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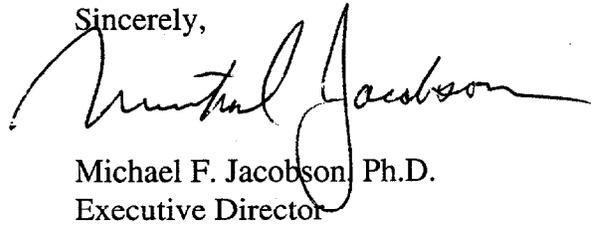
Dr. Mary Ditto
Center for Food Safety and Applied Nutrition
FDA
200 C St. SW HFS-206
Washington, DC 20204

Re: Olestra

Dear Dr. Ditto:

I have enclosed a copy of a letter to the editor of the *Annals of Internal Medicine*. The letter comments on a study that belittled the possibility that olestra causes gastrointestinal symptoms. I would appreciate your adding it to the docket on olestra.

Sincerely,



Michael F. Jacobson, Ph.D.
Executive Director

1999 DEC 16 P 3:46

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Annals of Internal Medicine

LETTER

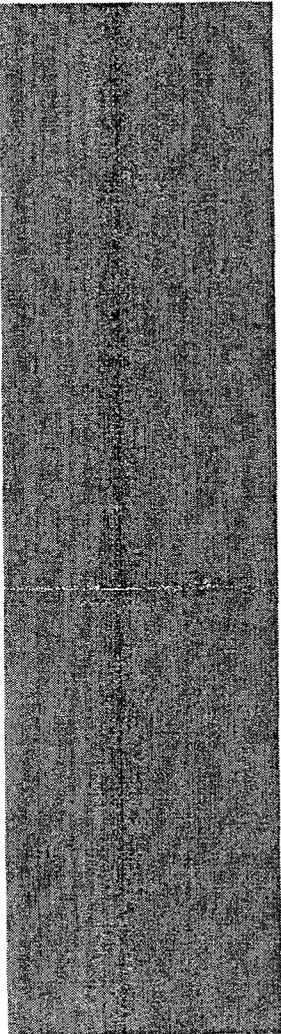
**Olestra Snacks Compared with
Regular Snacks***Annals of Internal Medicine*, 7 December 1999.Related Article

To the Editor: Sandler and colleagues (1) state that anecdotal reports of severe diarrhea and abdominal pain associated with ingestion of olestra have not been substantiated by controlled testing. In fact, several clinical trials have shown such effects.

Procter & Gamble (the maker of olestra) conducted two 8-week studies indicating that daily consumption of 20 g of olestra (equivalent to 2.5 ounces of potato chips) increased rates of loose stools and diarrhea, fecal urgency, and flatulence. The Food and Drug Administration (FDA) concluded that those studies showed that olestra causes increased rates of severe symptoms (2). On the basis of those and other studies, the FDA requires a notice—"Olestra may cause abdominal cramping and loose stools"—on products containing olestra. Another Procter & Gamble study tested persons who thought they had previously reacted to olestra. That study confirmed that eating 20 g of olestra daily for several days can cause severe diarrhea (Klontz K. Personal communication to Thorsheim H. Food and Drug Administration, 26 December 1995). A study (underwritten by Unilever) found that daily consumption of olestra (mean, 24 g/d) increased "urgent calls to stool" and other symptoms (3).

Sandler and colleagues state that "clinically meaningful" symptoms are not associated with unregulated consumption of olestra. Still, in the highest decile of consumers, olestra doubled the incidence of more frequent bowel movements and loose stools. These persons had symptoms on 18% of person-days, compared with only 12% of days in the control group (the authors' Table 4). Olestra consumers missed some or all of their activities on 0.4% of days, compared with 0.2% in the controls.

The FDA has received more than 20 000 reports of gastrointestinal symptoms attributed to olestra, including



hundreds from people who went to emergency departments or physicians' offices. Clinicians should be aware that olestra may cause severe gastrointestinal symptoms and should question patients about their consumption of foods containing olestra.

Michael F. Jacobson, PhD
Center for Science in the Public Interest
Washington, DC 20009

References

1. **Sandler RS, Zorich NL, Filloon TG, Wiseman HB, Lietz DJ, Brock MH, et al.** Gastrointestinal symptoms in 3181 volunteers ingesting snack foods containing olestra or triglycerides. A 6-week randomized, placebo-controlled trial. *Ann Intern Med.* 1999;130:253-61.
2. Food and Drug Administration. Food additives permitted for direct addition to food for human consumption: olestra, final rule. *Federal Register.* 1996;61:3117-73.
3. **Kelly SM, Shorthouse M, Cotterell JC, Riordan AM, Lee AJ, Thurnham DI, et al.** A 3-month, double-blind, controlled trial of feeding with sucrose polyester in human volunteers. *Br J Nutr.* 1998;80:41-9.

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