

and an approximately equal distribution of participants concluded that olestra did or did not affect the absorption of other nutrients.

Frito-Lay concluded from these studies that the olestra label statement did influence consumer perception, much like it did in 1996. Frito-Lay also concluded that consumers still did not understand the various parts of the label statement and viewed it incorrectly as a warning.

FDA reviewed the consumer perception studies of the label statement submitted by P&G and Frito-Lay in 1999 and found them to be similar to the 1996 studies in methodology and types of questions asked (Ref. 33). This set of studies concentrated on the GI portion of the required label statement and perceptions of safety about products made with olestra. As with the 1996 studies, the studies were limited by choice and wording of questions and did not include, as a control, a "no information" statement. FDA notes that it is difficult, without careful controls, to distinguish whether a label statement miscommunicates information, is ignored, or is ineffective. Another important limitation to this study is the lack of measurement of initial attitudes toward olestra. Testing of initial attitudes and preconceptions is needed in order to identify the direction of the label statement's effect (*i.e.*, whether the consumer is more accurately informed or not informed).

FDA concludes that P&G's tracking study showed that consumers became more aware of olestra-containing snack foods as products were introduced nationally, and that increasing awareness was accompanied by concern about possible GI effects caused by these products. However, FDA also concludes that the tracking survey does not establish the role (if any) the required label statement plays in consumers' association of olestra-containing foods and GI effects. It cannot be determined from this study whether the rise in product awareness and association with GI effects was due to news reports, advertisements, promotions, or reading the label statement.

FDA concluded that the 1998 and 1999 studies reinforced conclusions from the 1996 studies and support several new conclusions. The new conclusions include the following scenarios: (1) Consumers became more concerned about the safety of olestra-containing products between 1996 and 1998, prior to the introduction of olestra-containing food into national distribution; (2) consumers familiar with olestra-containing snack food (Olean brand name) are very likely to

make an association between olestra and possible GI effects; and (3) consumers newly introduced to olestra-containing products by the introduction of Olean brand products into local stores and the accompanying advertising and promotion are just as likely to make the association between olestra and GI effects as those who already knew about Olean products.

FDA notes that the 1998 study gave respondents a choice of "I don't know" about safety. Given this option, 45 to 49 percent of participants in the 1998 study chose the response "I don't know" when asked about safety, and only 10 to 13 percent of participants in the 1998 study chose the response "unsafe." In contrast, in the 1996 survey, when participants did not have an option to choose "I don't know" when asked about safety, 38 to 61 percent of participants chose the response "unsafe."

G. 1998 FAC Discussion of the Label Statement

The FAC discussed the required label statement on the last day of the 3-day meeting (June 17, 1998), after new data and information concerning possible GI and nutritional effects were presented and discussed. The FAC was to consider whether, in light of the new data and information concerning the consumption of olestra, the label of olestra-containing products should be changed in any way. The FAC was also asked to consider what factual information, if any, regarding the consequences of consuming olestra-containing products should be disclosed on the product label. FDA began the session by discussing the scope of the agency's authority, under the act, regarding labeling. The sponsor (P&G) made presentations to the FAC, followed by Frito-Lay, and CSPI. The FAC asked questions at the end of each presentation. Following this portion of the meeting, each FAC member was polled regarding the label statement.

Polling the individual members of the FAC about whether the label statement should be changed revealed a wide variation in opinions on the labeling issue.⁴³ A majority of members, however, did agree that the label statement should be modified in some way in order to make its messages more clear to the consumer. Several members stated that some labeling information about olestra was needed, based in part on their view that olestra-containing foods were still relatively new products and that consumers were not entirely familiar with these products. Some

members of the FAC suggested there be a sunset clause on the label statement because after consumers became familiar with olestra, there would no longer be a need for a label statement.

Members made various suggestions for different wordings of the label statement to clarify to consumers the likelihood that olestra would cause GI effects and the nature of those effects. Other members expressed concern that consumers might confuse olestra's effect with more serious GI symptoms. Some members of the FAC concluded that olestra's GI effects did not warrant a special label statement, especially because consumers might mistakenly attribute more serious GI symptoms to the olestra. Other members thought a label statement should include information to tell the consumer to seek medical attention if symptoms persist. Several members said they believed that the current data did not support keeping the portion of the label statement on abdominal cramps.

A majority of the members of the FAC specifically agreed that the portion of the label statement regarding "vitamins added" should be removed and replaced with an asterisk following the vitamins in the ingredient listing and a footnote indicating that the added vitamins are not a nutritionally significant source or not nutritionally available. Both P&G and CSPI agreed that this approach was an acceptable and effective way to explain that the presence of the vitamins in the ingredient listing is not meant to imply that these foods are a source of these vitamins.⁴⁴

A majority of members of the FAC agreed that there is no basis, at this time, for adding back any carotenoid, and that the role carotenoids play, if any, in human health is not yet understood. Members did say that the sponsor and the agency should be aware of the evolving understanding of the health effects of carotenoids, and consider that information and its bearing on the use of olestra. Some members expressed reservations about not having any statement on the label about olestra's potential to interfere with the absorption of fat-soluble nutrients such as carotenoids, and suggested that the statement about "other nutrients," might be clarified by changing the phrase to "nutrients found in fruits and vegetables."

IV. FDA's Conclusions

A. The Applicable Legal Standard

Under section 409(c)(3) of the act, a food additive shall not be approved if

⁴³ Transcript, vol. 3, pp. 101–174.

⁴⁴ Transcript, vol. 3, pp. 92–93.