

June 28, 2002

Michael F. Jacobson, Ph.D.
Executive Director
Center for Science in the Public Interest
1875 Connecticut Ave., N.W.
Washington, D.C. 20009-5728

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Dear Dr. Jacobson:

This is in response to your letter of April 16, 2002, concerning the food additive, olestra. Along with your letter of April 16, you submitted two attachments¹: Attachment II, "Center for Science in the Public Interest (CSPI), Olestra Adverse-reaction Reports, Seventh Report to the FDA," and Attachment III, "Summaries of Adverse Reaction Reports of People Who Consumed Olestra." Attachment II summarizes data on 206 case reports collected between May 5, 2000 and January 31, 2002. Attachment III is a sample of summary descriptions of individual reports of adverse events attributed to olestra consumption. These materials have been entered into the record for Food Additive Petition Numbers 7A3997 and 0A4708.

You have stated in your letter that these reports are similar to those previously submitted by CSPI or Procter & Gamble (P&G), and that FDA has received many reports of adverse reactions attributed to the consumption of olestra, including reports of hives. You expressed that P&G has not sent FDA a report on adverse events in over a year. You recommend that FDA reject P&G's petition on removal of the label on olestra-containing snack products and instead make the label more prominent.

As you know, FDA has considered the reports received from both CSPI and P&G concerning adverse events attributed to olestra and discussed these at a Food Advisory Committee (FAC) meeting held June 15-17, 1998. While we received additional reports of a similar nature since that time, we know of no new issues that have not been considered previously. P&G continued to provide periodic reports through January 2001, and submitted a publication in June 2001 that discussed the data collected through passive surveillance (Postmarketing Surveillance of New Food Ingredients: Results from the Program with the Fat Replacer Olestra. Regulatory Toxicology and Pharmacology 33, 224-233 (2001)).

Regarding the issue of rechallenge studies on individuals who reported allergic reactions to the

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¹ We note that we received two attachments, Attachments II and III.

consumption of snacks containing olestra, P&G submitted to FDA a published study on November 19, 2001, entitled, "Randomized, Double-Blind, Placebo-Controlled, Food Allergy Challenge to Olestra Snacks (Regulatory Toxicology and Pharmacology 34, 178-181 (2001)). In this study a number of people who reported having an allergic reaction to olestra snacks were rechallenged. That study reports that none of the individuals were found to have a positive response to olestra upon eating olestra-containing potato chips or to a skin prick test with olestra.

The agency is currently considering a food additive petition (FAP 0A4708) concerning the label statement that FDA required on an interim basis at the time of the agency's approval of olestra. We note that CSPI has filed comments on this petition. The agency is considering, and will respond to, all substantive comments on the petition based on the data and the science at the time that the agency issues an order that approves or denies the petition.

As with all additives in the food supply, FDA will continue to monitor and evaluate all data and information that bear on the safe use of olestra.

Sincerely yours,

Alan M. Rulis, Ph.D.
Director
Office of Food Additive Safety
Center for Food Safety
and Applied Nutrition

cc:HF-1 HF-2 HF-10 HF-40 HF-41 HFA-224 HFA-305 HFS-1 HFS-22 HFS22CCO HFS-200

HFS-205 HFS-255 **FAP 7A3997 FAP 0A4708**

R/D:HFS-255:MDDitto:5/1/02: HFS-205:GHPauli:5/1/02: HFS:255-LSKahl:5/2/02

418-3102:Jacobs17b FDA #02-2328 CTS # 80299

INIT: HFS-200:AMRulis:5/02/02

HFS-001:JALevitt:6/18/02

F/T: HFS-255:ADarby: 6/28/02