

not belong in the same category as cigarettes, but provided no factual information or rationale in support of the opinion expressed.

FDA does not agree that olestra-containing foods should be required to bear a label statement indicating that consumption of these foods may reduce the absorption of carotenoids and that carotenoids may protect against certain diseases, nor does FDA agree that it should require addition of specific carotenoids to olestra-containing foods. Current evidence supports the connection between the consumption of fruits and vegetables (many of which contain carotenoids) and reduced risk for certain diseases. The available data do not, however, establish any identifiable nutritional or prophylactic benefits specifically for carotenoids, either individually or collectively (61 FR 3118 at 3149) other than their provitamin A function. This position is consistent with the conclusions of the 2000 report of the IOM Panel on Dietary Antioxidants and Related Compounds which found no basis for establishing a DRI for beta-carotene or other carotenoids.<sup>63</sup> The 1995 "Dietary Guidelines for Americans" recommend healthy dietary habits, including eating fruits and vegetables, but do not present any new scientific information related to possible beneficial health effects specifically attributed to the consumption of carotenoids. Based on the lack of an identifiable nutritional or prophylactic benefit for carotenoids (other than their provitamin A activity), FDA has no basis at this time to require a label statement about carotenoids and their potential health effects or to require the addition of specific carotenoids to olestra-containing foods.<sup>64</sup>

FDA determined in its 1996 final rule that, based on the existing scientific evidence, including the 8-week studies examining the nutritional effects of daily olestra consumption, that there was no justification or need to require compensation of olestra-containing foods with specific carotenoids (61 FR 3118 at 3149). The data and information obtained since the time of the 1996 final rule do not change the agency's 1996 conclusion.

The issue of olestra's effect on carotenoids was discussed by the FAC in both 1995 and 1998. Most members of the FAC agreed in 1995 that the effect

of olestra on the bioavailability of carotenoids is not a fact that is material in light of the consequences that may result from consumption of olestra-containing foods and therefore the effect does not warrant disclosure on the label of such foods (61 FR 3118 at 3162). Subsequently, in 1998, a majority of the FAC expressed the view that there were no new data to show that the potential effect of olestra on carotenoids represents a public health concern.<sup>65</sup>

(Comment 26) A comment from academia to the current petition stated that the issue of olestra, carotenoids, and chronic disease should be considered by an impartial body such as the NAS to determine whether there is reasonable certainty that reductions in carotenoid levels will not increase the risk of various diseases. The comment states that the approval process for olestra was flawed because in the first review, the committee did not include cancer or nutritional epidemiologists or other experts who are qualified to review the issue of carotenoid intake and its effect on risk of chronic disease. The comment also stated that in the second review, the committee did not consider evidence considered by the first committee, but only considered new evidence.<sup>66</sup> The comment asserted that since the June 1998 FAC meeting, there have been a substantial number of publications indicating that low carotenoid status may be linked to increased risk for certain diseases and included copies of three published articles on carotenoids.<sup>67</sup> The comment also states the results of a 1996 survey of 13 members of the NAS Committee on Diet, Nutrition, and Cancer who authored the 1982 review of Diet, Nutrition, and Cancer.<sup>68</sup> The survey asked the following questions: (1) "Are you reasonably certain that carotenoids contained in fruits and vegetables are not related to the apparent benefits of these foods in reducing cancer risk?" and (2) "Are you reasonably certain that reductions in blood levels of carotenoids will not increase the risk of cancer?" The comment stated that seven members answered "no" to both questions and that not one member could affirm that they could be reasonably certain that reductions in

blood carotenoids would not increase cancer risk. Based on the results of the survey, the comment concluded that the FDA's conclusion of olestra's "reasonable certainty of no harm" is not supported by expert scientific opinion. The comment asserted that the effects of carotenoids are poorly understood and we cannot be reasonably confident that reduction in blood carotenoid levels will cause no harm. The comment also stated that the logic that we cannot be certain whether it is the carotenoids in fruits and vegetables that are protective against disease violates the precautionary principle and FDA's guideline of reasonable certainty of no harm because the burden of proof should be on the petitioner to show that carotenoids are not the protective factors in fruits and vegetables.

This comment raises the issue of whether olestra's use in savory snacks is safe (section 409(c) of the act), given the potential effects of olestra consumption on serum carotenoids levels. This issue is beyond the scope of the petition before FDA which concerns labeling. FDA notes that even if the comment is correct that olestra's use in savory snacks is unsafe due to the additive's effect on serum carotenoids, such lack of safety cannot be rectified through labeling. Indeed, as noted, in the 1996 final rule, FDA concluded that olestra is safe for use in savory snacks, a conclusion reached after a review of the evidence in the record concerning carotenoids and human health. If the comment wishes to have FDA consider this safety issue, they must file a citizen petition requesting such consideration, 21 CFR 10.30, not raise it as a collateral issue in this proceeding. FDA addresses the issue of labeling for olestra's effect on carotenoids in its response to the previous comment. FDA addresses the issues raised about the 1995 meeting of the OWG and FAC and the 1998 meeting of the FAC in response to comment 43 of this document.

### C. Labeling for Special Populations

(Comment 27) Some comments to the current petition stated that the olestra label should include a statement that olestra-containing foods should not be given to children. One comment stated that olestra should be marketed in childproof containers or the food label should include the statement "Keep out of reach of children." One comment expressed concern that there is a lack of testing and evaluation of olestra in young children, and that even small packages may be a relatively high dose in children when considered on the basis of grams of olestra per kilogram of body weight. Two comments reported

<sup>65</sup> Transcript, vol. 3, pp. 101-174.

<sup>66</sup> FDA assumes that the first review referred to by the comment is the 1995 meeting of the OWG and FAC and that the second review referred to by the comment is the 1998 meeting of the FAC.

<sup>67</sup> The publications submitted with the comment are the same as those discussed in the previous comment (Refs. 39 through 41).

<sup>68</sup> The survey was conducted in May 1996 by Drs. Walter Willett and Meir Stampfer of the Department of Nutrition, Harvard School of Public Health.

<sup>63</sup> FDA notes that in its report, the panel considered the 1999 research articles referred to by CSPI (Refs. 39 through 41).

<sup>64</sup> FDA notes that the addition of vitamin A to olestra-containing foods compensates for any provitamin A losses caused by the inhibitory effect of olestra on carotenoid absorption.