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Lester M. Crawford, D.V.M., Ph.D.
Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane (HF-1/14-71/PKLN)
Rockville, MD 20857

Dear Deputy Commissioner Crawford,

This is a note in regard to the apparent FDA change in policy regarding food recalls for allergen mislabeling. The Food Allergy and Anaphylaxis Network has indicated that they are aware of several instances when persons had a reaction to undeclared allergen (that was verified with testing) and yet a recall was not suggested. Apparently, there has been a paradigm shift in regard to allergen recalls. I am very worried about this apparent policy change and its implications for the safety of persons with food allergy. While recalls are voluntary, FDA oversight is essential to ensure the safety of persons with food allergy.

I am a researcher and clinician at the Jaffe Food Allergy Institute in New York, advisor to the Food Allergy and Anaphylaxis Network, the Food Allergy Initiative, and the International Food Information Council. I am funded by the NIH and USDA for food allergy research. I am also Chair of the Committee on Adverse Reactions to Foods of the American Academy of Allergy, Asthma and Immunology. Finally, among numerous studies I have published regarding clinical issues in food allergy, I have also published studies concerning consumer issues related to mislabeled/poorly labeled foods.^(1;2) Ironically, my career in food allergy research began because of a call to the institution where I was training (Johns Hopkins) during which an FDA official was asking me about the various risks attributable to food contamination with tree nuts and the need for recalls.

While my community activities and research makes me expert in regard to issues in food allergy, it is my experience in patient care that drives home for me the importance of re-evaluating this apparent shift in FDA policy. Our patients are not being protected if valid complaints are not addressed with an appropriate response. You are certainly aware of the scope of this issue (www.cfsan.fda.gov/~dms/alrgpart.html) and rise in recalls⁽³⁾ that underscore the need for vigilance in this area.

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It is my sincere hope that the issue raised by FAAN is not representative of a paradigm shift and that the FDA will continue to monitor issues regarding allergen mislabeling with appropriate responses including recalls. I would be pleased to discuss the issue further with you or a representative

Sincerely,



Scott H. Sicherer, MD
Associate Professor of Pediatrics

References

- (1) Altschul AS, Scherrer DL, Munoz-Furlong A, Sicherer SH. Manufacturing and labeling issues for commercial products: relevance to food allergy. *J Allergy Clin Immunol* 2001; 108(3):468.
- (2) Joshi P, Mofidi S, Sicherer SH. Interpretation of commercial food ingredient labels by parents of food- allergic children. *J Allergy Clin Immunol* 2002; 109(6):1019-21.
- (3) Vierk K, Falci K, Wolyniak C, Klontz KC. Recalls of foods containing undeclared allergens reported to the US Food and Drug Administration, fiscal year 1999. *J Allergy Clin Immunol* 2002; 109(6):1022-6.

CC:

Food Allergy & Anaphylaxis Network
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