

Procter & Gamble

The Procter & Gamble Company
Winton Hill Technical Center
6071 Center Hill Avenue, Cincinnati, Ohio 45224-1703

2660 '00 MAR -6 A9:29

March 3, 2000

Docket Management Office
5630 Fisher's Lane
Rockville, MD 20852

Dear Madam:

We wish to submit the enclosed report and cover letter entitled "Consumer Research on Olestra Interim Label" to the olestra docket #00F-0792 so that it is publicly available. This material was previously submitted to Mary Ditto of FDA's Office of Pre-market Approval on April 22, 1999.

Please let me know if you have any questions (513-634-6808).

Thank you.

Sincerely,

THE PROCTER & GAMBLE COMPANY

Greg Allgood/ra

Greg Allgood, Ph.D.
Associate Director
Regulatory & Clinical Development

Enclosure

00F-0792

RPT9

Procter & Gamble

*The Procter & Gamble Company
Winton Hill Technical Center
6071 Center Hill Avenue, Cincinnati, Ohio 45224-1703*

22 April 1999

Mary Ditto, Ph.D.
Food and Drug Administration
Office of Premarket Approval
HFS-206, VERB-1285
200 C Street, SW
Washington, D.C. 20204

Re: Submission of Consumer Research on Olestra Interim Label

Dear Dr. Ditto:

This provides the results of a consumer research study conducted by P&G on the interim labeling requirement for olestra prescribed by FDA (61 FR 3188-3173; January 30, 1996). Key points from these data were presented at the Food Advisory Committee (FAC) meeting held in June, 1998. These results augment those submitted 1 April 1996.

Quantitative research (detailed questionnaire) was conducted with consumers from 21 April through 5 May, 1998. The purpose of this research was to obtain quantitative data on consumer perceptions of the olestra interim label. The study was a multi-site test among 314 representative heads of household, age-balanced by census data. The study panelists were recruited at shopping malls in 22 geographically dispersed cities across the U.S. The study used methods which are standard for developing consumer products. After reading the interim label, consumers were asked to respond to a series of questions regarding safety and gastrointestinal (GI) effects. A summary of the research is provided in Appendix 1.

The basic learning from this test is that the interim label 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 interim label. After reading the label, the majority of consumers perceived that the label was a warning label rather than an information label, that the product was unsafe, and that the government was warning them that the product was unsafe. After reading the label, the majority of consumers perceived that they would have GI effects and many consumers would attribute severe effects such as bloody stools to olestra. This is not consistent with the clinical data showing eating olestra snacks does not result in meaningful GI symptoms. As expressed by the Chair of the FAC, this misperception may lead consumers to delay medical treatment and physicians to inappropriately attribute severe symptoms to olestra. These findings are discussed below.

Consumer Interpretation of Interim Label: Perceptions About Safety

In the final rule for olestra, the FDA concludes that "all safety issues have been addressed adequately and that ... the use of olestra in savory snacks will be safe ..." However, 61% of the consumers interviewed in this research believed not only that olestra snacks were unsafe based on their interpretation of the current interim label, but also that the government was telling them that the products were unsafe. Sixty-two percent of the consumers stated that they would avoid eating snacks containing olestra. Fifty-seven percent believed that the interim label was a warning label, not an information label.

These results demonstrate that while the FDA had thoroughly reviewed, evaluated, and approved olestra for use in snack products, the message of the interim label implies that the product is not safe and that the government says it is not safe.

Consumer Interpretation of Interim Label: Perceptions About Gastrointestinal Effects

The results of this research (Table 1) indicate that if consumers were to experience gastrointestinal (GI) effects after eating snacks made with olestra, many would believe these

symptoms were likely to be caused by olestra. For example, 83% of the consumers participating in the study believed that if they experienced GI symptoms of abdominal cramping or loose stools after eating olestra snacks, they would believe that these symptoms were likely to be caused by olestra. Fifty percent of the consumers thought that if they experienced severe diarrhea after eating olestra snacks, they believed that this effect was likely to be caused by olestra. Fifty-five percent of consumers believed that if they experienced abdominal cramping or loose stools after eating only a handful of olestra snacks (6 chips), they believed that these symptoms were likely to be caused by olestra. If they were to experience abdominal cramping or loose stools within two (2) hours after eating the olestra snacks, 68% of the consumers believed that they were likely caused by olestra. About one-quarter of consumers would attribute bloody stools to olestra.

Table 1. Results from Quantitative Label Research Study

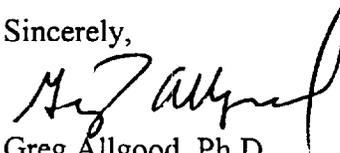
Based on the Label, Experiences Likely or Not Likely to be Caused by Olestra	Likely Caused by Olestra (% Consumers)	Not Likely Caused by Olestra (% Consumers)
• After eating salted snacks containing Olestra you experience abdominal cramping or loose stools	83	17
• After eating salted snacks containing Olestra yo experience severe diarrhea	50	50
• After eating salted snacks containing Olestra you experience vomiting	25	75
• After eating a handful (6 chips) of salted snacks containing Olestra you experience abdominal cramping or loose stools	55	45
• Within 2 hours after eating salted snacks containing Olestra you experience abdominal cramping or loose stools	68	32

- | | | |
|--|----|----|
| • After eating salted snacks containing Olestra, you experience bloody stools | 24 | 76 |
| • After eating salted snacks containing Olestra one time,you experience diarrhea for several days | 24 | 76 |
| • After eating salted snacks containing Olestra one time you experience vomiting for several days | 17 | 83 |

The above consumer perceptions are clearly not consistent with the clinical data. Clinical data that were reported at the FAC, including the acute consumption study, the rechallenge study, and the 6-week consumption study, demonstrate that there are no meaningful differences in GI effects between consumers eating olestra and those eating full-fat snacks. The studies clearly demonstrate that olestra is not causative in severe effects and that the vast majority of consumers do not notice an increase in digestive symptoms with eating olestra snacks. Therefore, the interim label is clearly misleading consumers in their perceptions of the likelihood of the occurrence and severity of GI symptoms.

