January 4, 2006

Andrew C. von Eschenbach, M.D., Acting Commissioner
U.S. Food and Drug Administration
5600 Fishers Lane, Room 14-71
Rockville, MD 20857

Re: Docket No. 87F-0179

Dear Dr. von Eschenbach:

This is CSPI's 10th report to the FDA of adverse reactions to the food additive olestra. This report includes 396 adverse-reaction reports that CSPI received between October 19, 2004 and December 20, 2005, from consumers who believe that they or family members were adversely affected by olestra (Attachment I). CSPI has now submitted a total of 3,753 reports.

These new reports are similar to those that CSPI (and Procter and Gamble) submitted previously. To submit a report to CSPI, consumers have to recognize that olestra may have caused their symptoms and then work hard to find our web site and olestra adverse-reaction clearinghouse (assuming they have a computer and Internet access), which we have not been actively publicizing. Notwithstanding these barriers, we continue to receive a steady stream of complaints, despite the absence of media publicity and a warning notice on labels.

The adverse-reaction reports continue to reflect all kinds of gastrointestinal misery. Most of the victims reported severe symptoms after eating just an ounce or two of chips. Forty-one of the 396 victims sought medical attention, including 13 who went to the emergency room. Please see Attachment II for summaries of some of the victims' experiences.

The most recent report (December 20, 2005), from a Montana truck driver, indicates the potential for disaster if a person suffers adverse effects while driving or engaging in other dangerous activity. An hour after eating Original Fat Free Pringles with olestra, the 42-year-old man, who was driving a tractor-trailer truck full of mail, became severely nauseous. In freezing cold weather, he started to faint while he was falling out of the truck, and then he vomited profusely. After resting for a couple of hours, he climbed back into his truck and drove for a while until he experienced another wave of vomiting.

That happened once more. It took two days for him to recover. The man says, "This whole ordeal put me in great danger driving a heavy truck on icy mountainous roads."

He not only got sick himself, but he endangered other motorists and delayed delivery of his load of mail.

The well over 20,000 reports that have now been submitted to the FDA by CSPI and Procter and Gamble constitute more reports than for all other food additives in history combined. Still, one can be confident that the number of reports submitted represents only a small fraction of the number of people affected by olestra. In addition, Procter and Gamble is no longer sending reports to the FDA. We urge the FDA to ask Procter and Gamble to submit all reports from consumers who required medical care (and a summary of all other reports) since January 2001. Even if the FDA is unconcerned that a food additive that it has approved causes adverse reactions, at the very least, as a health agency, it should track the number and kinds of reactions.

We urge the FDA once again to reinstate the olestra warning notice on packages of olestra-containing products. The need for a warning is stronger than before, since Frito-Lay changed the brand name for its olestra-based products from "WOW" to "Light" chips last year. Consumers who were trying to avoid olestra by avoiding WOW products are unwittingly buying Light chips and sometimes getting sick. We understand that sales of Light chips are significantly greater than the WOW chips. Consistent with that, CSPI has been receiving more adverse-reaction reports: 114 reports between March 1 and August 31, 2004, compared to 194 reports between March 1 and August 31, 2005.

FDA should require a prominent warning label on the fronts of packages stating that olestra can cause severe diarrhea or cramps. 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. Many consumers have undergone unnecessary pain and medical expenses because the label did not help them track down the cause of their symptoms.

Sincerely,

Michael F. Jacobson, Ph.D.
Executive Director

cc: Robert Brackett, Laura Tarantino, Alan Rulis, Mary Ditto, Dockets Management
(Attachment I is being sent only to Dockets Management.)

Attachment II
Summaries of Selected Adverse Reaction Reports Related to Olestra
10th Center for Science in the Public Interest Report to the FDA

#10-19 [11/5/04] A 48-year-old woman sought medical attention for severe abdominal pains after consuming olestra.

#10-26 [11/08/04] A 14-year-old girl had severe abdominal cramps after consuming olestra.

#10-45 [12/4/04] A 25-year-old man had severe abdominal cramping, diarrhea, and vomiting after eating chips made with olestra.

#10-51 [12/5/04] A 24-year-old woman driving a car was forced to pull off the road suddenly while trying to find a restroom after eating olestra.

#10-81 [12/9/04] A 3-year-old girl developed severe diarrhea lasting ten hours after eating chips containing olestra.

#10-103 [2/2/05] A 44-year-old woman sought medical attention for abdominal cramps, flatulence, and fecal urgency after eating olestra.

#10-121 [2/22/05] A 66-year-old man felt dizzy, vomited repeatedly after eating olestra, and went to the emergency room.

#10-126 [2/27/05] A 55-year-old man suffered shortness of breath due to gas after eating chips containing olestra.

#10-141 [3/11/05] A 38-year-old woman and her 6-year-old son had extreme flatulence after consuming olestra.

#10-143 [3/5/05] A 73-year-old man went to the emergency room for treatment of severe abdominal cramps after eating olestra.

#10-145 [3/18/05] A 36-year-old woman sought medical attention for severe abdominal pains that lasted more than two weeks after consuming olestra.

#10-164 [4/12/05] A 22-year-old pregnant woman went to the emergency room after ingesting olestra. Doctors initially feared she was having a miscarriage.

#10-172 [4/17/05] A 54-year-old woman suffered from severe abdominal and lower back pain, along with loose and greasy stools, after consuming chips containing olestra.

#10-178 [4/18/05] A 37-year-old woman was given six bags of intravenous fluids in the emergency room after suffering vomiting and diarrhea for two days. The symptoms began after she ate a product containing olestra.

#10-196 [5/6/05] A 29-year-old woman experienced dizziness and severe cramping after eating a product containing olestra.

#10-213 [5/16/05] A 27-year-old woman who was 11 weeks pregnant sought medical attention after eating chips that contained olestra. She had severe abdominal cramps.

#10-219 [5/24/05] A 32-year-old woman underwent a battery of tests by two doctors to determine the source of her nausea, flatulence, and stomach cramps after regularly consuming chips made with olestra. She continues to have digestive problem s a year later.

#10-234 [6/4/2005] A 51-year-old woman was taken to the emergency room by ambulance for severe stomach pains after eating olestra. Her husband was also ill.

#10-282 [7/10/05] Seven- and ten-year-old siblings experienced severe stomach pains, greasy stools, and vomiting after eating chips containing olestra.

#10-396 [12/20/05] A 42-year-old man suddenly became nauseous, blacked out, then vomited profusely after consuming chips made with olestra.