



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

FEB 23 2001

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VIA FACSIMILE AND U.S. MAIL

Jonathan W. Emord, Esq.  
Emord & Associates, P.C.  
1050 17th Street, N.W.  
Suite 600  
Washington, D.C. 20036

Dear Mr. Emord:

On December 22, 2000, I notified you by letter that the Food and Drug Administration (FDA) intended to complete its review of a health claim for antioxidant vitamins with respect to cancer (Docket No. 91N-0101) by February 23, 2001.

The agency has continued to work steadily on the review of the antioxidant vitamins claim, and this review is the highest priority for the staff involved. I must, however, regretfully inform you that the agency has not yet completed its review.

As I stated in earlier letters, 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 1991-93 review. Further complicating the agency's review is the fact that the proposed claim addresses relationships between a number of antioxidant vitamins and a number of different types of cancers. FDA is closely examining the evidence regarding the relationship between each antioxidant vitamin and each cancer. FDA's response will be quite lengthy. Although the scientific and management staff have continued to work diligently, this complex review is not yet done. Further, some of these same staff were needed to respond to your correspondence with respect to your proposed vitamin B claim. These factors have prevented us from meeting the February 23, 2001, deadline.

We are continuing to work as hard as we can to complete the antioxidants review. At this time, we now expect to be able to issue our decision by March 30, 2001. The agency

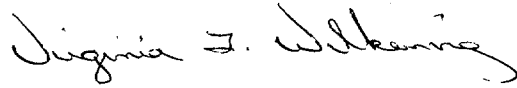
91N-0101

LET'S

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sincerely apologizes for this further delay. We fully appreciate the need to complete this review as soon as possible and we continue to make every effort to do so. The agency appreciates your ongoing patience.

Sincerely,

A handwritten signature in cursive script, appearing to read "Christine J. Lewis".

for Christine J. Lewis, Ph.D.  
Director

Office of Nutritional Products, Labeling  
and Dietary Supplements

Center for Food Safety  
and Applied Nutrition