The data presented above are discussed in more detail in the report of the research attached as Appendix 1. The consumer test methodology and questionnaire provided in Attachments 2 and 3 are CONFIDENTIAL trade secret information. Thus, we request that Attachments 2 and 3 in Appendix 1 be exempt from disclosure under 5 USC 552(b)(4), 21 CFR 171.1(h)(3) and 21 CFR 20.61. Advance notice before any disclosure is requested under Executive Order 12600 by mail to the undersigned.

Sincerely,



Greg Allgood, Ph.D.

Associate Director

Regulatory & Clinical Development

Appendix 1

Quantitative Label Research Study

This summarizes the key findings from quantitative research conducted 4/21/98 to 5/5/98. The purpose of this study was to understand the communication of the olestra interim label and how it impacts consumer perceptions of snacks containing olestra.

Study Design: This study was a multi-site test in which panelists viewed the olestra interim label and answered questions. The purpose of this research was to understand communication of the olestra interim label and how it impacts consumer perceptions of snacks containing olestra.

The studies were conducted among 314 representative heads of household, age balanced by census data (18+ yrs.), in 22 U.S. cities (Attachment 1.) Panelists must not have participated in a marketing research survey within the past 3 months, and not be associated with a marketing/consulting/advertising/media business or one that manufactures or distributes food products. These panelists were recruited over 14 days at shopping malls in 22 geographically dispersed cities across the US. The study protocol and screening questionnaire are provided in Attachment 2.

Data Collection: During the study panelists answered questions from self-administered questionnaires describing their perception of the olestra interim label. Each panelist was shown the olestra interim label on a concept board before beginning the questionnaire. The label concept board remained with the panelists while they completed the questionnaire. The label is provided in Attachment 3.

After reading the label, panelists answered questions describing their perceptions of the type of label, safety of the snacks containing olestra, whether or not they would avoid snacks containing olestra, whether or not the government is saying snacks containing olestra are safe or should be avoided, and types of symptoms that are likely or not likely to be caused by consuming snacks containing olestra. A copy of the questionnaire is provided in Attachment 4.

Data Analysis: Data was tabulated and analyzed through the computer program Quantum v5e (Quantime Corporation). Data table summaries are provided in Attachment 5. Comprehensive data sets are provided in Attachment 6.

Key Findings:**Regarding General Consumer Perceptions of Olestra-**

- Fifty-seven percent of the consumers think the label on snacks made with olestra is a warning label vs. an information label.
- Consumer perception is that the label on snacks made with olestra is telling them the product is unsafe (61%). Sixty-two percent of consumers said that, based on the label, they would avoid eating snacks containing olestra.
- Based on the label, 61% of the consumers said the government is telling them olestra is unsafe. Also, based on the label, 40% of the consumers said the government is telling them they should avoid eating salted snacks containing olestra.

	<u>Olestra Interim Label</u>
Base - Total Interviews	314
<u>Type of Label</u>	
Warning Label	57
Information Label	34
Nutrition Label	9
<u>Based on the Label, Product Safe or Unsafe</u>	
Safe	39
Unsafe	61
<u>Based on the Label, Would Avoid Product</u>	
Yes	62
No	38
<u>Based on the Label, Government saying Product Safe or Unsafe</u>	
Safe	38
Unsafe	61
<u>Based on the Label, Government saying Should Avoid Product</u>	
Yes	40
No	60

Regarding Consumer Perceptions of Gastrointestinal Symptoms Associated with Olestra-

- Based on the label, 83% of consumers perceived that abdominal cramping or loose stools experienced after eating snacks containing olestra was likely caused by olestra.
- Based on the label, many consumers perceived that severe diarrhea (50%) or bloody stools (24%) experienced after eating snacks containing olestra was likely caused by olestra

- Based on the label, more than half of consumers believed that abdominal cramping or loose stools experienced 2 hours after eating salted snacks containing olestra (55%) or experienced after eating a handful of salted snacks containing olestra (68%) was likely caused by olestra.

	<u>Likely Caused by Olestra</u>	<u>Not Likely Caused by Olestra</u>
<u>Based on the Label, Experiences likely or not likely to be caused by Olestra</u>		
• After eating salted snacks containing Olestra you <u>experience abdominal cramping or loose stools</u>	83	17
• After eating salted snacks containing Olestra you <u>experience severe diarrhea</u>	50	49
• After eating salted snacks containing Olestra you <u>experience vomiting</u>	25	75
• After eating salted snacks containing Olestra you <u>experience bloody stools</u>	24	75
• After <u>eating a handful (6 chips)</u> of salted snacks containing Olestra you <u>experience abdominal cramping or loose stools</u>	55	44
• <u>Within 2 hours</u> after eating salted snacks containing Olestra you <u>experience abdominal cramping or loose stools</u>	68	31
• After eating salted snacks containing Olestra one time, you <u>experience diarrhea for several days</u>	24	75
• After eating salted snacks containing Olestra one time, you <u>experience vomiting for several days</u>	17	83

Appendix 1

Quantitative Label Research Study

Attachment Index

<u>Attachment</u>	<u>Description</u>
Attachment 1	Demographics of Panelists
Attachment 2	Study Protocol and Screening Questionnaire
Attachment 3	Label Tested
Attachment 4	Sample Questionnaire
Attachment 5	Data Table Summaries
Attachment 6	Comprehensive Data Sets