The NDR Act authorizes the following entities to receive NDR information for limited transportation purposes: the National Transportation Safety Board and the Federal Highway Administration for accident investigation purposes; employers and prospective employers of motor vehicle operators; the Federal Aviation Administration (FAA) regarding any individual who holds or has applied for an airman's certificate; air carriers regarding individuals who are seeking employment with the air carrier; the Federal Railroad Administration (FRA) and employers or prospective employers of locomotive operators; and the U.S. Coast Guard regarding any individual who holds or who has applied for a license, certificate of registry, or a merchant mariner's document. The Act also provides that individuals can learn whether information about themselves is on the NDR file and can receive any such information.

On October 19, 1996, Pub. L. 104–324 was enacted into law. Section 207 of that Act contained an amendment to the NDR Act of 1982, as amended (49 U.S.C. 30305), authorizing the Commandant of the Coast Guard to request and receive NDR information regarding any officer, chief warrant officer, or enlisted member of the Coast Guard or Coast Guard Reserve (including a cadet or an applicant for appointment or enlistment of any of the foregoing, and any member of a uniformed service who is assigned to the Coast Guard).

Procedures for Requesting and Receiving NDR Information

The procedures that the Commandant of the Coast Guard would use to receive NDR information on these Coast Guard members would be the same as those used by the U.S. Coast Guard to receive information regarding individuals who hold or who have applied for a license, certificate of registry, or a merchant mariner's document.

The Commandant of the Coast Guard may not initiate a request for NDR information. Rather, the individual member or applicant must do so. To initiate a request, the individual must either complete, sign and submit a request for an NDR file search, or