

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC

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Dear Mr. Emord:

On October 24, 2000, I notified you by letter that the Food and Drug Administration (FDA) intended to complete its review of a health claim for omega-3 fatty acids with respect to coronary heart disease (Docket No. 91N-0103) by October 31, and its review of a health claim for antioxidant vitamins with respect to cancer (Docket No. 91N-0101) by November 30.

As you know, the agency issued its decision on the omega-3 fatty acids health claim on October 31. Further, in connection with Whitaker v. Shalala, Civil Action No. 00-0123, FDA issued its decision on a health claim for B vitamins with respect to vascular disease (Docket No. 99P-3029) on November 28, 2000. With respect to the health claim for antioxidant vitamins, the agency has been working steadily, and this review has been the highest priority for the staff involved. Nonetheless, I must regretfully inform you that the agency has not yet completed its review.

As I stated in my earlier letter, FDA's review of the claim for antioxidant vitamins with respect to cancer has been complicated by the large number of new human studies that were conducted since FDA's original 1991-1993 review. Moreover, because of the skills and expertise needed, many of the same scientific staff and management staff assigned to this review were also assigned to the omega-3 fatty acid claim and the B vitamin claim. Despite the fact that these staff have been working diligently to complete the antioxidants review, it simply is not yet done. At this time, I expect that we will be able to issue our decision by December 22, 2000.

Again, I sincerely apologize for this additional delay. I know this must be extremely frustrating for you and your clients. Please be assured that FDA regards this matter with the utmost seriousness and importance, and that we are working as hard as we can; but for the complexity of the health claim for antioxidants, and the need for the same staff to work on the

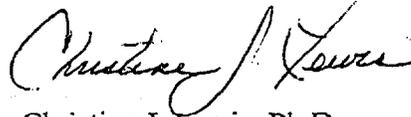
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health claim for B vitamins, we would have completed our consideration of antioxidants by now. In any event, all of us fully appreciate the need to complete this review as quickly as possible. The agency greatly appreciates your continued patience.

Sincerely,



Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition