

*Calorie Control Council*

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June 13, 2005

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane  
rm. 1061  
Rockville, MD 20852

RE: Docket No. 95P0099

In April 1995, the Calorie Control Council submitted to the Food and Drug Administration a citizen petition requesting that the Commissioner of Food and Drugs amend the food labeling regulations to permit the use of the term "polyols" in lieu of "sugar alcohols" in the nutrition panel on the food label. The Council noted that this modification would reduce consumer confusion and submitted nationally projectable consumer research conducted for the Calorie Control Council confirming that the consumer is indeed confused by the term "sugar alcohol".

The nationally projectable survey, conducted by Market Facts and submitted to the FDA by the Calorie Control Council, found that 78 percent of those surveyed think the term "sugar alcohol" indicates that a product contains some sugar even when the product is labeled "sugar free." Sixty-nine percent believe the product contains some alcohol. Attached below are additional examples of consumer confusion related to the use of the term sugar alcohol. The relevant portions are shown in bold.

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June 2, 2005 Thursday

SECTION: WIRE - FEATURES; Pg. E4

LENGTH: 659 words

HEADLINE: Common germ uncommonly causes death

BODY:

DEAR DR. DONOHUE: What is pneumococcal sepsis? My wife and I cannot get answers explaining why my 41-year-old daughter died of it. She lived in an apartment with her 13-year-old daughter and 9-year-old son. My daughter and granddaughter both

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had pneumonia. My granddaughter went to the hospital and recovered. My daughter went to the ICU and died four days later. Can you shed any light on this? -- F.

A: The pneumococcus (NEW-moe-KOK-us) germ is a common bacterium found in the nose and throat of 10 percent of healthy adults and up to 40 percent of healthy children. On occasion, it can turn lethal when it escapes to other body sites, especially when it does so in infants younger than 2, adults older than 65 or people whose immune systems are not up to snuff.

In your daughter's and granddaughter's cases, the germ found its way into their lungs and brought on pneumonia. In your daughter's case, the germ escaped from her lungs and entered her bloodstream -- that's sepsis, and it is often a fatal infection.

I can't tell you why this sequence of events occurred. It happens, even to very healthy people. Until recent times, penicillin controlled almost all pneumococcal infections. Now some pneumococcal strains have become resistant to penicillin and require other antibiotics. Perhaps your daughter and granddaughter had a resistant strain.

There is a vaccine for the pneumococcus germ, and it is now given to all babies. It is also highly recommended for those over 65. Popularly it is called the pneumonia vaccine. In addition, it should be given to people of any age with illnesses that make them susceptible to pneumococcal infection. That includes people with diabetes, liver and kidney disease, heart failure and those who do not have a spleen.

I have no words to console you for such an unexpected tragedy. I have no words to ease the loss your grandchildren face with the death of their mother. Be assured you have my and my readers' sympathy.

**DEAR DR. DONOHUE: I am enclosing a candy wrapper that says "sugar free." On the list of ingredients there appears "sugar alcohol." Is this false advertising, as it appears to be to me, or is it just grossly misleading? -- B.C.**

**A: "Sugar alcohol" is a source of confusion to everyone. These substances aren't sugars, and they aren't alcohol. They got the designation because their chemical structure looks similar to the structures of sugars and alcohols. The term is misleading. Someone should come up with a substitute.**

**Sugar alcohols are used as artificial sweeteners, and the foods they are added to can be legitimately and truthfully labeled as being sugar-free.**

**Sugar alcohols have fewer calories than does sugar. They raise blood sugar slightly and slowly.**

**They have no alcohol effect at all.**

**Mannitol, xylitol, sorbitol and isomalt are common sugar alcohols. You can find them in many products. Overdoing their use can bring on diarrhea.**

**DEAR DR. DONOHUE: The doctor at the Veteran's Administration has prescribed felodipine for my high blood pressure.**

My private doctor recommends I take Toprol XL.

Toprol XL is expensive, and the VA does not carry it. Your opinion, please? -- R.S.

A: Costly blood-pressure medicine is not necessarily the best blood-pressure medicine. The best medicine for an individual patient is the one that lower pressure with the fewest side effects and the least expense.

Felodipine, brand name Plendil, is a calcium-channel blocker. It stops minute amounts of calcium from entering the tiny muscles that surround arteries. When calcium enters those muscles, they constrict, narrow the vessel and raise blood pressure.

Toprol XL is the brand name for metoprolol, a beta-blocker medicine. It dilates arteries too but in a way different from felodipine.

If your pressure is controlled with felodipine, then you don't need the more expensive medicine. If it isn't, then you do need a medicine change. There are many to choose from.

LOAD-DATE: June 2, 2005

***Diabetes Forecast, Practical Living --Ask Us, July 2005, page 16***

My sister-in-law bought me "sugar-free" candy. Of course she didn't read the nutritional information before she bought the candy, as I would have. When I read the nutrition label I was surprised to find that three pieces had 18 grams of carbohydrates!

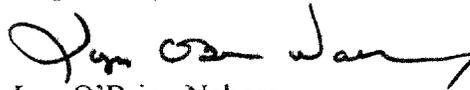
Where were the carbs coming from? Under sugar, on the nutrition label, the total grams were zero. Under sugar alcohol, there were 18 grams, which explains where the carbs were coming from.

**How can anything be labeled as "sugar-free" if there is sugar alcohol in the ingredients? Sugar alcohol seems to have the same carbohydrates as regular sugar. Is sugar alcohol any better for people with diabetes than regular sugar?**

(Signature withheld)

These examples further underscore consumer confusion concerning the term "sugar alcohol." Again, the Calorie Control Council urges that the term "sugar alcohol" be replaced with the term "polyol" in 21 CFR 101.9(c)(6).

Respectfully submitted,



Lyn O'Brien Nabors  
Executive Vice President