Procter&Gamble

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

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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 "Procter & Gamble Comments to: Food and Drug Administration Docket No. 87F-0179, Food Additives Permitted for Direct Addition to Food for Human Consumption: Olestra, April 1, 1996" to the olestra docket #00F-0792 so that it is publicly available. All of this material has been previously submitted to the Dockets Management Branch on April 1, 1996.

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

Thank you.

Sincerely,

THE PROCTER & GAMBLE COMPANY

Greg Allgood

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

Enclosure

87F-0179

RPT4

Procter&Gamble

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6071 Center Hill Avenue, Cincinnati, Ohio 45224-1703

April 1, 1996

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

Re: Food Additives Permitted for Direct Addition to Food for Human Consumption; Olestra (Docket No. 87F-0179)

Dear Sir or Madam:

This provides the comments and results of consumer research studies conducted by The Procter & Gamble Company (P&G) on the interim labeling requirement for olestra prescribed by FDA (61 FR 3118-3173; January 30, 1996). This fulfills P&G's agreement to conduct this research as outlined at 61 FR 3160.

Procter & Gamble is the petitioner for approval to market the food additive olestra for use as a replacement for conventional fats in the preparation of savory snacks. In addition, P&G is the marketer of savory snack products under the Pringles brand. Thus, P&G has an interest in the final rule and the labeling of foods containing olestra.

The interim labeling requirement for olestra reads:

> "**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."

Both qualitative (focus groups) and quantitative research (detailed questionnaire) were conducted. The objective of the focus groups was to determine the clarity of communication of the Agency's required interim label and to develop potentially more informative label(s) for placement in quantitative research. The purpose of the quantitative research was to understand the communication of the interim label and alternative labels, issues the various labels raise, and how the labels impact consumers' understanding of foods containing olestra.

This research consisted of (1) nine focus group sessions among adults or teens to provide qualitative information on what consumers learned from reading a variety of information labels and (2) testing among 1306 adults and 420 teens to provide quantitative data on what consumers learned from each of four information labels. Summaries of the research and full study reports are provided in Appendices 1 and 2, respectively.

The basic learning from this testing is that the interim label does not communicate clear and understandable messages to consumers. Most consumers were confused by both the GI-effects and nutrients-effects information statements. Regarding this general confusion, several learnings emerged. These are discussed below, first for the nutrient portion of the information labels and then for the GI-effects portion.

Regarding the Effects on Nutrients Statements

The Agency pointed out in 61 FR 3160 that if a material fact about a representation made in labeling is not disclosed then the labeling is misleading. The Agency has provisionally considered that it is a material fact that vitamin absorption can be reduced and vitamins have been added back to compensate. However, qualitative research indicates that when consumers understood there are no net consequences on vitamins A, D, E, and K, they questioned the need for any statement or were suspicious of the statement. We learned that consumers find the concept of nutrition effects and compensatory addition difficult to comprehend without extensive amounts of information. In fact after reading nutrient statements, some consumers inappropriately concluded that olestra is not safe based on presumed vitamin effects. In the focus groups, personal dialog with individual consumers was needed to reach significant understanding of what was intended to be understood.

We believe that the purpose of the nutrient portion of the information statement is to communicate to consumers: (1) that they will experience no net nutritional effect from the vitamins added to olestra foods, and (2) that the olestra food is therefore not fortified as a result of the vitamins declared in the ingredient statement. This position is consistent with that of the Food Advisory Committee. The Committee generally indicated that their chief concern was to avoid the potential for confusing consumers who might inappropriately conclude that the disclosure of vitamin A, D, E, and K addition in the ingredient statement would provide a nutrient benefit. The Agency was advised by the Committee to deal with this in the way normally used for the presence of functional ingredients in labeling. (FAC Meeting, November 16, 1995; Transcript, pages 276-278.)

We believe (1) if any material fact needs to be disclosed regarding nutrient effects, it is only that the vitamins added do not provide significant nutritional benefit, i.e., that the consumer receives no net additional vitamins and will therefore not consider the product to be fortified; and (2) there is no need to disclose that vitamin absorption can be reduced and vitamins have been added back. The quantitative research (Appendix 2) shows that:

> A simple label statement that the vitamins in the ingredient statement do not provide a nutritionally significant source best communicates to consumers the fact that there would be no effect on their status of vitamins A, D, E, and K. (Appendix 2, page 3)

> Labels which state that vitamins A, D, E, and K have been added do communicate this fact to consumers. However, these labels are more likely to leave adults with the impression that their vitamin status will change as a result of eating an olestra food. This demonstrates that statements to this effect have the potential to mislead the consumer to believe the product is fortified. (Appendix 2, page 3)

Labels with the term "other nutrients" confused consumers because they were left to speculate for themselves on what this terminology might mean. The quantitative research (Appendix 2) shows that:

> Inclusion of a reference to effects on "other nutrients" appears to provide no meaningful understanding to consumers. Nearly two-thirds of consumers concluded that there were no effects on the other nutrients identified regardless of whether the label cited effects on "other nutrients." For those consumers who did register this message, they incorrectly concluded that a variety of nutrients (for example, vitamins C and B) known not to be affected by olestra were in fact being affected. (Appendix 2, page 4)

<u>This consumer data supports the Agency's appending a simple statement to the ingredient statement that the vitamins A, D, E, and K added do not provide a nutritionally significant source</u>. This would be similar to how fat ingredients are labeled for fat-free products [21 CFR 101.62(b)(ii)].

