

CSPI, submitted comments to both the 1996 final rule and the current petition.

Although section 409 of the act establishes no comment period for food additive petitions, and the agency generally does not solicit comments in notices announcing the filing of a food additive petition, it is FDA's practice to consider any relevant comments submitted prior to the agency's decision on a petition.⁹ In this document, FDA separately discusses data from telephone surveys and passive surveillance regarding GI effects, new studies regarding GI effects, and active surveillance and other information regarding nutritional effects of olestra. As part of its discussion of these areas, FDA describes and responds to comments relevant to the topic. FDA discusses and responds to comments on other topics (such as the wording of the label statement, the prominence and placement of the label statement, and the need for a label statement) in a separate section (see section V of this document). In responding to the submitted comments, FDA has considered all of the data and information available in the record that bear on the olestra label statement, including the data and information in the 1996 final rule as well as the new information in the current petition.

III. Data and Information Since the 1996 Final Rule

A. Introduction

Olestra-containing snacks were introduced into test markets in April 1996, and national marketing began in February 1998. P&G established a system of passive surveillance to collect reports of possible effects that consumers associated with eating olestra-containing snacks. This surveillance system was in place when test marketing began. P&G has submitted reports to the agency, as well as analyses of such reports. P&G also established its program for active surveillance to monitor, among other things, possible nutritional impacts of olestra consumption.

P&G conducted studies concerning possible GI effects from consuming olestra-containing snacks in "real-life" situations. Specifically, P&G conducted four controlled studies concerning possible GI effects in humans and submitted reports about those studies to FDA.¹⁰ The four controlled studies are described as follows:

- An Acute Consumption Study,
- A Six-Week Consumption Facilitated *Ad Lib* Study (also called the Home Consumption Study),
- A Rechallenge Study, and
- A Stool Composition Study.

In the current petition, P&G also submitted the following data and information:

- Reports and analyses of data collected through consumer focus group and perception studies,
- Surveys regarding GI symptoms,
- Updated literature reviews on carotenoids and disease, and
- A report and analysis of the first year of data collected in an Active Surveillance Study.

CSPI also submitted reports from individuals who attributed an effect to the consumption of an olestra-containing food (Docket No. 87F-0179). In some cases, CSPI obtained medical records from consumers and forwarded them to FDA for analysis.

Below, FDA describes in detail the studies and information submitted in support of this petition, comments to the 1996 final rule that discuss the labeling of olestra-containing foods, comments to the current petition, and other relevant information.

B. Surveys and Postmarket Passive Surveillance Regarding GI Effects

1. Telephone Surveys Regarding GI Complaints

a. *P&G*. P&G sponsored two telephone surveys to investigate the frequency and severity of GI complaints, to investigate the frequency of consumption of foods that consumers believe cause GI symptoms, and to determine knowledge about reported GI symptoms from olestra-containing foods. Both of these surveys were performed before olestra-containing foods were available for sale in those markets. The first survey was done in February 1997 in Indiana (in Marion County, where Indianapolis is located), which was later a test-market for olestra-containing foods. This survey also served as a pilot study for the second survey, which was a national survey of the U.S. population completed in September 1997. National marketing of olestra-containing foods began in February 1998.

The petitioner acknowledged limitations in the design of the first survey completed in Indiana. For example, because the first survey was also the pilot study, the study

instrument had not yet been validated.¹¹ Also, the sample size was small and not shown to be representative of the general population surveyed. Despite these limitations, the petitioner concluded from the survey that GI symptoms were very common among the adult respondents polled. Asked about the previous three month period, respondents reported most frequently the GI symptoms of gas (34.6 percent), diarrhea (33.2 percent), and abdominal cramps (25.8 percent). Of those respondents who experienced one or more GI symptoms, 14 percent reported seeking medical attention because of the symptom. More than half of those who experienced a GI symptom said it was of moderate to severe intensity. The other result noted by the petitioner in this study was that there are a number of common foods (e.g., beans, onions, spicy foods) that respondents said caused them to have GI symptoms, but more than 80 percent of these respondents said they continued to eat these foods. Approximately half of the respondents had heard of olestra and among that group, 18 to 28 percent associated olestra with a GI symptom such as abdominal cramping or diarrhea.

The second survey was a larger, national survey that was designed with a reliability check, and a portion of the survey was designed to be a truly random sample of respondents. In this survey, 40.5 percent of respondents reported having one or more GI symptoms in the previous month. Of those respondents reporting a GI symptom, 21.8 percent had abdominal pain or discomfort, and 26.9 percent reported diarrhea or loose stools. More than 65 percent of respondents rated each of their symptoms as moderate to severe in intensity, and 14 percent consulted physicians about their symptoms. When asked about specific foods, respondents reported having GI symptoms after eating foods such as beans (22 percent) or spicy foods (34.4 percent). Despite symptoms, approximately 80 percent continued to consume these foods. The petitioner also found that women were more likely than men to report GI symptoms, and that abdominal pain, discomfort, and bloating were more commonly reported by women. There was little difference between males and females for reports of diarrhea. More than half the respondents in this study had heard of olestra, and of those, a varying number associated olestra with different GI

⁹ See discussion of comments in the filing notice for this petition (65 FR 11585-11586, March 3, 2000).

¹⁰ A copy of the petition submitted by P&G, as well as copies of the studies, surveys, and other

supporting materials listed here, can be found at the Division of Dockets Management, Docket No. 00F-0792.

¹¹ Data obtained from the first survey was used to validate the study instrument for use in the second survey.