



Frito-Lay, Inc.

Al Bru
President and Chief Executive Officer.
Frito-Lay North America

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December 21, 1999

Jane Henney, M.D.
Commissioner of Food and Drugs (HF-1)
Room 14-71
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857-1706

Dear Commissioner Henney:

Frito-Lay, Inc., the world's largest producer of snack foods and the marketer of WOW! made with olestra, has a direct and substantial interest in the terms and conditions of olestra's approval for use. We, therefore, are enclosing for your consideration a comprehensive position paper setting forth the basis for Frito-Lay's strongly held belief that the mandatory label statement on products made with olestra (i.e., This product contains olestra. Olestra may cause abdominal cramping and loose stools. . . ") should be eliminated.

The position paper is based on the fundamental statutory requirement that all food labels be "truthful and not misleading." The required label statement does not meet that criterion. Indeed, the label statement is false, and by requiring manufacturers such as Frito-Lay to place the statement on its products, the FDA causes the products to be misbranded - a consequence that the FDA surely did not intend and must not countenance.

It has been almost four years since the FDA mandated the appearance of the information statement on all packages of snack foods made with olestra. The scientific data collected since the approval of olestra in 1996 demonstrate that the required label statement is not supported by science. The available evidence, discussed in detail in the enclosed paper, shows that consumption of snack foods made with olestra causes no significant gastrointestinal effects of any kind. Nevertheless, the required label statement tells consumers that it does and, to date, FDA has taken no action to eliminate it.

In addition to giving consumers false information, the required label statement misleads them. Although the label attempts to convey certain information about the addition of vitamins to products made with olestra, and the reasons for that addition, that information is widely misunderstood by consumers. Moreover, the simple presence of the required information statement on food labels leads consumers to believe erroneously that olestra products are unsafe, even though the FDA has determined olestra to be a safe food additive.

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Frito-Lay wants to ensure that consumers know that our WOW! Brand snack products are made with olestra. We feel that both the burst on the front of the bag that states "Made with Olean® Brand Fat-Free Cooking Oil" and the declaration of olestra in the required Ingredient Statement provides the consumer with that information. Frito-Lay feels that it is important for consumers to have a choice, and we want to make sure that those consumers who choose to reduce fat in their diet can easily identify our WOW! Brand products.

Frito-Lay shares your publicly espoused view that government-mandated labeling statements for foods should be based on science. A food labeling system based on sound science is not only prudent domestic policy, it is, as you know, at the heart of U.S. objections to labeling schemes being put forward by the European Union and others with respect to biotech foods. Abandoning a science-based policy at home, accordingly, could have tremendous ramifications for U.S. trade relations internationally. To continue to require the olestra information statement in the face of overwhelming scientific evidence that consumption of olestra results in no significant gastrointestinal effects undermines the integrity of our science-based system and threatens U.S. credibility abroad. The fact that this scientific evidence has been fully known and available to FDA for well over a year, yet no action has been taken, raises questions about the Agency's commitment to science-based regulation.

Information provided to the consumer on the food label should be "truthful and not misleading." It is, therefore, essential that the requirement for the olestra information statement, established by FDA in January, 1996 as an "interim" requirement, be removed immediately. Frito-Lay urges the Agency to take immediate action to accomplish this result by amending its food additive regulation for olestra to eliminate the false and misleading interim label statements.

We appreciate your consideration of our attached position document. If you have any questions, please don't hesitate to call us.

Sincerely,



Al Bru
President and Chief Executive Officer
Frito-Lay North America

Copies to:

Mr. Joe Levitt, Director, Center for Food Safety and Applied Nutrition

Dr. Alan Rulis, Director, Office of Premarket Approval, Center for Food Safety and Applied Nutrition

**JUSTIFICATION FOR THE
IMMEDIATE AMENDMENT OF THE
OLESTRA INFORMATION STATEMENT**

Submitted by Frito-Lay, Inc.

December 21, 1999

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I. BACKGROUND

A. Rulemaking History

In 1987, the Procter & Gamble Company (P&G) filed a petition with the Agency seeking approval for use of olestra in savory snacks. FDA's Food Advisory Committee (FAC) met in November 1995 to review the petition and concluded that olestra's use in savory snacks presents a "reasonable certainty of no harm." Following a public comment period, FDA approved olestra for use in savory snacks. 1/ The Agency concluded that olestra is safe for consumption; however, it required that snack foods made with olestra bear the following statement set off in a box, either on the principal display panel or the information panel of the label:

This product contains olestra. Olestra may cause abdominal cramping and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E, and K have been added.

