PolyCell Technologies

Bioactive Solutions for Health and Nutrition

June 25, 2013

Vincent de Jesus
Nutrition Programs Staff
Office of Nutrition, Labeling and Dietary Supplements
Food and Drug Administration
College Park, Maryland 20740

Supplemental Information

Dear Mr. de Jesus:

The following and attachments are supplemental information to clarify questions raised by FDA regarding certain clinical data contained in the Petition to Amend Health Claim – Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease (21 C.F.R. 101.81) submitted by PolyCell Technologies and DKSH Italia.

The questions relate to the control protocol used in a set of clinical studies conducted at the University of Minnesota that included two barley and one oat beta-glucan test groups, along with a common control group. In response to these questions, we have consulted with the authors of these studies and based on their advice, are submitting additional published papers that document the trial protocol, test and control groups, and comparable results. These documents are included in an attachment labeled "Supplemental Information".

Briefly, the University of Minnesota cereal β-glucan trials under the direction of Dr. Joanne Slavin included 2 separate studies of concentrated barley fiber and one study of an enriched oat beta-glucan product. Both barley fiber trials were conducted using barley beta-glucan made by aqueous concentration process known as the glucagel™ method. These studies were conducted sequentially over a period of several years between 2003 and 2006. Each test arm in these trials contained 45 subjects randomly chosen subjects who consumed a form of beta-glucan over a six week period. A common control group consisting of 45 randomly assigned subjects consumed a dextrose placebo over a six week period. Data was collected on lipid parameters, glucose and insulin, satiety, and an array of physical and biochemical parameters. The results were detailed in 7 scientific publications and presentations between 2004 and 2008.

Sincerely yours,

Tom Jorgens

Tom Jorgens
President

Attachment: Supplemental Information

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Supplemental Information

Petition to Amend Health Claim – Soluble Fiber from Certain Foods and Risk of Coronary Heart Disease 21 C.F.R. 101.81 (PolyCell Technologies LLC)

The following pages contain supplemental information to the previously submitted Petition to Amend Health Claim by PolyCell Technologies and DKSH Italia

The documents in this supplement include additional publications from a series of clinical trials with cereal beta-glucan conducted at the University of Minnesota, St. Paul, Minnesota from 2003 to 2006. These documents include:

1) Smith, Kristen N; Queenan, Katherine; Thomas, William; Fulcher, Gary; Slavin, Joanne, Comparison of barley beta-glucan vs. placebo in hypercholesterolemic subjects, Source: FASEB Journal Volume: 18 Issue: 4-5 Pages: Abst. 128.3 Published: 2004.

2) Smith, Kristen N, et. al., Cholesterol lowering effect of barley β-glucan in hypercholesterolemic subjects, Poster presentation at Experimental Bio (FASEB) 2004 (poster companion to publication in above.)

3) Queenan, Katherine; Smith, Kristen; Thomas, William; Fulcher, Gary; Slavin, Joanne, Practical dose of concentrated beta-glucan from oats improves blood lipid profile, FASEB Journal Volume: 19 Issue: 4, Suppl. S, Part 1 Pages: A89 March 4, 2005.

4) Smith, Kristen Nicole; Thomas, Will; Queenan, Katherine; Fulcher, Gary; Slavin, Joanne, Comparison of barley beta-glucan vs. placebo in hypercholesterolemic subjects, FASEB Journal, Volume: 19 Issue: 4, Suppl. S, Part 1 Pages: A89 Published: March 4 2005

5) Queenan, Katie M.; Smith, Kristen, N; Thomas, William; Fulcher, R. Gary; Slavin, Joanne L., Concentrated oat β-glucan, a fermentable fiber, lowers serum cholesterol in hypercholesterolemic adults in a randomized controlled trial, Nutrition Journal, 2007, 6:6 March 2007.

6) Comparison of Outcome Changes from Baseline, Summary Table, Data published in Queenan et.al, Concentrated oat β-glucan, a fermentable fiber, lowers serum cholesterol in hypercholesterolemic adults in a randomized controlled trial, Nutrition Journal, 2007, 6:6 March 2007., and in Smith, Kristen Nicole; Thomas, Will; Queenan, Katherine; Fulcher, Gary; Slavin, Joanne, Physiological Effects of Concentrated Barley b-Glucan in Mildly Hypercholesterolemic Adults. JACN 2008, 27, 3 p 434-440.