

April 16, 2002

Lester Crawford, D.V.M., Ph.D., Deputy Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Crawford:

Enclosed are 206 adverse-reaction reports that CSPI received between May 5, 2000 and January 31, 2002, from consumers who believe that they or family members were adversely affected by olestra (Attachments I and II). CSPI has now submitted a total of 2,893 reports.

These new reports are similar to those that CSPI (and Procter and Gamble) submitted previously. To submit a report to us, consumers had to work hard to find our web site and adverse-reaction clearinghouse, considering that we have not been publicizing them at all. That fact, plus the general lack of publicity in the mass media, lower product sales, and the dropping out of the marketplace of consumers who are sensitive to olestra, may account for the decreasing rate of reports received.

The adverse-reaction reports describe all kinds of gastrointestinal misery. Eighty percent of the victims reported one or more severe symptoms, usually after eating just an ounce or two of chips. Examples include (see also Attachment III):

- * Some people who suffered severe symptoms were hospitalized, had surgery for assumed hemorrhoids, fistula, gallstones, and colon disorders, and endured medical tests such as colonoscopy, X-Ray, MRI, blood chemistry tests, and stool cultures. The various tests were unable to identify any medical cause for the patients' symptoms and conditions.
- * Some people remarked on the large amount of time and money that was needed to investigate and resolve their symptoms. Others remarked that they may have suffered longer because they did not have the time or money to investigate what was wrong.
- * Some people said they had been trying to avoid olestra but ate the chips unknowingly at a party or a friend or relative's house. One man was particularly frustrated to have unknowingly eaten olestra-containing chips served to him at a restaurant.

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- * Numerous people were angry that they didn't notice the warning label, saying that it was too small and inconspicuous. Some people said that they would not have bought the chips if they had seen the warning label.
- * One woman was terribly embarrassed when she became incontinent while driving children in a car-pool and could not get off the road before her diarrhea began. Other people were incontinent or had symptoms while driving, shopping, dining at restaurants, exercising, or visiting friends or relatives' homes. One man said he fainted and threw up at a wedding where he was a groomsman after eating Fat Free Pringles chips
- * Many people experienced extreme pain, and several women compared it to labor pain in childbirth. Others said that the cramps made them feel like they were dying or made them unable to move. One woman was particularly frightened because she had difficulty breathing.
- * Several people expressed fear because of their conditions (particularly in response to prolonged diarrhea, severe cramping, and rectal bleeding), and because they did not know what to do or what was wrong with them. One woman who saw yellow-orange oil in her stools called Frito-Lay and was told such occurrences were "normal."
- * People reported having to leave work early or not go to work because they couldn't control their symptoms. A few people had to take sick leave in order to recover.
- * Some parents said their children had "accidents" after they ate olestra chips. One mother said her son soiled 4 sets of clothing in 3 hours, while another child lay sick in bed for a number of days. One 7-year-old boy could not eat anything for a week after having Lay's potato chips containing olestra.

The FDA's stock and glib response to CSPI's concerns has been the same as Procter and Gamble's: There is no proof that the symptoms reported were due to olestra. (Of course, there is no way that one *could* prove that olestra caused symptoms in any individual case.) But it must be the biggest coincidence in the world that just hours after eating olestra chips some people experienced fecal incontinence -- a highly unusual phenomenon for healthy people -- as well as other gastrointestinal symptoms that controlled studies proved olestra can cause and that the symptoms abated after the consumers stopped eating olestra snacks (and the symptoms sometimes recurred following another ingestion of olestra).

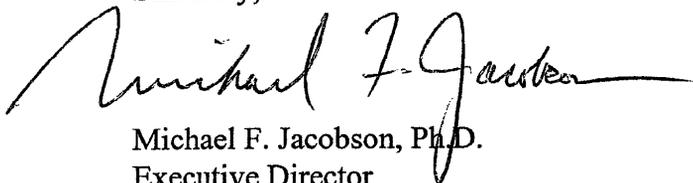
In addition to gastrointestinal symptoms, a few people reported experiencing hives after eating olestra products. The reaction might be due to olestra, a contaminant in olestra, another ingredient of the chips, or something else entirely. For the past several years, CSPI has urged the FDA to require Procter and Gamble to conduct challenge studies. Once again, we urge the FDA to do so.

