

the subjects' stool water content increased when they consumed olestra. Thus, FDA is denying CSPI's hearing on this point (§ 12.24(b)(3)).

V. Summary and Conclusion

The act requires that a food additive be shown to be safe prior to marketing under section 409 of the act. Under § 170.3(i), a food additive is "safe" if there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use. In the agency's January 30, 1996, final rule approving olestra, FDA concluded that the studies conducted to establish the

safety of this additive demonstrate that olestra is safe for its intended use in savory snacks.

The petitioner has the burden to demonstrate the safety of the additive in order to gain FDA approval. Nevertheless, once FDA makes a finding of safety in an approval document, the burden shifts to an objector, who must come forward with evidence that calls into question FDA's conclusion (*American Cyanamid Co. v. FDA*, 606 F2d. 1307, 1314–1315 (D.C. Cir. 1979)).

Despite its many allegations, CSPI has not established that FDA overlooked significant information in the record in reaching its conclusion that olestra is

safe. In such circumstances, FDA has determined that the objections do not raise any genuine and substantial issue of fact that would justify an evidentiary hearing on any of the objections raised (§ 12.24(b)). Accordingly, FDA is overruling CSPI's objections and is denying CSPI's requests for a hearing in their entirety.

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Assistant Commissioner for Policy.

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