This information statement was intended to advise consumers about potential GI effects associated with olestra consumption and to inform them that vitamins A, D, E, and K are added to compensate for olestra's ability to prevent the absorption of these lipophilic vitamins and other nutrients. FDA characterized the information statement as an "interim" labeling requirement and pledged to submit to the FAC, within 30 months of olestra's approval, all post-market surveillance data, as well as any additional safety information it received. FAC conducted this 30-month review on June 15-17, 1998.

B. FAC Conclusions

The data presented to the FAC, and discussed more fully below, were extensive. P&G submitted the results of four placebo-controlled, double-blind studies designed to assess olestra's GI effects. All four showed no meaningful GI impact, even among people choosing to eat large amounts of snack foods made with olestra. The FAC also considered several studies of consumers' perceptions with respect to the mandated information statement. Those studies revealed a failure by consumers to understand the message that the information statement is intended to convey. In fact, many consumers took away an entirely inaccurate message from the label statement.

Following its consideration of this information, a majority of the FAC members concluded that snack foods made with olestra: 1) were not a significant source of gastrointestinal effects, and 2) did not significantly alter the absorption of lipophilic vitamins and carotenoids. Fourteen of the 17 committee members expressed the view that, in light of the new data and information presented, the information statement should be changed in some way.

1/ 61 Fed. Reg. 3117 (January 30, 1996).

II. FRITO-LAY'S CONSUMER PERCEPTION DATA DEMONSTRATE THAT CONSUMERS FAIL TO UNDERSTAND THE INFORMATION STATEMENT AND CONSEQUENTLY HAVE A FALSE UNDERSTANDING OF OLESTRA AND ITS EFFECTS

As the largest producer of snack foods made with olestra in the world, Frito-Lay is in a unique position to collect information with respect to consumers' experiences with snack foods made with olestra. As part of its monitoring efforts in this regard, Frito-Lay has conducted two consumer perception studies with respect to the olestra information statement. The first study took place in February and March, 1996, shortly after FDA's approval of olestra, and involved two phases and a total of 457 participants (hereinafter Study I; phase 1 [n = 229] and phase 2 [n = 228]). The second study took place in January and February, 1999 and involved a total of 233 respondents (hereinafter Study II). 2/

A. Consumer Uncertainty about the Safety of Olestra is Exacerbated by the Information Statement

In Study I, a total of 457 respondents (prequalified as savory snack eaters) were shown the information statement and asked "Based on this label, do you believe products containing olestra are safe?" Although FDA has concluded that olestra is safe for consumption, and the information statement is intended to provide consumers with additional information, the results of Study I clearly show that the majority of consumers did not conclude olestra was safe to eat. Specifically, only 15% of the participants concluded that snack foods made with olestra were safe, 21% characterized olestra as unsafe, and the majority -- 64% -- described themselves as uncertain.

Moreover, the results of the second phase of Study I -- designed to compare respondents perceptions with respect to olestra before and after viewing the information statement -- demonstrated that the information statement exacerbates rather than improves consumers' faulty impression that snack foods made with olestra are not safe. In that phase, 229 respondents were asked to characterize the safety of olestra before and after viewing the information statement. Before viewing, 49 participants characterized olestra as safe and 18 as unsafe, while 162 were uncertain. After viewing the label, the number of those characterizing olestra as safe fell to 36 and those characterizing it as unsafe rose to 55. The majority (138) remained uncertain.

The accuracy of consumers' impressions with respect to the safety of olestra has not improved in the almost four years since olestra was approved. In Study II, 233 participants were shown the same background information as in the 1996 study and asked if they thought a product made with olestra is safe, unsafe, or whether they are uncertain. Before seeing the information statement, 64% (i.e., 149) were uncertain and 6% (i.e., 15) characterized olestra as unsafe. After seeing the information statement, however, the number of participants that described olestra as

2/ In response to a request by FDA staff, Frito-Lay has submitted a summary of the results of Study II to FDA's docket on olestra (i.e., Docket No. 87F-0179).

unsafe more than doubled to 16% (i.e., 37). An analysis of this data revealed that the information statement had the greatest impact on consumers that initially believed snack foods made with olestra were safe. Nineteen migrated away from this perception after viewing the information statement. Twenty participants who initially were uncertain about olestra's safety migrated to the unsafe group after seeing the label. Notably, not even one participant that initially characterized olestra as unsafe changed their position after reviewing the information statement.

B. The Information Statement Causes Consumers to Believe Incorrectly that Olestra Causes Frequent GI Effects

The information statement does not indicate the frequency with which olestra can be expected to have GI effects, only that such results "may" occur. Even if that indication were accurate (which, for the reasons discussed more fully below in Section III, it is not), the information statement nevertheless leaves consumers with the false impression that olestra causes frequent GI effects. In Study II, after reading the information statement, more than 25% of the participants stated that they believed they would experience GI effects 20-50% of the time they ate products made with olestra. That percentage was actually slightly higher than in the 1996 study (i.e., 22%).

