

symptoms (diarrhea (33 percent), loose stools (4 percent), cramps (11 percent), other GI problems (23 percent)).

FDA notes that in both these surveys, the percent of individuals reporting a GI symptom was high. FDA also notes that while the great majority of respondents in both surveys indicated that they consumed foods that caused them GI symptoms, the survey did not obtain information about the severity of these symptoms (Ref. 2).

b. *CSPI*. In 1996, CSPI commissioned a telephone survey in cities where olestra-containing foods were test marketed (Cedar Rapids, IA, Eau Claire, WI, and Grand Junction, CO), and submitted a report of the results to FDA.¹² The purpose of CSPI's survey was to determine how many people in the test market had tried olestra-containing snacks, and of those who had eaten olestra-containing snacks, how many had experienced GI symptoms. A random digit dialing sampling system was used, until a total of 506 telephone interviews were conducted in June and July 1996. CSPI said that 27 percent of individuals surveyed had tried the newly marketed olestra-containing chips, and of those, 20 percent reported experiencing GI symptoms characterized by CSPI as an adverse GI effect. Respondents characterized these events as mild (58 percent), moderate (23 percent), or severe (9 percent). CSPI also found that the majority of respondents (78 percent) had seen negative reports in the press about olestra, although only 28 percent said they were concerned about these possible effects. Based on this telephone survey, CSPI predicted that a large number of adverse events would be caused by the national marketing of olestra-containing foods. CSPI performed a separate survey of the original respondents who had not eaten olestra-containing chips but ate other chips to assess the frequency of GI events associated with consumption of conventional savory snacks and found that only 0.5 percent associated an adverse GI effect with eating a triglyceride savory snack.

CSPI commissioned a second survey, which was conducted in April and May 1997 in the Indianapolis area where olestra-containing foods were test-marketed. The purpose of the survey was to ascertain the consumption of olestra-containing foods and possible rate of adverse effects. CSPI submitted a report of the results to FDA.¹³ CSPI

reported that the majority of respondents said they had eaten savory snacks in the past 8 weeks (68.8 percent), and that a smaller portion of respondents (32.7 percent) said they had eaten olestra-containing foods. CSPI said that when respondents were asked whether they had eaten a specific brand of chips that contain olestra, they said yes, but when asked whether they had eaten olestra, these consumers responded that they had not eaten olestra. Of the group of respondents who had eaten an olestra-containing food, 8.3 percent reported experiencing what was characterized as an adverse effect after eating the olestra-containing food.

In its review of the data and information submitted by CSPI, FDA found that the studies provided information about the prevalence of use of olestra-containing foods, awareness of GI symptoms associated with olestra, and sources of information that consumers were using to learn about GI symptoms associated with olestra. FDA disagreed, however, that these studies could provide information about the cause of these GI symptoms. FDA found that the study design was inadequate to determine the cause of GI symptoms. Additionally, it is known from food-borne illness outbreaks that attribution biases can influence consumers and lead to the erroneous attribution of symptoms to a particular food. CSPI's survey does not allow for the evaluation of erroneous attribution of GI symptoms to consumption of olestra-containing chips, *i.e.*, other plausible causes for illness reports were not considered (Ref. 3).

2. Postmarket Passive Surveillance by P&G

P&G established a system of passive surveillance to collect consumer reports associated with the consumption of olestra-containing foods. Passive surveillance refers to the collecting of spontaneous, voluntary reports about a product. In its petition, P&G presents an overview of both the utility and limitations of data obtained from spontaneous, postmarket consumer reports. P&G characterized postmarket passive surveillance as a means of identifying and characterizing potential issues, including safety issues, once a product has entered the marketplace and been utilized by the population at large. The population experience with a product will be much broader than that derived during premarket testing because the number of individuals participating in premarket testing is necessarily limited. A reporting rate may be calculated based on the total

amount of product sold and the number of reports received. P&G notes, however, that there are a number of limitations with passive surveillance reporting. For example, these data do not lend themselves to assessment of causality because of the lack of controlled conditions and various confounding factors, such as a high background incidence of reported GI effects. Voluntary reporting, such as that obtained in P&G's passive surveillance system, is also subject to a number of biases including the level of attention the subject is receiving in the news media. Because reporting is voluntary and subject to interpretation, and because the total number of "exposures" can only be estimated, a true incidence rate cannot be calculated from passive surveillance.

Reports to P&G under its passive surveillance program for olestra were, for the most part, collected via calls made by consumers to a toll-free telephone number displayed on olestra-containing foods. Such calls were taken directly by P&G via its own toll-free telephone number. Calls were also forwarded to P&G by other snack food manufacturers (specifically, Frito-Lay). In some cases, information from such calls (but not the calls themselves) was forwarded to P&G by other snack manufacturers. Information was collected from callers as to the product used, specific product code information (where available), amount consumed, the nature of the complaint, symptom onset and duration, recurrence, characteristics and treatment, concomitant medications, and physician or other health professional involvement. Where physician contact was involved, or a medically significant event was reported, the petitioner attempted to obtain more detailed information including release of medical records for evaluation.

Consumer reports were reviewed by trained medical affairs staff at P&G. Additionally, the petitioner established a committee (Olestra Postmarketing Surveillance Committee) of medical experts outside of P&G whose membership included specialists in GI disease (both adult and pediatric GI), epidemiology, and pharmacology to review the reports received, and to make recommendations about the implications, if any, of these reports on the safety of olestra. The petitioner submitted reports to FDA of complaints associated with olestra consumption beginning in April 1996 with the test marketing of snacks made with olestra.

The petitioner reported that there were peaks in the number of reports received after the test marketing and

¹² CSPI submitted this report to Docket No. 87F-0179.

¹³ CSPI submitted this report to the Docket No. 87F-0179.