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Olestra To Lose Gastrointestinal Warning

By ACSH Staff — August 5, 2003

Products containing Olestra, the zero-calorie fat substitute, will no longer bear a label informing consumers of purported unpleasant gastrointestinal (GI) side effects. The Food and Drug Administration (FDA), after reviewing a six-week study that involved 3000 people, ruled that Olestra "caused only mild, infrequent GI effects," according to an FDA press release. The FDA also decided to continue the requirement for food manufacturers to add vitamins A, D, E, and K to counteract Olestra's effects on the absorption of these specific vitamins.

Olestra (marketed as "Olean" by Procter and Gamble P&G) is a soybean- and sugar-based product that has sensory properties similar to naturally occurring fats; however, unlike natural fats, Olestra passes through but is not absorbed into the body. Therefore, it provides no calories or saturated fat. Olestra is used in P&G's fat-free Pringles chips and in PepsiCo's Wow potato chips. According to P&G, Americans have consumed more than 3 billion servings of Olestra since the fat substitute was approved by the FDA in 1996.

The 3000-person study that the FDA cited in its decision was based on data from two groups of people: "Half ate chips with olestra and half ate chips they thought contained olestra but really didn't," Food Additive Chief George Pauli told the Associated Press. Those who consumed olestra had only marginally more frequent bowel movements. "We found that most studies couldn't even detect a difference from regular chips. The effects that were reported were mild and didn't really have an effect on people's lives," continued Pauli, contrary to the allegation by Michael Jacobson of the Center for Science in the Public Interest that "Procter & Gamble's own studies prove olestra causes diarrhea, cramps, and other symptoms."

Some participants in the study, inspired by the warning label, imputed abdominal pain and diarrhea to Olestra, but appendicitis and intestinal viruses were the real culprits, according to the FDA.

The previous Olestra label read "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." Now, the Olestra-containing products will only be required to have an asterisk beside each of the added vitamins, referring customers to a "dietarily insignificant" footnote.

Post-market consumer studies have illustrated consumers' confusion regarding the previous warning label. "They did not understand that the label meant there would be no loss of vitamins," according to the FDA. "These post-market studies also indicated that consumers erroneously believed that vitamins and minerals not affected by Olestra would be lost."

Pauli added that mild abdominal pain, similar to that experienced by some people after consuming

Olestra, also occurs after people eat high-fiber fruit, which does not possess a warning label.

"We're pleased that the FDA has taken this action and we think their decision is great news for consumers," said Greg Allgood, an associate director for Procter & Gamble's Health Sciences Institute, in a statement to the *New York Times*.

Olestra, having no fat or calories, may help those who are trying to lose weight by limiting caloric intake. According to the Dietary Guidelines for Americans, fat intake should not exceed 30% of one's total calories consumed, while saturated fat consumption should not be greater than 10% of the total daily intake of calories.

Although the FDA's decision to remove the Olestra warning labels is effective immediately, consumers may find that it will take time for the new product packages without labels to appear.