Perhaps even more significant, however, are the potential effects of this misunderstanding. The majority of consumers in Frito-Lay's consumer perception studies (55% in 1996 and 58% in 1999) stated that they would delay seeking medical attention if they experienced GI effects after eating products made with olestra. Thus, as noted by Dr. Brandt at the 1998 FAC meeting, the information statement could actually be preventing consumers from seeking necessary medical attention for serious GI effects because they erroneously attribute GI symptoms to consumption of snack foods made with olestra. 3/

C. The Information Statement Fails to Convey Clearly to Consumers Olestra's Relationship with Lipophilic Vitamins and Other Nutrients

Participants' responses in Study I revealed that the information statement also caused a great deal of confusion among consumers with respect to olestra's impact on nutrient absorption. Study II confirms that the confusion has not been resolved since snack foods made with olestra have been available nationally.

In Study I, participants in both phases were asked, after seeing the information statement, whether vitamins and nutrients other than A, D, E, and K are affected by olestra. Of the 459 participants, 56% said yes; 44% said no. The results in Study II were virtually the same. An approximately equal distribution of the 233 participants responding concluded that olestra does (53%) or does not (47%) affect the absorption of "other nutrients." Thus, despite the information statement's seemingly direct, uncomplicated indication that olestra **does** affect absorption of "other

3/ Brandt, Food Advisory Committee Meeting Transcript, Day Three, p. 138 (June 1998).

nutrients," almost half believed olestra has no effect. The 50:50 breakdown in responses implies that the study participants were guessing.

Perhaps of even greater concern, however, is the perverse message the information statement seems to be conveying to consumers with respect to Vitamin A, D, E, and K levels. The 459 participants in Study I were asked how snack foods made with olestra affect the level of vitamins A, D, E, and K in the body. The vast majority (69%) responded that olestra decreases the levels of these vitamins, despite the notification in the information statement that vitamins A, D, E, and K are added. Study II produced virtually identical results. After reading the information statement, only 24% of participants concluded that snack foods made with olestra have no effect on the levels of vitamins A, D, E, and K in the body.

D. The Results of Consumer Perception Studies Conducted by P&G Are Consistent with Frito-Lay's Research

P&G's research with respect to consumers' understanding of the interim information statement underscores the conclusions from the studies conducted by Frito-Lay. P&G conducted two studies, involving more than 2,000 participants from 30 geographically diverse sites. Participants were shown the information statement and then responded to questions about the perception of safety invoked by the message. As in the Frito-Lay studies, the message did not convey a perception of safety. Although FDA has determined that olestra is safe for use in savory snacks, 61% of the participants described olestra as unsafe, and 40% said that the information statement was the government's way of advising them to avoid the product.

Other wholly erroneous impressions were evident as well. For example, when asked what would happen to the levels of vitamins A, D, E & K in the body after eating snack foods made with olestra, 43% responded that the levels would change. This response - also consistent with the responses Frito-Lay received to similar questions - is flatly at odds with the intent of the statement in the information statement that, because olestra inhibits the absorption of these nutrients, vitamins A, D, E, and K have been added to compensate. Although this statement may have been intended to convey material information, it clearly is not serving the purpose for which it was intended. In fact, it is confusing and misleading consumers.

P&G's study also revealed a misunderstanding among consumers with respect to olestra's GI effects. After viewing the information statement, consumers expressed the incorrect belief that olestra consumption would frequently result in GI changes. For example, eighty-three percent of 314 consumers asked about the likely cause of symptoms they experience while eating snacks made with olestra stated that they would attribute abdominal cramping or loose stools to olestra. Of this same group, substantial numbers would attribute very serious GI symptoms to olestra (i.e., 50% severe diarrhea; 25% vomiting), despite the fact that the information statement is devoid of any such suggestion and there is no scientific data to support that type of cause and effect relationship.

Smaller focus groups conducted by P&G as an adjunct to the larger consumer studies suggest a possible reason for consumers' evident tendency to

misattribute serious GI effects to olestra. Because other foods that are associated with GI changes bear no label statements to that effect (e.g., beans), the presence of a GI statement on snack foods made with olestra suggests olestra's GI effects are different and more severe. The scientific data, discussed more fully below, demonstrate that this simply is not the case.

III. GIVEN EXISTING SCIENTIFIC DATA, THE INFORMATION STATEMENT CONVEYS FALSE AND MISLEADING INFORMATION ABOUT OLESTRA AND THE PRODUCTS IN WHICH IT IS USED

A. Available Scientific Data Demonstrate No Relationship Between Olestra Consumption and Significant GI Effects

Since olestra's approval in January 1996, P&G has conducted four controlled clinical studies designed to assess the effects of olestra consumption on GI symptoms. These studies were submitted to the FAC at its June 1998 meeting. None of these studies reveals a relationship between olestra and significant GI effects of any kind.

