

to other factors related to fruit and vegetable intake. Intervention studies designed to test whether carotenoids (specifically beta-carotene) had any direct protective benefits for health did not show any benefit compared to the control (placebo supplement), and indicated that there was an increased incidence in disease (lung cancer) for certain at-risk sub-populations (smokers). The panel did not propose establishing a dietary reference intake (DRI) for beta-carotene or any other carotenoid (Ref. 27).

FDA considered the NAS report on carotenoids and concluded that the evidence concerning carotenoids and the conclusions that could be drawn from the evidence about carotenoids and human health had not substantially changed since the 1996 decision. FDA acknowledges that investigations are continuing on carotenoids to better understand biochemical mechanisms and genetic controls of these substances, and what, if any, role carotenoids have in human health (Ref. 28).

In the fall of 2000, FDA consulted with the NEI for an update as to whether there had been a change in the understanding of the science regarding lipophilic carotenoids and eye health since FDA last consulted with NEI on this question prior to the 1996 final rule (Ref. 29). The NEI said that no specific vitamin or carotenoid had been established as protective against macular degeneration (Ref. 30). The NEI also said that the ongoing "Age-Related Eye Disease Study" (AREDS) includes a randomized clinical trial of an antioxidant combination (beta-carotene, Vitamins C and E) or zinc that is evaluating the effect of these nutrients on macular degeneration and cataracts.⁴⁰ Other investigations continue to explore the hypothesis that oxidative damage to the retina increases the risk of macular degeneration and that antioxidant nutrients and carotenoid pigments concentrated in the macula may protect against this damage (Ref. 30).

⁴⁰ Since FDA's consultation with the NEI in the fall of 2000, the ongoing AREDS study published a report of a randomized clinical trial of an antioxidant combination (beta-carotene, Vitamins C and E) or zinc evaluating the effect of these nutrients on macular degeneration and cataracts (Ref. 31). Results of the study showed that a combination of antioxidants (vitamin C, vitamin E, beta carotene) and zinc reduced the probability for the development of advanced age-related macular degeneration (AMD) in study subjects who were at high risk for developing AMD. The groups given only antioxidants, or only zinc, did not show this reduction in rates of at least moderate visual acuity loss.

F. Consumer Perception Studies of the Label Statement

P&G and Frito-Lay submitted data from studies designed to test consumer understanding of the label statement required by the 1996 final rule as comments to that final rule. Additional reports of testing, conducted after the original comment period for the label statement closed on April 1, 1996 (61 FR 3118 at 3160), were also submitted to the agency. These reports are discussed in the following paragraphs.

1. 1996 Consumer Studies

On April 1, 1996, P&G submitted consumer studies conducted on the label statement required on olestra-containing foods. These studies were completed before olestra-containing foods were available in the marketplace. The petitioner did both qualitative (focus group) and quantitative (mall intercept, detailed questionnaire) testing. The objective of the qualitative research was to determine how consumers comprehended the required label statement and to develop potentially more informative label statement(s) for use in subsequent quantitative research. The objective of the quantitative research was to understand how the required label statement and alternative label statements communicate to consumers, to understand issues raised by the various label statements, and to understand how the label statements affect consumers' understanding of olestra-containing snack foods.

In the qualitative research, three focus group sessions were conducted in each of three cities (total of nine focus group sessions) among adults or teens. Participants saw a realistic product package and several possible versions of the olestra label statement, and were told that a version of these statements might appear on product packages. Participants discussed their impressions of the product and the various label statements in their own words. The group went through each label statement line by line.

In the quantitative research, a detailed questionnaire was presented to 1,726 respondents, adults and teens, recruited at shopping malls at 40 different sites around the country. Respondents were randomly assigned to a group to assess one of four conditions for wording or presentation of the label statement. Respondents were shown the assigned information statement on a realistic product package that included a nutrition facts panel, ingredient list, and other product information. They then answered questions about the product,

the information statement, and the effects of olestra.

The petitioner concluded from these studies that the required label statement did not communicate clear and understandable messages to consumers. The petitioner found that most participants in the studies were confused by label statements about both the GI effects and the nutrient effects.

The petitioner asserted that the data demonstrate that consumers, after reading the "vitamins added" portion of the required label statement, are left with the impression that eating olestra-containing foods will change their vitamin status. After reading the nutrient statements, some participants inappropriately concluded that olestra is not safe based on presumed vitamin effects. The petitioner stated that the qualitative research indicated that when participants understood that there are no net consequences on vitamins A, D, E, and K, the participants questioned the need for any statement or were suspicious of the statement. The petitioner stated that this study shows that consumers find the concept of nutritional effects and compensatory addition difficult to comprehend without extensive amounts of information. The petitioner concluded from the results of the quantitative studies that a simple label statement indicating 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.

Also, the petitioner concluded that the term, "other nutrients," appears to provide no meaningful information to consumers. The petitioner reported that a majority of participants concluded that there were no effects on other nutrients regardless of whether the label statement cited effects on "other nutrients." For those participants who did notice the message, they incorrectly concluded that a variety of nutrients, some known not to be affected by olestra (for example, vitamins C and B) were, in fact, being affected.

The petitioner stated that results from the focus group study on the GI portion of the label statement showed that the currently required label statement may cause consumers to incorrectly attribute GI symptoms to the consumption of olestra, including GI symptoms that olestra does not cause and GI symptoms that are not listed on the label statement. The petitioner said that the research supports the conclusion that the label statement may cause consumers to wrongly attribute symptoms because participants