



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
College Park, MD 20740

NOV 20 2006

Charles J. Raubicheck, Esq.  
Frommer Lawrence & Haug LLP  
745 Fifth Avenue  
New York, New York 10151

Re: PHASE-2® (Phaseolus vulgaris) Pharmachem Laboratories, Inc.  
Structure/Function Claims

Dear Mr. Raubicheck:

This letter is in follow-up to our November 3, 2006, discussion regarding proposed claims for Pharmachem Laboratories' PHASE 2 ingredient.

In response to the November 19, 2004, Warning Letter and subsequent correspondence, you submitted data and information to us on January 27, 2005; September 20, 2005; October 21, 2005; and April 19, 2006. Based on the review of your submission, we do not object to the following structure/function claims for this dietary ingredient or for dietary supplement products containing this ingredient:

- "May assist in weight control when used in conjunction with a sensible diet and exercise program."
- "May reduce the enzymatic digestion of dietary starches."

Thank you for your patience in this matter.

Sincerely,

Michael M. Landa  
Deputy Director  
for Regulatory Affairs  
Center for Food Safety  
and Applied Nutrition