The first study analyzed stool composition to determine olestra's impact on stool frequency, total daily stool output, and stool water and electrolyte content, clinically measurable indicators of diarrhea. The study was conducted on a double-blind basis and employed a placebo group, as well as a positive control (i.e., consumption of sorbitol-containing candy). Sixty-six subjects were tested for a total of 12 days. The results of the first six days established baseline data, the following six days constituted the treatment period.

Olestra is inert and passes from the body without being digested. Not surprisingly, therefore, the results of the study showed an increase in stool weight proportional to the amount of olestra consumed. The study also showed a dose-dependent softening of stools in those participants who consumed olestra and an increase in the number of bowel movements (1 1/4 vs. 2/day) for those in the group consuming the larger amount of snack foods made with olestra. Minimal increases in stool water were observed (2 teaspoons/day in the 20g/day olestra group and about 2.5 teaspoons/day in the 40 g/day group). However, there were no clinically meaningful increases in objective measures of diarrhea (i.e., total stool output, bowel movement frequency, stool water, electrolyte output) in the olestra group. Significant changes (indicative of clinical diarrhea) in all four measures of stool quality were observed in the sorbitol control group.

The data from the stool composition study were evaluated by Dr. Hugh Gallo-Torres, FDA Division of Gastrointestinal and Coagulation Drug Products, Center for Drug Evaluation and Research. Dr. Gallo-Torres offered the following assessment of the data, presented at the FAC meeting by Dr. Ken Falci: "My overall conclusion is that these changes are not clinically significant." ^{4/}

^{4/} Dr. Ken Falci for Hugh Gallo-Torres, Food Advisory Committee Meeting Transcript, Day One, pp. 276-280 (June 1998).

The second study was a double-blind, placebo-controlled test involving 1,092 consumers (a.k.a. the theater test). Since snack foods made with olestra have become commercially available, the majority of consumers who have reported GI changes to P&G, Frito-Lay, and the Center for Science in the Public Interest have reported experiencing those changes after eating an olestra product on only one occasion. The theater test attempted to replicate these anecdotal reports. Participants were permitted to eat up to 13 ounces of unlabeled potato chips made with olestra or vegetable oil while watching a movie in a theater. 5/

The results of the study showed no significant differences in the incidence of GI symptoms in the group of participants that ate potato chips made with vegetable oil compared to the group that ate chips made with olestra. In fact, a higher percentage of those eating potato chips made with vegetable oil reported GI changes than those who ate the olestra product. The data from the theater study have been evaluated by the Food and Drug Administration. Dr. Patrick McCarthy considered the data and concluded that "the results did not show a significant difference in reported symptoms between (olestra and vegetable oil) groups." 6/

The third study, also double-blind and placebo-controlled, lasted six weeks. The greater length was designed to evaluate the effects of olestra consumption in the home. It involved 3,181 participants, ages 2-89, who were given up to eight free bags of chips per household per week and told to record their consumption and GI effects every day for the full six weeks of the study. 7/ The overall rate of self-reported GI changes did not differ between the two groups. Likewise, there were no differences between the two groups with respect to the percentage of subjects reporting the two specific GI effects highlighted in the information statement (loose stools and abdominal cramping).

The only difference between olestra and vegetable oil panelists was that the olestra group reported more days in which they experienced more frequent bowel movements. The difference, however, amounted to only about one additional symptom day over the course of the six-week study for the heaviest olestra eaters. Further analysis showed some minor increases in days of report of loose stools, gas, and more frequent bowel movements in adult men and women, primarily at higher intake levels. The increase was only about one symptom day for the duration of the 42-day study. Importantly, participants' reports revealed no difference between the olestra and

5/ Cheskin, Miday, Zorich, and Filloon, "Gastrointestinal symptoms following consumption of olestra or regular triglyceride potato chips: a controlled comparison," *Journal of the American Medical Association* 279:325-327 (1998). The average participant ate approximately 2 ounces of chips.

6/ Dr. Patrick McCarthy, Food Advisory Committee Meeting Transcript, Day One, pp. 287-290 (June 1998).

7/ This resulted in olestra consumption levels approximately six times higher than those observed in the real world.

vegetable oil chip groups with respect to the impact of GI effects on their daily activities. 8/

The fourth study, also double-blind and placebo-controlled, was a rechallenge study designed to determine if those people who have reported GI changes to olestra snack food producers are uniquely sensitive to olestra. Ninety-eight people who had previously reported GI symptoms were recruited. The participants consumed two ounces of potato chips cooked either in olestra or vegetable oil once a week for four weeks (i.e., each participant ate potato chips made with olestra twice and chips made with vegetable oil twice). Interestingly, participants in this re-challenge study reported a higher incidence of GI changes than in the background study (described below). However, no differences were noted between the olestra and vegetable oil potato chip groups in frequency, severity, time to onset or duration of any reported GI changes. None of the symptoms reported by those consuming olestra chips was described as "severe" by the participants.

