

olestra-containing foods. Respondents' knowledge about olestra's ability to interfere with the absorption of fat-soluble components of the diet was not tested directly, so it is not possible to assess the role that prior knowledge has in respondents' interpretation of the label statement.

The studies demonstrate that consumers do not understand that the addition of the vitamins was intended to produce no *net* effect in the body. The studies also show that respondents tended to believe that the statement about the inhibition of absorption applied to many other nutrients, including those on which olestra has no effect.

Without the absorption statement, somewhat fewer respondents believed that vitamin A, D, E, and K levels would be changed by consuming olestra, but fewer respondents were also aware that olestra reduced the absorption of these vitamins. Even without an absorption statement, substantial fractions of respondents believed that consuming olestra-containing foods would change both fat-soluble and fat-insoluble vitamin levels, presumably because of prior beliefs about olestra. Variations on the wording of the portion of the label statement regarding vitamin absorption and addition made consumers more aware of the vitamin absorption effect of olestra, but none remedied the miscommunication.

FDA concludes, based on this work, that neither the current label statement nor the alternative label statements tested on product packaging clearly communicate to consumers the effect of olestra on vitamin absorption. Without more detailed information or familiarity with olestra, consumers drew inappropriate inferences about the scope and magnitude of the additive's effect on vitamin absorption.

2. 1999 Consumer Studies

In 1998 and 1999, the petitioner conducted quantitative consumer research using a detailed questionnaire, and submitted the study to the agency on April 22, 1999 (Docket No. 00F-0792). The petitioner's stated purpose for this study was to obtain quantitative data on consumer perceptions of the required label statement. Participants were asked to respond to a series of questions regarding safety and GI effects after reading the required label statement.

The petitioner reported that 61 percent of participants thought that the products bearing the required label

statement were unsafe.⁴² The same percentage believed that the label statement was the government's way of telling them that the product was unsafe. A majority viewed the label statement as a warning, and not as an information statement. After reading the label statement, 83 percent of respondents believed that they could experience symptoms after eating a handful of chips, and approximately a quarter of these respondents would attribute extremely serious symptoms to olestra (severe diarrhea lasting several days, bloody stools, or vomiting lasting up to several days). The petitioner noted that extensive clinical data on olestra show that the additive does not cause such symptoms. The petitioner concluded from the results of this study that the label statement is misleading and conveys messages to consumers that are not consistent with the total body of clinical data on olestra or with FDA's intention in requiring the label statement.

P&G also sought to assess consumer perceptions about the current and alternative label statements. Twenty alternative label statements were tested and rated on a scale of 1 to 9 for the degree of safety perceived from the label statement (1 is "not at all safe," 9 is "very safe"). For the GI portion of the label statement, P&G reported that respondents' perception of the degree of safety of olestra-containing foods after viewing the alternative GI statements ranged from 3.8 to 6.8. Alternative GI statements that provided a familiar frame of reference (comparison to beans, or onions for example), or that stated that GI symptoms were not a likely consequence, resulted in a greater perception of safety than those statements that provided generalized GI symptom data or context to qualify or describe GI symptoms. In this study, P&G found that the statements that elicited the lowest perception of safety were statements that specified GI symptoms, including those that are in the current label statement. For the nutrient portion of the label statement, P&G reported that more than 80 percent of study participants who read an ingredient declaration statement in which the vitamins A, D, E, and K were marked with an asterisk and accompanied with an explanatory phrase ("not a nutritionally significant source") and that no longer had the phrase "other nutrients," believed that levels of vitamins A, D, E, and K and

other nutrients would not change after eating olestra-containing foods.

P&G also conducted research by a national tracking survey to measure consumer awareness of olestra and to determine whether consumers had concerns about olestra's potential GI effects (Docket No. 00F-0792). Survey results were obtained between January 1998 (just prior to the start of national marketing of olestra-containing foods) and May 1999. P&G reported that the results of the tracking survey showed that population awareness of olestra-containing foods increased substantially during this period (from 38 percent to well over 70 percent). The study also showed that respondents who were familiar with olestra-containing foods were quite concerned about possible GI effects. The percentage of "aware" consumers who were at least somewhat concerned about GI effects averaged 74 percent at the beginning of the tracking survey, and 70 percent after national marketing of olestra-containing food was fully underway.

Frito-Lay also conducted new studies on consumer perceptions of the olestra label statement to determine whether that statement was still capable of influencing consumer perception, as it did in 1996 (FAP 0A4708, exhibit 7 and August 13, 1999, Docket No. 00F-0792). Because the 1996 perception study was conducted shortly after FDA's approval of olestra but before availability of olestra in any product on the market, no participant in the 1996 study had eaten a product made with olestra. Frito-Lay therefore considers that the 1996 study showed the effect of the label statement on a "naive" population. Since the 1996 study, Frito-Lay points to numerous significant events involving olestra, including the nationwide availability of Frito-Lay products made with olestra, the FAC meeting held by FDA in 1998, and many national and local news stories about olestra. The new testing of the label statement was conducted with the protocol used in Frito-Lay's 1996 studies.

Frito-Lay reported that in its 1999 study, before seeing the required label statement, 64 percent of respondents were uncertain about safety, but only 6 percent said products made with olestra were unsafe. After viewing the label statement, the number of respondents who thought olestra products were unsafe more than doubled. No one who originally thought olestra products were unsafe changed their opinion after viewing the label statement. Frito-Lay presented results showing that only 24 percent of study participants concluded that products made with olestra do not affect the levels of vitamins in the body,

⁴² By comparison, in the 1996 survey 45 percent of respondents, after viewing the required label statement, considered products containing olestra to be unsafe (Ref. 33).