

CSPI

Center for
Science in the
Public
Interest

Publisher of *Nutrition Action Healthletter*

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March 13, 2000

Dockets Management
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

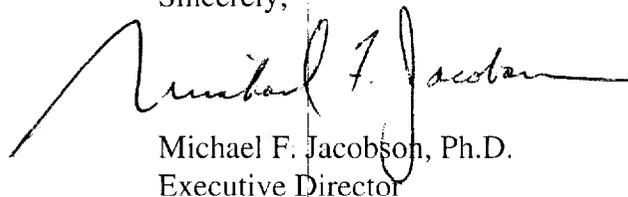
Docket 99P-4208

Dear Sir or Madam:

On September 27, 1999, CSPI submitted a petition to the FDA calling for better labeling of products that contain sorbitol and other sugar alcohols. That petition cited numerous studies and research reports. On November 2, 1999, we submitted letters from 35 people who suffered gas, abdominal pain, uncontrollable diarrhea and related gastrointestinal symptoms after consuming products containing sorbitol. Those letters -- in response to the brief article (enclosed) in the October 1999 issue of CSPI's *Nutrition Action Healthletter* -- demonstrate that sugar alcohols' causation of problems is not a theoretical matter, but one that affects a large number of consumers. I have enclosed letters from four more people who believe that they or a family member was affected by sorbitol or mannitol. Note that one of those individuals was affected by sorbitol in a prescription drug, indicating the need for CFSAN to work with FDA's Center for Drug Evaluation and Research to ensure that warning labels are provided on drugs, too.

We again urge the FDA to require better labeling as soon as possible to prevent unnecessary suffering in both children and adults.

Sincerely,



Michael F. Jacobson, Ph.D.
Executive Director

99P-4208

C 2

October 6, 1999

CSPI - Sorbitol
Suite 300
1875 Connecticut Ave. NW
Washington DC 20009

Dear CSPI:

I am responding to the article in Nutrition Action Health Letter, October, 1999.

I have experience the symptoms you described, though much more intense, including vomiting. I attributed the reaction to aspartame until I read the article. I had eaten a couple handfuls of Goelitz sugar free jelly beans, and within a few hours was experiencing severe bloating (so much so that I looked several months pregnant), and within 5 to 6 hours was having sharp cramping, explosive diarrhea, uncontrollable shaking, and projectile vomiting (and all at the same time). I have never been so sick.

I avoided any sugar free foods for some time, until I accidentally ate some sugar free TCBY (I think, maybe Columbo) soft serve frozen yogurt. One small cup produced a similar reaction, but fortunately without the vomiting.

I have a feeling these are reactions to Sorbitol. Please send me any information you have on Sorbitol/Mannitol reactions, and please include my experiences in your research if you wish.

Sincerely,



Grand Rapids, MI

November 6, 1999

CSPE – Sorbitol
Suite 300
1875 Connecticut Ave, N.W.
Washington, D.C. 20009

Dear Sir or Madam:

I am glad to hear that you are looking into expanding the warning labeling for sorbitol. I have been affected by sorbitol on at least three occasions.

I had a houseguest about a year ago who requested Kellogg's Frosted Mini-wheats for breakfast. I started eating them as well. I experienced the bloating and diarrhea you described in the article. I cut out caffeine and diet sodas, and increased fiber, by eating more Mini-wheats, to try to solve the problem. One day at the grocery store they displayed the Mini-wheats at eye level, and the label caught my eye. I noticed that the cereal contained sorbitol, which seemed surprising since they also contained sugar. I remembered sorbitol as being on a list of items to be avoided by people with bowel problems that I got from George Washington University Hospital. I cut out the Mini-wheats and my condition improved dramatically.

I had a similar experience with Edy's Light Gourmet Frozen Yogurt, coffee fudge flavor. I eventually noticed that the bloating and discomfort was associated with eating that product, and when I checked the label I found it contained sorbitol.

Finally, this past summer during a long hot spell I started buying Tropicana Juice bars – the low calorie version. I ate two or three a day for about a week and started experiencing bloating, urgency, and diarrhea. Since that was the only change in my eating habits around that time, I checked the package label and noted that sorbitol was listed. Again, the symptoms cleared up when I discontinued eating the product.

Because sorbitol is being added to so many foods, I think it is important that the warning be expanded, especially if you determine that many people have a sensitivity to it. I would really like to see a listing in Nutrition Action of common food products containing sorbitol so I can avoid them.

Please do not publish my name due to the personal nature of this information, but feel free to call if you want any additional information.


fue


Bethesda Md 20824

Nov. 30, 1999
Just read your article on Sorbitol.

I had problems with Sorbitol or Mannitol many times before I realized it was the Sorbitol. The stomach aches were awful and lots of diarrhea, bloating. Believe me, I purchase Nothing with it in! Being a diabetic I thought it would help. Noway!

Sincerely,
~~_____~~
~~_____~~
Harrisburg Pa. ~~_____~~

[REDACTED]
Philadelphia, PA [REDACTED]
February 1, 2000

CSPI - Sorbitol
Suite 300
1875 Connecticut Ave. N W
Washington, DC 20009

Dear Sir / Madam,

The October 1999 issue of Nutrition Action Health Letter invited letters from persons who have been affected by sorbitol.

Six years ago, when my daughter was just 11 months old, she had to take the medicine INH for tuberculosis. She had no symptoms of this disease, but had a positive skin test for tuberculosis. The dose of INH for a child of her weight was two teaspoons, which, I found out later, was mostly sorbitol. She started the dose on a Tuesday, and was completely healthy prior to the dose. On Wednesday, she was fighting me as soon as she smelled the medicine, and had diarrhea which smelled strongly of the medicine.

I was back in the Pediatrician's office on Thursday and told the doctor she didn't even want to eat. It was a horrible time, as it is critical to take this medicine without stopping. But the sorbitol was really making my child sick. The doctor was not convinced it was the medicine causing the diarrhea and lack of appetite, but put my child on the pill form of INH (no sorbitol). The diarrhea cleared up in two days and my child had no problems thereafter. She took INH for 1 year, with no diarrhea.

By chance, I found a neighbor whose child also took the sorbitol-laced medicine. She also had numerous problems with diarrhea and cramping.

The article states that the FDA should require a warning on food which contains less than 10 grams of sorbitol at a sitting. I would like to expand that to include a warning on medicine. Or eliminate sorbitol from medicine altogether. I was very, very fortunate that my daughter's doctor switched that medicine to one which did not contain sorbitol.

Sincerely,

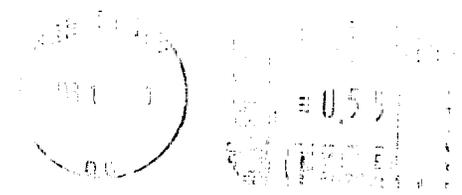
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