The results of this study have also been evaluated by FDA scientists. Dr. Karl Klontz evaluated the data and concluded that "there was no difference in the incidence of reported GI symptoms following Olean chip versus full-fat chip consumption." 9/ These results demonstrate that those who report GI changes after eating snack foods made with olestra are not uniquely sensitive to olestra. 10/

B. Anecdotal Post-Market Consumer Reports of GI Changes Do Not Provide Reliable or Meaningful Information with Regard to Olestra's Impact on the GI System

Critics of olestra have often cited consumer reports of GI effects as evidence of olestra's deleterious impact on human health. In addition to the extensive scientific data discussed above, a number of other factors undermine the reliability of the consumer reports.

First, there has been a marked decline in the rate of consumer reported GI changes the longer olestra has been on the market. While sales have remained strong, the total number of consumer reported GI changes has dropped suggesting

8/ Sandler, Zorich, Filloon, Wiseman, Lietz, Brock, Royer, and Miday "Gastrointestinal symptoms in 3181 volunteers ingesting snack foods containing olestra or triglycerides -- A 6 week randomized, placebo-controlled trial," *Annals of Internal Medicine* 130:253-261 (1999).

9/ Dr. Karl Klontz, Food Advisory Committee Meeting Transcript, Day One, pp. 280-287 (June 1998).

10/ Zorich, Biedermann, Riccardin, Bishop, and Filloon, "Randomized, double-blind, placebo-controlled, consumer rechallenge test of Olean salted snacks," *Regulatory Pharmacology and Toxicology* 26:200-209 (1997) (reporting results for first 57 subjects); Zorich, Biedermann, Riccardin, Bishop, and Filloon, "Follow-up to the study: Randomized, double-blind, placebo-controlled, consumer rechallenge test of Olean salted snacks," *Regulatory Pharmacology and Toxicology* 27:2 (1998).

that factors other than physiological changes attributable to olestra have played a large role in consumer reports to Frito-Lay and others. Following FDA's approval of olestra, Frito-Lay conducted a one year test market of olestra snack foods in Indiana. During that test market, Frito-Lay sold more than 2.5 million bags of snack foods made with olestra. The company received eighty-three percent of all reports of GI changes within the first 11 weeks, when media attention was high. During the remainder of the test market, the rate of GI reports dropped, significantly. For the last half of that test market, Frito-Lay received an average of less than one call per week reporting GI changes, yet sales and distribution of the product remained steady.

The number of consumer reports since Frito-Lay's snack foods made with olestra have become nationally available is consistent with this general downward trend in the rate of reporting. Since the national launch of the WOW!TM product line, the ratio of complaints to sales is four times lower than in the test market. There are approximately 10 product compliments for every complaint.

Second, scientific data indicate that there is a high rate of background GI effects in the general population. Professor Robert Sandler M.D. (Center for Gastrointestinal Biology and Disease, University of North Carolina) and co-workers conducted a study to establish a baseline of GI symptoms before olestra chips were available on a nationwide basis. Of the individuals contacted, 40% stated that they had at least one GI symptom within the last month; 21-24% within the last day. Of those that reported pain or bloating, 70% identified the symptoms as moderate to severe in intensity. For those reporting diarrhea, 90% described the effects as moderate to severe. Fifteen percent stated that their daily activities were decreased by half when they had these symptoms, 9-19% stated that they consulted their physicians, and 40-60% took medications for these symptoms.

These data demonstrate that consumers experiencing common GI effects often describe the symptoms they experience as severe. It also suggests that the GI effects that some consumers report experiencing after consuming snack foods made with olestra may simply be a coincidence, attributable to unknown causes. The rechallenge study conducted by P&G, described above, strongly supports that hypothesis.

Finally, and perhaps most significantly, analyses of post-market consumer reports of GI effects have revealed no reliable link with olestra consumption. P&G established an external panel of five physicians to analyze all GI consumer reports received by the manufacturers of snack foods made with olestra (i.e., Frito-Lay, P&G, and Nabisco). For persons seeking medical attention for their symptoms, the panel assessed the plausibility of events being associated with olestra by evaluating the timing of the event, disappearance of symptoms, biologic plausibility, and, when applicable, the results of rechallenge.

