

concluded that the available data did not establish any identifiable nutritional or prophylactic benefits for carotenoids, either individually or collectively, aside from the provitamin A function (61 FR 3118 at 3147–3149).

Thus, FDA found no scientific basis for requiring the addition of any carotenoid to olestra-containing foods. The agency also found that the actual magnitude of olestra's effects on carotenoid absorption was likely to be within the range of the normal variation of such absorption due to diet and bioavailability, providing additional assurance that the effect of olestra on the absorption of carotenoids did not raise concern. Accordingly, FDA concluded that there was no basis for requiring a statement about carotenoids on the label of olestra-containing food.

### *B. Opportunity for Comment and Consideration of New Data*

#### 1. Request for Comments on the Label Statement Required by the 1996 Final Rule

Because section 409 of the act prohibits, among other things, approval of a food additive if doing so would cause misbranding, the agency concluded that the olestra label statement should be imposed as a requirement as part of the food additive petition process (§ 172.867(e)). The agency acknowledged, however, that the specific wording had not been tested or subject to an opportunity for comment. Thus, the agency requested comments on the label statement from interested persons on such issues as the need for labeling, the adequacy of its content, and the agency's current word choices (61 FR 3118 at 3160).

After the publication of the 1996 final rule, the agency received timely comments on the label statement,<sup>4</sup> as well as objections to the 1996 final rule.<sup>5</sup>

#### 2. P&G's Commitment To Further Studies

In a letter to the agency dated January 24, 1996, the petitioner stated its intention to conduct focus group testing

of the required olestra label statement, to establish a postmarket surveillance system, to conduct additional studies of olestra exposure (both amounts consumed and patterns of consumption), and to conduct additional studies regarding the effects of olestra consumption (61 FR 3118 at 3160 and 3168). FDA responded that P&G was to conduct the studies it had identified in its letter to FDA, consistent with the timetables identified in that letter (61 FR 3118 at 3168).

P&G did carry out the surveillance and studies outlined in its letter of commitment, and performed additional studies not mentioned in the January 1996 letter. After the publication of the 1996 final rule, P&G carried out its commitment to establish a system of passive surveillance to collect spontaneous reports of possible effects that consumers associated with the consumption of olestra-containing snacks. This system included establishing an outside panel of medical experts to review reports, followup on reports of serious illness, and provide FDA information about reports received.

P&G also carried out its commitment to conduct studies on the exposure and effects of olestra. The active surveillance program that P&G sponsored was designed to examine the impact of olestra consumption on endpoints such as serum concentrations of carotenoids and vitamins, olestra consumption patterns (including frequency and amounts), and GI symptoms.

These data and information were presented to the FAC in June 1998, and were eventually incorporated into the petition that is the subject of this rulemaking.

#### 3. FDA's Commitment To Convene an FAC Meeting

In the 1996 final rule, FDA committed to review and evaluate any new data and information bearing on the safety of olestra and to present such information to the agency's FAC within 30 months of the approval of the use of olestra in savory snacks (61 FR 3118 at 3168–3169; § 172.867(f)).

FDA convened a meeting of its FAC within 30 months of the approval of the use of olestra in savory snacks. At an open public meeting, held June 15–17, 1998, new data and information concerning olestra, obtained since the 1996 approval were presented (Ref. 1). These new data, which comprise the majority of material that P&G subsequently submitted in its petition, are discussed in section III of this document. FDA, P&G, the Center for Science in the Public Interest (CSPI), and other interested members of the

public made presentations to the Committee. After presentation of the new data, the FAC discussed the label statement specified in § 172.867(e). The complete set of transcripts of the June 1998 FAC meeting ("the transcript" or "transcript") is publicly available through FDA's Division of Dockets Management and through FDA's Internet site.<sup>6</sup>

#### 4. P&G's Petition To Remove the Requirement for the Label Statement

P&G submitted a food additive petition, dated December 1, 1999, to amend the food additive regulations in § 172.867 *Olestra* by removing the requirement for the label statement prescribed in § 172.867(e). This petition incorporated the studies and information that were performed after the publication of the 1996 final rule. As noted, much of that material was discussed by the FAC in 1998.

#### 5. Comments Received

FDA received approximately 80 letters, each containing one or more comments, on the olestra label statement.<sup>7</sup> Some of the comments were submitted in response to FDA's request in the 1996 final rule for comments on the olestra label statement. Other comments were submitted in response to the January 24, 1996, announcement of the approval of olestra for use in savory snacks. Because all of these comments addressed P&G's original petition, which was granted in 1996, in this document FDA refers to these comments as comments "to the 1996 final rule." Comments were also submitted in response to publication in the **Federal Register** of the filing notice for the current petition (65 FR 11585, March 3, 2000); in this document, FDA refers to these comments as comments "to the current petition."

Comments were submitted by P&G, Frito-Lay, Inc. (Frito-Lay), and other members of the food industry, as well as from individual consumers, consumer organizations, academia, trade associations, and a member of Congress. Several comments were filed by CSPI. Several parties, including Frito-Lay and

<sup>4</sup> The comments received by April 1, 1996, included the results of P&G's consumer focus group studies on the label statement. Frito-Lay also submitted consumer perception studies on the olestra label statement. These studies are discussed in section III.F.1 of this document. The agency continued to receive comments on the label statement after April 1, 1996. In this document, FDA addresses comments received on the label statement regardless of whether the comments were received by April 1, 1996.

<sup>5</sup> Timely objections were to be filed by February 29, 1996. FDA's response to these objections and requests for hearing is published elsewhere in this issue of the **Federal Register**.

<sup>6</sup> The Internet site is located at <http://www.fda.gov/ohrms/dockets/ac/cfsan98t.htm#FoodAdvisoryCommittee> (choose June 15, 16, and 17).

<sup>7</sup> FDA notes that one of the objections submitted by CSPI concerns the label statement required by the 1996 final rule.

<sup>8</sup> Although not part of the petition being considered in the current rulemaking, FDA reviewed comments regarding labeling that were addressed to the 1998 FAC. These comments raised no substantive issue that was not already considered as part of the current food additive petition.