



MAR 08 2013

Thomas P. Jorgens
President
PolyCell Technologies LLC
Valley Technology Park
510 County Road 71
Crookston, Minnesota 56716

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

Dear Mr. Jorgens:

This letter acknowledges receipt on February 21, 2013 by the Food and Drug Administration (FDA) of the petition that you submitted, on behalf of PolyCell Technologies LLC and DKSH Italia Srl., pursuant to Section 403(r)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(r)(4)). The petition requests that the agency amend §101.81 to include glucagel barley beta-glucan fiber (Glucagel™) among the certain foods eligible to bear the claim.

The petition is undergoing initial FDA review. In accordance with §101.70, within 100 days of receipt of your petition, you will be notified of FDA's decision to either file the petition for comprehensive review or to deny the petition. A denial may either be by FDA action within the initial 100-day period, which ends on May 31, 2013, or by a lack of action by FDA within the initial 100-day period, in which case the petition shall be deemed to be denied unless an extension is mutually agreed upon by FDA and the petitioner.

Please feel free to contact me at 240-402-1774 if you have any questions concerning this petition.

Sincerely yours,

Vincent de Jesus
Nutrition Programs Staff
Office of Nutrition, Labeling,
and Dietary Supplements
Center for Food Safety and Applied
Nutrition