The physician panel found no trend toward increased reporting of incidence or severity of GI effects with increased consumption and no differences by age or gender. In summary, Dr. Sandler stated at the 1998 FAC meeting that the "vast majority of reports are likely to be measuring the background rate of digestive

effects and not symptoms that are caused by olestra." 11/ Moreover, a reproducible pattern of consumer reports has been noted. Specifically, when olestra snacks were introduced, increased media attention corresponded to increased numbers of gastrointestinal reports by consumers. As media attention decreased, so did the reporting rate.

C. The Information Statement Provides Consumers with Erroneous Information with Respect to Olestra's GI Effects

The scientific data submitted by P&G demonstrate that consumption of snack foods made with olestra does not cause significant or serious GI effects. The reference in the information statement to gastrointestinal symptoms, therefore, misinforms consumers. The statement also misleads consumers because it inaccurately suggests olestra leads to frequent GI changes. Although, as discussed earlier, daily consumption of large amounts of snack foods made with olestra may increase the frequency of bowel movements and cause other minor GI changes (e.g., gas, softer stools), the absolute difference in symptom days between the control and olestra groups amounted to only one day over the course of six weeks. The information statement, however, suggests that consumers can expect GI symptoms attributable to olestra as a matter of course. For the average consumer, and for the high end consumer as well, this is simply at odds with the evidence.

In light of these considerations, Frito-Lay believes that the presently required on-package reference to GI changes is unnecessary and leads consumers to attribute incorrectly any GI changes they experience to olestra. In doing so, the current information statement may have the effect of persuading persons who are experiencing significant GI symptoms, for which medical treatment is indicated, to forego that treatment, believing olestra to be the cause of their symptoms. 12/

D. P&G Expert Panel

Earlier this year, P&G convened a panel of five distinguished experts in science, public health, and food law to review existing research with respect to olestra, particularly those studies that have been conducted since olestra's approval for use in January, 1996.13/ The expert panel also reviewed the transcript of FAC's June 1998 meeting concerning olestra. In June 1999, the panel met to consider whether the required information statement is consistent with available scientific evidence and should be maintained.

11/ Sandler, Food Advisory Committee Meeting Transcript, Day One, pp. 145-167 (June 1998).

12/ See Brandt, Food Advisory Committee Meeting Transcript, Day Three, p. 138 (June 1998).

13/ The panel members were Sanford A. Miller, Ph.D. (chair); Johanna T. Dwyer, D.Sc. R.D., Joanne R. Lupton, Ph.D., Richard A. Merrill, Esq., Michael W. Pariza, Ph.D.

The panel unanimously concluded, *inter alia*, that the "totality of the scientific evidence now available does not support retaining the current interim label for foods containing olestra." The panel recommended that the information statement be eliminated. To notify consumers of the addition of vitamins A, D, E, and K to snack foods made with olestra, the panel recommended that the ingredient list include an asterisk that is keyed to a statement that the food is "not a nutritionally significant source" of these vitamins.

IV. EACH INDIVIDUAL ELEMENT OF THE INFORMATION STATEMENT IS UNNECESSARY, INACCURATE OR MISLEADING AND SHOULD BE ELIMINATED

In light of the results of the consumer perception studies and the scientific data with respect to GI and other effects, Frito-Lay strongly believes the information statement is inaccurate and misleading and should be eliminated entirely as a labeling requirement for snack foods made with olestra. A brief discussion of each of the components of the currently mandated statement, and the specific reasons for removal, follows.

A. "This product contains olestra."

This statement is repetitive and unnecessary and, consequently, has no value for consumers. The presence of olestra in a savory snack product is apparent based on its listing in the ingredient statement. In addition, P&G, the makers of olestra (under the brand name Olean®) require that snack foods made with olestra bear the following logo on the front panel: "Olean® brand Fat-Free Cooking Oil". Moreover, given the higher price manufacturers pay for olestra relative to other cooking oils, manufacturers simply have no rational business reason not to highlight for consumers the presence of olestra. For all of these reasons, consumers are well aware of the presence of olestra in snack foods whenever it is used; no additional label statement is necessary.

B. "Olestra may cause abdominal cramping and loose stools."

This statement is inconsistent with the totality of available scientific data. As discussed above in Section III.A. of this position paper, the most recent available data -- four double-blind, placebo-controlled studies -- show no relationship between consumption of snack foods made with olestra and abdominal cramping. The only observed changes were stool softening, and a modest increase in the frequency of bowel movements, gas, and looser stools among some users from the group consuming the greatest amount of snack foods made with olestra for six weeks. Notably, however, the study participants reporting this effect did not characterize it as significant, stating that it would not interfere with daily activities. Under customary conditions of use, therefore, no association between consumption of snack foods made with olestra and significant GI effects has been demonstrated.

