



Food and Drug Administration  
Washington, DC

OCT 24 2000

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Dear Mr. Emord:

I notified you by a letter dated October 10, 2000, that the Food and Drug Administration (FDA) intended to complete its review of health claims for omega-3 fatty acids with respect to coronary heart disease (Docket No. 91N-0103), and for antioxidant vitamins with respect to cancer (Docket No. 91N-0101) by October 24. The agency has made every effort to complete these reviews within that timeframe. These reviews have been the highest priority for the staff involved. Because of the skills and expertise needed, however, many of the same scientific staff, as well as management staff, are assigned to both reviews. Most of these staff also worked on one or both of the reviews completed on October 10. Due to the complexity of the issues raised by the reviews of both the omega-3 fatty acids claim and the antioxidant vitamins claim, as well as staffing constraints, we are not able to bring the reviews to completion by the anticipated date.

With respect to the omega-3 fatty acids review, the new and complex issues raised by the use of a qualifier with a health claim have prevented the agency from completing the review within the timeframe we set forth two weeks ago. FDA is in the process of finalizing its evaluation of an appropriately qualified claim, and plans to issue its decision letter by October 31, 2000.

For the antioxidant and cancer claim, a large number of new human studies have been conducted since the agency's original 1991-1993 review. The agency's review has been further complicated by the fact that the proposed claim addresses relationships between more than one nutrient and a number of different types of cancers. The agency has reluctantly concluded it needs additional time to consider fully the complexity of the claims and the relevant information available in the record. The agency expects that it will complete its review and issue the decision letter by November 30, 2000.

I apologize for the additional delays. The agency greatly appreciates your patience.

Sincerely,

Christine J. Lewis, Ph.D.  
Director  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

91N-0103

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