Approximately 19,700 reports have now been submitted to the FDA by CSPI and Procter and Gamble. That is more than for all other food additives in history *combined*. As experts at health

agencies, such as the CDC, would attest and as a CSPI survey found, the number of reports submitted certainly represents only a small fraction of the number of people affected. In addition, we were surprised and dismayed to learn that over a year has passed since Procter and Gamble last sent a report to the FDA. We believe that is inconsistent with the company's January 24, 1996 agreement, and we urge the FDA to ask Procter and Gamble to submit all reports involving consumers who required medical care (and a summary of all other reports) since January, 2001.

We also urge you again to reject Procter and Gamble's and Frito-Lay's requests to delete the olestra label notice on packages of olestra-containing products. Indeed, we urge you to require a *prominent* warning label on the *fronts* of packages stating that olestra can cause *severe* diarrhea or cramps. Your action on this issue is essential to protect toddlers, children, adults, and seniors from the pain, harm, embarrassment, and inconvenience that olestra is continuing to cause.

Sincerely,

A handwritten signature in black ink, reading "Michael F. Jacobson". The signature is fluid and cursive, with a long horizontal stroke at the end.

Michael F. Jacobson, Ph.D.
Executive Director

cc: Joe Levitt, Alan Rulis, Mary Ditto, William Hubbard, Dockets Management

Attachment II

Center for Science in the Public Interest Olestra Adverse-reaction Reports Seventh Report to the FDA

Number of Reports: 206
Received between May 5, 2000 and January 31, 2002

1. Age

<10 years old	6 (3%)
10-19	16 (8%)
20-29	51 (25%)
30-39	60 (29%)
40-49	42 (20%)
50-59	21 (10%)
60-69	5 (2%)
70 and up	4 (2%)

2. Gender

Male	47 (23%)
Female	157 (77%)

3. Severe symptoms

Diarrhea	65 (32%)
Couldn't control bowels; soiled clothing	35 (16%)
Loose stools	48 (23%)
Nausca	19 (9%)
Fecal urgency	73 (35%)
Gas	79 (38%)
Bloating	51 (25%)
Cramps	93 (45%)
Vomiting	9 (5%)
Yellow-orange stains in underwear	21 (10%)
Greasy stools	44 (21%)
Oil in toilet	42 (20%)

4. One or more severe symptoms indicated 165 (80%)

5. History of gastrointestinal problems

Yes	36 (18%)
No	169 (82%)

6. Experienced safety problems 107 (52%)

Attachment III

Summaries of Adverse Reaction Reports of People who Consumed Olestra

#7-185 [10/29/01] A 50-year-old woman reported severe gas and cramps. She eliminated caffeine, chocolate, carbonated beverages, and more in an attempt to pinpoint the cause of her symptoms, to no avail. Finally, she discontinued eating Fat Free Pringles and all of her gastrointestinal symptoms disappeared. She was ready to go to the E.R. due to pain. She subsequently made an appointment with a GI doctor to have a colonoscopy.

#7-181 [9/28/01] A 37-year-old man reported simultaneous “violent” vomiting and “projectile” bowel movements approximately 14 hours after eating about one ounce of Wow potato chips. He became very dizzy and cold. His wife rushed him to the emergency room where his temperature registered only 92 degrees. He was diagnosed with hypothermia and was temporarily unconscious. He was given I.V. fluids and warm blankets.

#7-170 [8/26/01] A 31-year-old male reported severe vomiting and stomach cramps after eating 12 Original Fat Free Pringles chips. He fainted and threw up at a wedding in which he was a groomsman.

#7-169 [8/26/01] A 25-year-old woman reported severe cramping in her stomach, to the point where she could not stand up straight. She had eaten almost an ounce of Doritos Wow Nacho Cheesier chips. She described almost having a car accident due to stomach pain.

#7-152 [7/15/01] A 37-year-old woman reported severe diarrhea, fecal urgency, and abdominal cramps after eating Original and Sour Cream and Onion Fat Free Pringles. She was driving when the pain started and could not get off the road in time to get to the bathroom before the diarrhea began. She had 5 children in her van who were frightened.

#7-151 [7/13/01] A 32-year-old woman reported severe gas and abdominal cramping after consuming Fat Free Pringles. It occurred on her left side under her lungs and caused her to have difficulty taking deep breaths.

#7-149 [7/13/01] A 23-year-old woman reported severe loose stools, fecal urgency, gas, and cramps. She had been eating Tostitos with olestra for a couple of days and reported “not feeling well.” She attributed the symptoms to the chips when she had stools with yellow-orange oil in them and was concerned it was blood. She contacted Frito-Lay who informed her that this occurrence was “normal” and there was no need for alarm. She had to leave work due to the numerous symptoms.

#7-140 [6/20/01] A 32-year-old woman reported eating a few Wow Lays Regular potato chips and subsequently felt a tightening in her throat, thickness in her tongue, and difficulty swallowing. Her husband drove her to the emergency room where she was treated for an allergic reaction to Wow potato chips. This was the first allergic reaction to food she had ever

experienced; she continues to suffer from throat problems.

#7-119 [5/8/01] A 30-year-old woman reported severe diarrhea and pain on her right side after eating Wow potato chips. She was taken to the emergency room where she was checked for gallstones but was found to have none. She reported the pain to be so severe she could not care for her child. She continues to have occasional reoccurrences of pain.

#7-117 [4/25/01] A 26-year-old woman reported becoming extremely ill after consuming a handful of chips containing olestra. She was taken to the hospital and underwent emergency surgery to remove a portion of her colon.

#7-110 [4/25/01] A 44-year-old woman reported severe diarrhea, gas, bloating, and abdominal cramping subsequent to eating about 20 Fat Free Pringles. She experienced severe diarrhea for a week. She visited her doctor who scheduled her for a hemorrhoidectomy due to her anus having turned "inside out" from the irritation. She was also experiencing the beginnings of a fistula. During the procedure, a portion of her rectum was removed. She had internal hemorrhoids prior to eating the chips, but is certain the severe problems were directly related to them.

#7-86 [3/9/01] A 29-year-old woman reported severe abdominal pain after eating a bag of Ruffles Cheddar chips with olestra. She had to leave work due to the severity of the pain. During her two mile walk home, she felt she was going to vomit and pass out.

#7-77 [2/22/01] A mother reported that her 4-year-old son experienced vomiting, couldn't control his bowels, and soiled his clothing 12 hours after eating Lay's regular chips with olestra. She stated that he soiled 4 sets of clothing in 3 hours.

#7-55 [12/15/00] A 51-year-old woman reported severe gas and abdominal cramps after eating approximately 15 to 20 Lay's potato chips with olestra. She thought she was having a heart attack and went to the emergency room. The visit cost her \$410.00.

#7-53 [12/12/00] A 43-year-old woman reported severe diarrhea, gas, and abdominal cramping. She also soiled her clothing. She had been eating chips with olestra as part of her diet and had been experiencing pain and gas ever since she began.

#7-42 [10/10/00] A 54-year-old man reported severe diarrhea and abdominal cramps after eating Pringles containing olestra. He had eaten them over a 16-day period but the symptoms did not subside for over a month after discontinuing them. He visited the emergency room when the pain became severe and was forced to take sick-leave from work.

#7-19 [8/22/00] A mother reported that her 7-year-old son had severe nausea, gas, abdominal cramps, and fecal urgency after eating Pringles and Lay's potato chips containing olestra. Additionally, she reported he was unable to eat anything for a week.

CSPI

Center for
Science in the
Public
Interest

Publisher of *Nutrition Action Healthletter*

May 1, 2002

Jennie C. Butler, Chief
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20857

Dear Ms. Butler:

Enclosed please find CSPI's submission to Docket No. 98P-0418. I appreciate your returning the reports so that the personal information could be appropriately concealed.

Thank you for your time and assistance. Should you have any questions, please contact me at 202-777-8328.

Regards,



Marisa Hebble
Executive Research Associate