Not only is the label inaccurate with respect to olestra's GI effects, as a result of its inconsistency with available scientific evidence, it has the potential to persuade consumers who are suffering from medically significant GI symptoms to attribute them to olestra rather than seek medical attention. Dr. Brandt, Chairman of the FAC, recently reiterated his concern in this regard:

With respect to the label, I have to express the same concern I expressed in '95. I think the label is much too strong. I think it prevents people who may have significant gastrointestinal illness from seeking medical help and evaluation. I think the testimony we heard from several people, consumers, certainly suggests to me that they have something that can't be explained by simple consumption of olestra and yet this label suggests to them that that is the explanation. 14/

Frito-Lay's consumer perception studies support Dr. Brandt's conclusion. As noted earlier, the majority of consumers in those studies stated that they would delay seeking medical attention if they experienced GI symptoms after eating products made with olestra. Thus, some consumers that experience GI symptoms, some of which could be quite serious and for which medical attention should be sought, will choose not to do so because they believe that the information statement is informing them that they will experience significant GI effects after eating snack foods made with olestra and that olestra is the cause.

At the 1998 FAC meeting, Dr. Karl Klontz, a medical officer with CFSAN, summarized the medical records of 21 consumers that *did* seek medical attention for GI symptoms which they attributed to olestra. The symptoms they attributed to olestra included several very serious conditions (e.g., acute appendicitis, gastritis, irritable bowel syndrome, acute gastroenteritis, urinary tract infection, ovarian cyst, and Clostridium difcil colitis). 15/ Analysis of the records showed that olestra was a possible cause of the complaint in only three of these 21 cases. For every patient like those in Dr. Klontz's study who sought medical attention, Frito-Lay's consumer research strongly indicates there will be many more who, although they may suffer from serious conditions like acute appendicitis or a urinary tract infection, would not seek medical attention, erroneously attributing their symptoms to olestra.

Although the scientific data demonstrate that olestra does not cause significant GI effects, the information statement for snack foods made with olestra indicates that it does, misinforming consumers and potentially prompting them to attribute medically significant GI symptoms to olestra. The reference in the information statement to this effect should, therefore, be eliminated.

14/ Brandt, Food Advisory Committee Meeting Transcript, Day Three, p. 138 (June 1998).

15/ Dr. Karl Klontz, Food Advisory Committee Meeting Transcript, Day One, pp. 271-275.)

C. "Olestra Inhibits the Absorption of Some Vitamins and Other Nutrients"

1. Vitamin Absorption

Olestra is lipophilic and can sequester lipophilic vitamins and nutrients that are simultaneously present in the GI system. Accordingly, in its final rule approving the use of olestra in savory snack foods, FDA required the addition of compensatory concentrations of lipophilic vitamins (A, D, E, and K) to foods made with olestra. Because carotenoids are also lipophilic they too have the potential to be sequestered by olestra. The Agency mandated post-market surveillance to determine the effect of snack foods made with olestra on blood vitamin and carotenoid levels.

The active post-market surveillance data demonstrated that addition of vitamins A, D, E and K to snack foods made with olestra prevents vitamin loss. Similarly, blood carotenoid levels were unaffected by consumption of snack foods made with olestra. A detailed study of consumption and blood concentrations of lipophilic vitamins and carotenoids showed some variability in the concentrations of α -carotene, β -carotene, and lutein, but no association with olestra consumption levels. 16/ No association between olestra intake and total blood carotenoids, vitamin A, vitamin D, lycopene, zexanthine, and β -cryptoxanthin was found either, even in high end olestra consumers. 17/

These data demonstrate that the addition of vitamins A, D, E and K to products made with olestra compensates fully for any absorptive effect of olestra. The information statement concerning absorption, therefore, is unnecessary and should be eliminated. Consumers' self-reported consumption patterns with respect to olestra support the conclusion that olestra is not affecting intake of lipophilic vitamins. A random digit dial phone study, designed to study patterns of olestra consumption under "real world" conditions, found no change in the portion of people eating at least one serving of fruits or vegetables within the last 24 hours – evidence that people are not substituting snack foods made with olestra for fruit or vegetables. 18/

16/ Dr. Mark Thornquist, Cancer Prevention and Research Program, Fred Hutchinson Cancer Research Center, University of Washington, Food Advisory Committee Meeting Transcript, Day Two, pp. 181-93 (June 1998).

17/ The study did find, however, that increased consumption of snack foods made with olestra was associated with increased blood concentrations of vitamin K, suggesting that FDA may have set the level of vitamin K addition to snack foods made with olestra too high.

18/ Kristal, et. al., Fred Hutchinson Cancer Research Center, University of Washington, Food Advisory Committee Meeting Transcript, Food Advisory Committee Meeting Transcript, Day 2, pp. 170-81 (June 1998).

