

## Expert Opinion Letter

### Evaluation of the Generally Recognized as Safe (GRAS) Status of Phase 2<sup>®</sup> White Bean (*Phaseolus vulgaris*) Extract

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The undersigned, recognized Experts (hereinafter "Experts"), qualified by scientific training and relevant international experience to evaluate the safety of food and food ingredients, was requested by Pharmachem Laboratories, Inc. to assess the safety of the use of Phase 2<sup>®</sup>, also known as Phaseolamin 2250<sup>®</sup> and Phase 2 Starch Neutralizer<sup>™</sup>, a standardized extract derived from the common white bean (*Phaseolus vulgaris*) that has been shown to inhibit the activity of the digestive enzyme  $\alpha$ -amylase. Alpha-amylase is an enzyme found in plants, animals, and microorganisms that catalyzes the hydrolysis of complex carbohydrates into simpler saccharides such as maltose and glucose that can be absorbed. Inhibition of human  $\alpha$ -amylase may promote weight loss by hindering the digestion of complex carbohydrates, thereby reducing the absorption of carbohydrate-derived calories.

Pharmachem Laboratories, Inc., hereafter referred to as Pharmachem, wishes to establish by scientific procedures that the use of Phase 2<sup>®</sup> for nutritive value, by impairing carbohydrate digestion, may be self-affirmed to be Generally Recognized as Safe (Self-GRAS) as a dietary supplement and for general addition to qualified foods for which no defined standard of identity exists. Self-GRAS is proposed for use at levels providing an upper limit of aggregate intake of 6 g of Phase 2<sup>®</sup> per day from dietary supplement and qualified food use applications.

A GRAS determination for the Phase 2<sup>®</sup> product was based on the weight of the information provided in a comprehensive report prepared by CANTOX U.S. Inc., to assist the Experts. This report was a compilation of documentation supporting the safety of Phase 2<sup>®</sup> under the intended conditions of use. The Experts independently and critically evaluated the report and other materials deemed appropriate, and conferred by telephone.

The following summary basis for the discussion of GRAS status was provided in the report and evaluated by the Experts:

- The source material of the Phase 2<sup>®</sup> aqueous extract, the common white kidney bean (*Phaseolus vulgaris*), possesses a long history of safe use in the human diet when cooked and eaten as food;
- Phase 2<sup>®</sup> manufacturing process is well controlled and yields consistent product quality;