



Food and Drug Administration
5100 Paint Branch Parkway
College Park, Maryland 20740

MAY 23 2006

Mr. Robert M. DeWitty, Esq.
Vigconic (International) Ltd.
111 S. Calvert Street Suite 2700
Baltimore, Maryland 21202

Re: Docket No. 2005-P0495

Dear Mr. DeWitty:

This letter responds to your citizen petition dated December 13, 2005 requesting that the Food and Drug Administration (FDA) clarify, in writing, and FDA letter received in response to a premarket notification.

In accordance with Title 21 of the Code of Federal Regulations (21 CFR) 10.30(e)(2), this letter is to advise you that we have not been able to reach a decision on your petition within the first 180 days of its receipt because of other Agency priorities and the limited availability of resources.

Sincerely yours,

A handwritten signature in cursive script that reads "Barbara O. Schneeman".

Barbara O. Schneeman, Ph.D.
Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

2005P-0495

LET 1