2. "Other Nutrients"

The phrase "other nutrients" in the information statement's reference to olestra's tendency to inhibit absorption is not defined or otherwise explained to consumers. It is intended to refer, however, to the potential for olestra to affect carotenoid absorption. The consumer perception data discussed above reveal that consumers fail to understand, or simply ignore, the reference. Moreover, although consumption of fruits and vegetables is correlated with an array of positive health benefits, none of these benefits has been attributed specifically to carotenoids. ^{19/} The reference to inhibited absorption of "other nutrients", therefore, provides no material information to consumers and, as the consumer perception data suggest, leaves consumers confused as to its meaning. Accordingly, this reference should be eliminated from the information statement.

D. "Vitamins A, D, E, and K have been added"

Although accurate, the purpose of this statement is widely misunderstood by consumers, as discussed earlier. FDA included this statement in the information statement to indicate that vitamins had been added to the product but not for the purposes of fortification. The required label statement fails to do that. It gives consumers no information as to the reason(s) why vitamins are added. A majority of FAC members concluded that the current statement is ineffective and recommended instead that the listing of the added vitamins in the ingredient statement be linked to a statement that informs consumers that the product is not a significant source of these vitamins. Frito-Lay endorses FAC's position and urges FDA to adopt it. The linked statement will ensure that consumers know the product has not been fortified to provide a nutritional benefit with respect to vitamins A, D, E and K.

^{19/} Intervention trials published since the approval of olestra showed no definitive link between β -carotene and lung cancer or cardiovascular disease. In fact, the studies found that β -carotene consumption is correlated with an increased risk of lung cancer in certain circumstances (for example, see Omenn et al 1996, *New England Journal of Medicine*, 334:1150-1155).

The much-touted link between lycopene, another carotenoid, and prostate cancer is similarly tenuous. Although an epidemiologic study demonstrated a decreased risk of prostate cancer with increased tomato consumption (believed to be attributable to lycopene; see Giovannucci et al 1995, *Journal of the National Cancer Institute* 87:1767-1776), researchers have not been able to reproduce these results. Researchers have also been unable to establish a direct association between carotenoid intake and age-related macular degeneration (ARMD). A connection between the two has been postulated because the macula contains a high concentration of carotenoids, and some early studies revealed a potential association between decreased incidence of ARMD and intake of spinach and collard greens (see Seddon et al 1994, *Journal of the American Medical Association* 272:1413-1420).

V. REQUIRING MANUFACTURERS TO PLACE THE INFORMATION STATEMENT ON SNACK FOODS MADE WITH OLESTRA CAUSES THE PRODUCTS TO BE MISBRANDED

Under Section 403(a) of the Federal Food, Drug, and Cosmetic Act, a food is legally misbranded if its labeling is false or misleading in any particular. The information statement is false because it suggests that consumption of olestra leads to significant GI effects. The scientific data show no such relationship.

The information statement also misbrands snack foods made with olestra because it is misleading, which creates unwarranted consumer anxiety regarding the use of products that contain olestra and substantially contributes to consumer avoidance of such products. The consumer perception studies conducted by Frito-Lay and P&G demonstrate that the statement causes consumers to question the safety of olestra, when, in fact, FDA has determined that olestra is safe. The statement also causes confusion with respect to the nutritional effects of olestra. The vast majority of consumers seem to believe that olestra decreases the level of vitamins A, D, E and K in the body, despite the fact that (1) these vitamins are added to snack foods made with olestra to compensate for potential absorption by olestra and that FDA intended the information statement to convey that message to consumers; and (2) the scientific data show no change in blood levels of these vitamins following olestra consumption.

VI. CONCLUSION

In light of the data and information that have become available since FDA approved the use of olestra in savory snacks in 1996, the interim information statement requirement must be eliminated in its entirety. The information statement causes consumers to believe falsely that olestra is unsafe, despite the fact that FDA reviewed the available scientific data and determined the substance to be safe. The scientific data compiled since FDA's review fully support that judgment. They also demonstrate that the information statement's reference to olestra's GI effects has no foundation in science yet may have the unfortunate and deleterious effect of causing individuals with medically serious GI conditions to forego medical treatment because they incorrectly attribute their symptoms to olestra. The information statement also causes substantial confusion among consumers with respect to olestra's effects on endogenous vitamin levels.

Mandatory food label statements should provide material, health or safety related information to consumers. The olestra information statement does not rise to that level. In fact, by conveying false and misleading information to consumers, it essentially forces manufacturers to misbrand their products. Any special label requirement for snack foods made with olestra, other than a notation to inform consumers that the product does not provide a nutritionally significant level of vitamin A, D, E or K (conveyed through the use of a statement preceded by an asterisk and keyed to the relevant vitamin ingredients in the ingredient statement), is, therefore, unnecessary, at odds with longstanding FDA policy, and, arguably illegal. For these reasons, Frito-Lay urges the Agency to act immediately to amend the food additive regulation for the olestra interim information statement.