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#### 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, it is proposed that 21 CFR part 101 be amended as follows:

#### PART 101—FOOD LABELING

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

**Authority:** Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. New § 101.80 is added to subpart E to read as follows:

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

(a) *Relationship between dietary sugar alcohols and dental caries.* (1) Dental caries, or tooth decay, is a disease caused by many factors. Both environmental and genetic factors can affect the development of dental caries. Risk factors include tooth enamel crystal structure and mineral content, plaque quantity and quality, saliva quantity and quality, individual immune response, types and physical characteristics of foods consumed, eating behaviors, presence of acid producing oral bacteria, and cultural influences.

(2) The relationship between dietary sugars consumption and tooth decay is well established. Sucrose is one of the most, but not the only, cariogenic sugar in the diet. Bacteria found in the mouth are able to metabolize sugars producing acid and forming dental plaque. Prolonged exposure of the tooth enamel to acids from dental plaque causes tooth enamel to demineralize, or decay. Frequent between-meal consumption of sugary foods, particularly foods that easily stick to the teeth, can cause tooth decay.

(3) U.S. diets tend to be high in sugars consumption. Although there has been a decline in the prevalence of dental caries in the United States, per capita consumption of sugars has not declined, and the disease remains widespread throughout the population. Federal government agencies and nationally recognized health professional organizations recommend decreased consumption of sugars.

(4) Dietary sugar alcohols can be used to replace dietary sugars in food. Sugar alcohols are significantly less cariogenic than dietary sugars. Thus, replacing dietary sugars with sugar alcohols helps to maintain dental health.

(b) *Significance of the relationship between sugar alcohols and dental caries.* Sugar alcohols do not promote