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# EXPERT PANEL CONSENSUS STATEMENT CONCERNING THE GENERALLY RECOGNIZED AS SAFE (GRAS) STATUS OF YEAST BETA-GLUCAN FOR USE AS A FOOD INGREDIENT

## INTRODUCTION

At the request of Biothera Inc. (Biothera), an Expert Panel (the "Panel") of independent scientists, qualified by their relevant national and international experience and scientific training to evaluate the safety of food ingredients, was specially convened to conduct a critical and comprehensive evaluation of the available pertinent data and information on yeast beta-glucan, and determine whether, under the conditions of intended use as a food ingredient, yeast beta-glucan, derived from bakers yeast, *Saccharomyces cerevisiae*, would be safe and Generally Recognized as Safe (GRAS) based on scientific procedures. In the United States, bakers yeast extract is affirmed as GRAS for direct addition to food, and bakers yeast protein and glycan are permitted direct food additives. The Panel consisted of the below-signed qualified scientific experts. Prof. Joseph F. Borzelleca, Ph.D. (Virginia Commonwealth University, Medical College of Virginia), Prof. Robert J. Nicolosi, Ph.D. (University of Massachusetts Lowell), and Prof. Gary M. Williams, M.D. (New York Medical College) *Curricula vitae* evidencing the Panel members' qualifications for evaluating the safety of food ingredients are provided in Attachment 1

The Panel, independently and collectively, critically examined a comprehensive package of data provided by Biothera and compiled by Cantox Health Sciences International (Cantox). In addition, the Panel evaluated other information deemed appropriate or necessary, including scientific data obtained from the literature and other published sources through September 2006 by Cantox. The information evaluated by the Panel included data pertaining to the method of manufacture and product specifications of the yeast beta-glucan ingredient, supporting analytical data, information establishing the compositional similarity of Biothera's yeast beta-glucan to bakers yeast glycan, the intended use levels of yeast beta-glucan in specified food products, consumption estimates for all intended uses, background dietary consumption of bakers yeast and ingredients derived thereof, and a comprehensive assessment of the available scientific literature pertaining to the safety of yeast and other beta-glucan ingredients.

Following independent critical evaluation of such data and information, the Panel convened on 27 November 2006 and unanimously concluded that the proposed uses in traditional foods described herein for yeast beta-glucan derived from *S. cerevisiae*, meeting appropriate food-grade specifications and manufactured according to current Good Manufacturing Practice (cGMP), are safe. The Panel further concluded that these uses are GRAS based on scientific procedures. A summary of the basis for the Panel's conclusion is provided below