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Borrowed Science is Junk Science

By Don Cox, PhD, vice president, Healthcare Group Research and Development

The FTC's position that research supporting the safety and efficacy of probiotics must be strain-specific has implications for another immune-enhancing ingredient: beta glucans.

For years, beta glucan marketers have pointed to a large body of research as evidence of the immune benefits of their ingredients. Often times most, if not all, of the research was conducted

with a glucan product other than their own. In some cases, the glucans were not even of the same source. Some were mushroom-based glucans while others were derived from cereal grains or yeast.

New research from Biothera debunks the myth that all beta glucans are created equal. At the National Cancer Institute's Frontiers in Basic Immunology meeting last year, Biothera presented data demonstrating that subtle differences in the molecular structure of various beta 1,3/1,6 glucans can significantly affect their ability to enhance innate immune system responses.¹ In other words, structure matters.

Derived from the cell walls of yeast, fungi, cereal grains and other sources, beta glucans are polysaccharides characterized by a basic structure of chains of glucose molecules. Glucans from different sources can vary in terms of backbone structure, presence of/absence of branching linkages, frequency and length of these linkages, molecular weight and higher order aggregates that naturally form. Biothera's research demonstrated that even slight variations in these characteristics might affect bioactivity.²

To illustrate this point, Biothera conducted an *in vivo* study using three similar beta 1,3/1,6 glucans from three separate sources. In the face of a health challenge, the survival rate of animals given Biothera's Wellmune WGP[®] was more than double of those receiving the same dose of other sources of beta glucans with similar primary structures. In



Biothera's Wellmune WGP is the subject of six clinical studies that are peer-reviewed and published, or pending publication.

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addition, an *in vitro* assessment found that the Wellmune WGP had the highest level of human immune cell (neutrophil) bind-

ing, resulting in more activated immune defenders. Even among glucans with similar structures, the differences in bioactivity can be significant.

For food scientists, it is important to evaluate a beta glucan based on research using that specific ingredient. Research supporting one beta glucan does not necessarily support another because of the differences in molecular characteristics and functional properties.

"These kinds of results emphasize the importance of exploring the health implications of food ingredients at the molecular level, and demonstrating the safety and efficacy of those ingredients on finished food products," said Roger Clemens, DrPH, CNS, FACN, FIFT, adjunct professor at the USC School of Pharmacy. "The sophistication of the next generation of food ingredients and more healthful food products requires interdisciplinary teams that encompass the breadth of food, nutrition and health sciences."

In addition to confirming the existence of product-specific research, food, beverage and supplement manufacturers would benefit from asking the following questions when evaluating beta glucan products:

- How has the ingredient's safety been verified? The data package should be published in a peer-reviewed toxicology and related scientific journal, and reviewed by leading governmental regulatory organizations, including the FDA, Health Canada and EU EFSA, as

well as by qualified scientific and medical professionals.

- Is the ingredient well characterized with known composition and basis for its reported health benefits? It is absolutely critical that the beneficial health activity be attributed to a known chemical component(s). Any scientist touting unidentified components as responsible for a proposed health benefit is putting your brand, your company and your customers' safety at risk.

- Has the mechanism of action been elucidated, defined and published? Ingredient characterization is critical to understanding mechanism of action.

- What types of research studies and data are available to support the efficacy of the ingredient? Peer-reviewed, randomized, double-blind, placebo-controlled clinical studies remain the gold standard. Other forms of human clinical studies can be valid and support product efficacy. *In vitro* studies and preclinical are important during the early stages of development, but may not be directly applicable to humans, and their applicability can only be elucidated in classic Phase I, II and III studies.

- How was each clinical study designed? Study design is critical to eliminating unintentional bias on the part of researchers or study subjects through the use of at least double-blinded protocols, if not triple-blinded study designs. The best clinical protocols adhere to ICH (International Committee on Harmonization) guidelines.

A comprehensive review of the research supporting a beta glucan—or any functional ingredient—is critical to distinguishing ingredients that *deliver* real health benefits.

References:

1 Antitumor Activity of Soluble Beta-1,3/1,6 Glucans: Structure Matters. Frontiers in Basic Immunology 2009, Bethesda, MD. Sponsored by the National Cancer Institute.

2 Analysis of Side Chain Lengths of Branched, -1,3-Glucans by Alkaline Degradation. The International Carbohydrate Symposium in Oslo, Norway. August 2008.



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This unique, patented ingredient engages neutrophils — the most abundant immune cell in the body — to more quickly find and kill foreign challenges. Designed for year-round, not merely seasonal, immune support, Wellmune WGP is the ideal ingredient for adding real health benefits to foods, beverages and supplements. Visit us at www.wellmune.com or call 877-699-5100.

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