

required by the Federal Advisory Committee Act (FACA). FDA also believes that there is no basis to conclude that the 10 nutrition experts at the FAC meeting were not able to understand the views and information presented on carotenoids (61 FR 3118 at 3164).

As part of the 1996 final rule, FDA announced its intention to review and evaluate all data and information bearing on the safety of olestra received by the agency within the first 30 months after the approval of olestra and to present an evaluation of the data to the agency's FAC (§ 172.867(f)). Consistent with its obligation, in 1998 FDA presented to the FAC an evaluation of the data and information obtained since the 1996 approval of olestra. The purpose of the presentation was to receive advice from the Committee on whether there continued to be reasonable certainty that use of olestra is not harmful. Specifically, the 1998 FAC was asked to evaluate whether data and information obtained since the approval of olestra raised safety concerns regarding any GI effects that were not anticipated at the time of olestra's approval and whether any newly available data showed that consumption of olestra-containing foods had a significant adverse health effect due to olestra's interference with absorption of fat-soluble vitamins or other lipophilic substances.<sup>72</sup> The committee was also asked whether the label statement should be changed in light of new data and information. Because the FAC was asked if there were any new issues raised since the approval of olestra, the committee was asked to consider only the data and information obtained since the approval of olestra. Much of the new data focused on the effects of "real life" consumption of olestra-containing foods (*i.e.*, the Rechallenge Study, the Acute Consumption Study, and the Home Consumption Study). The studies conducted prior to the approval of olestra, such as the Fecal Parameters Study, examined the effects of olestra when consumed under conditions designed to assess safety and were previously considered by FDA in its review of the petition for the use of olestra in savory snacks. Although the 1998 FAC did not consider the petitioner's Fecal Parameters Study, the committee did consider the Stool Composition Study. Like the Fecal Parameters Study, the Stool Composition Study was designed to examine olestra's effect on objective stool characteristics but tested a higher

dose of olestra and collected stool samples on a greater number of days than was done in the Fecal Parameters Study. The committee also considered FDA's analysis of the reports collected through passive surveillance by P&G and CSPI, which include reports of GI symptoms such as diarrhea and abdominal pain.<sup>73</sup> Upon review of the data and information received since the 1996 final rule, a majority of the FAC concluded that there continues to be reasonable certainty of no harm concerning the use of olestra in savory snacks.<sup>74</sup> FDA believes that the data and information considered by the 1998 FAC were appropriate for the objective of the meeting, to determine whether the data and information obtained since the approval and marketing of olestra raise any issue not anticipated at the time of approval.

## VI. Summary

In its petition, P&G requested that FDA amend the food additive regulations in § 172.867 *Olestra* by removing the requirement for the label statement prescribed in § 172.867(e). Based on its analysis of data and information in the petition, as well as data and information in FAP 7A3997 (which resulted in the establishment of § 172.867(e)), FDA has concluded that olestra-containing foods should no longer be required to bear a label statement informing consumers of possible GI symptoms from consumption of olestra. FDA also has concluded that olestra-containing foods should no longer be required to bear a label statement informing consumers of possible effects of olestra on the absorption of some vitamins and other nutrients. Finally, FDA has concluded that olestra-containing foods should no longer be required to bear a label statement informing consumers that vitamins A, D, E and K have been added. Instead, the listing of the vitamins in the ingredient statement of olestra-containing foods will now be followed by an asterisk that is linked to the statement "Dietarily insignificant."

## VII. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

<sup>73</sup> Transcript, vol. 1, pp. 258–270.

<sup>74</sup> Transcript, vol. 3, pp. 101–174.

## VIII. Inspection of Documents

In accordance with § 171.1(h), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition (*see ADDRESSES*) by appointment with the information contact person. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

Additionally, a copy of P&G's December 1999 petition and additional supporting material that P&G supplied are publically available at the Division of Dockets Management (Docket No. 00F–0792).

## IX. Objections

Any person who will be adversely affected by this regulation may file with the Division of Dockets Management (*see ADDRESSES*) written or electronic objections by (*see DATES*). Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

## X. References

The following references have been placed on display in the Division of Dockets Management (*see ADDRESSES*) and may be seen by interested persons between 9 a.m. and 4 p.m. Monday through Friday.

1. Transcript of the meeting of the Food Advisory Committee (vols. 1–3), Reston, VA, June 15 through 17, 1998.

2. Memorandum from K. C. Klontz, FDA to M. Ditto, FDA, February 13, 1998.

<sup>72</sup> Transcript, vol. 1, pp. 22–25.