For example:

> "INGREDIENTS: POTATOES, OLESTRA,...ALPHA-TOCOPHEROL ACETATE (VITAMIN E*), VITAMIN A PALMITATE*, VITAMIN K*, VITAMIN D*.
>
> *NOT A NUTRITIONALLY SIGNIFICANT SOURCE."

This recommendation is consistent with the positions expressed by most of the Food Advisory Committee members (FAC Meeting, November 16, 1995; Transcript , pages 226-228 and 276-278)

Alternatively, the Agency could consider in lieu of a nutrition information statement requiring manufacturers to provide a 1-800-number for consumers to call to request accurate information on these complex issues.

Another alternative suggested by the research is a nutrition information statement such as:

> "Because Olestra reduces the absorption of vitamins A, D, E, and K, these vitamins have been added to maintain vitamin balance (or) to compensate for this effect."

None of these alternatives to the interim required labeling contains a reference to "other nutrients". FDA states in 61 FR 3161 that this term is included because any nutrient that is as lipophilic as the fat soluble vitamins would be affected by olestra, although there is no basis for adding them back. As stated before the Food Advisory Committee, there are no known nutrients of nutritional significance, beyond the fat soluble vitamins, which olestra has the potential to affect. Therefore, the inclusion of a statement regarding "other nutrients" cannot provide a material fact of consequence to consumers. The data provided to FDA show that the only fat soluble nutrients which will be affected by olestra that are of nutritional significance have been added back (i.e., vitamins A, D, E, and K). To require a labeling reference to "other nutrients" without further specificity leads consumers to suspect that many nutrients known not to be afected by olestra could be affected.

Regarding the GI Effects Statement

The qualitative focus group research (Appendix 1) indicates that providing an explanation of why olestra might cause GI effects added significantly to consumer understanding. For example, inclusion of a phrase like "Because olestra is not digested,..." was very helpful. This research also showed that consumers generally understood what "abdominal cramping" and "loose stools" were meant to communicate, but felt that less graphic terms, like "intestinal discomfort" and "laxative effect," communicated equally as well, and could, and should, be used to describe the GI effects. Some consumers were confused by the "cramping" term, questioning whether this would be a symptom females rather than males would experience.

The quantitative research shows that when labels contain specific words, such as, "abdominal cramping" and "loose stools," consumers register these terms. This research also showed that statements using the term "laxative effect" were as effective as statements using the term "loose stools" in communicating to consumers that they might experience the range of stool softening effects of olestra and were more effective at communicating the range of potential symptoms ("gas," "bloating") that may be associated with olestra use. (Appendix 2, page 5)

<u>Based on a synthesis of the overall learning from this research, an effective GI portion of the information label would read:</u>

> "Because it is not digested, olestra may cause intestinal discomfort or a laxative effect."

This is consistent with the majority of the Food Advisory Committee who felt that labeling similar to the label FDA proposed at the FAC meeting was acceptable (FAC discussion, November 17, 1995; Transcript, pages 60-62).

Regarding the Configuration of the Information Label Statement

The boxed configuration of the interim required statement as well as the other alternatives tested create concern about the safety of olestra. In focus groups, when statements were not boxed, there was less connotation of harm.

The quantitative data indicate that nearly half (45%) of adults who reviewed the interim required information statement perceived the product to not be safe (Appendix 2, page 7). This suggests that the FDA has prescribed a label which communicates to consumers that the product - which the Agency has thoroughly reviewed, evaluated, and approved - is not safe for them to eat. This is an inconsistent message to the consumers of America, that diminishes the credibility of the Agency and destroys public trust in what is approved by the Agency. We urge the Agency to seriously consider this impact on the public's view of FDA in making a decision regarding an information label.

Therefore, we recommend that the requirement for enclosing the information statement in a box be eliminated

Each of the learnings presented above is discussed in more detail in the reports of the focus group and quantitative research attached as Appendices 1 and 2. The consumer test methodology provided in Appendix 2, Attachment 2 is CONFIDENTIAL trade secret information. Thus, we request that Attachment 2 in Appendix 2 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.

Very truly yours,

Keith C. Triebwasser / ZKH

Keith C. Triebwasser, Ph.D.

cc: Dr. Helen Thorsheim, FDA (HFS-207)