



DEC 5 2 2000 11:11 AM -1 P2:35

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

Dear Mr. Emord:

On November 30, 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 December 22.

The agency has continued to work steadily on the review of this claim, as well as the review of a health claim for E vitamins that is at issue in Whitaker v. Shalala, Civil Action No. 00-0123 (Docket No. 99P-4375). We are also carefully considering your letter of December 12, 2000, regarding the agency's actions with respect to "Petition for Health Claim: Folic Acid, Vitamin B6, and Vitamin B12 Dietary Supplements and Vascular Disease" (Docket No. 99P-3029). The review of the antioxidant vitamins claim has remained the highest priority for the staff involved. I must, however, regretfully inform you that the agency has not 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, the agency's review has been complicated by the fact that the proposed claim addresses relationships between antioxidant vitamins and a number of different types of cancers. Each of these multiple relationships needs to be evaluated individually. Although the scientific and management staff have continued to work diligently to complete the antioxidants review, this complex review is not yet done. At this time, we now expect to be able to issue our decision by February 23, 2001.

The agency sincerely apologizes for this further delay. We are continuing to work as hard as we can to complete the antioxidants review. The quantity of analysis required for that has prevented us from meeting the December 22, 2000, deadline.

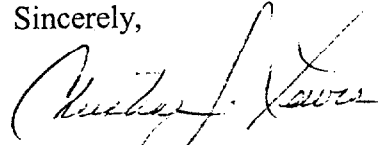
91N-0101

LET 4

Page-2 Jonathan W. Emord, Esq.

We fully appreciate the need to complete this review as soon as possible and are making every effort to do so. The agency appreciates your ongoing patience.

Sincerely,

A handwritten signature in black ink, appearing to read "Christine J. Lewis". The signature is fluid and cursive, with a large initial "C" and "L".

Christine J. Lewis, Ph.D.

Director

Office of Nutritional Products, Labeling
and Dietary Supplements

Center for Food Safety
and Applied Nutrition