



Jonathan W. Emord, Esq.  
Emord & Associates, P.C.  
5282 Lyngate Court  
Burke, VA 22015

DEC 30 2003

RE: Health Claim Petition - Chromium Picolinate and 1) insulin resistance, 2) cardiovascular disease when caused by insulin resistance, 3) abnormally elevated blood sugar levels, 4) cardiovascular disease when caused by abnormally elevated blood sugar levels, 5) type II diabetes, 6) cardiovascular disease when caused by type II diabetes, 7) retinopathy when caused by abnormally high blood sugar levels, and 8) kidney disease when caused by abnormally high blood sugar levels

Dear Mr. Emord:

This letter acknowledges receipt on December 19, 2003, by the Food and Drug Administration (FDA) of your health claim petition, submitted pursuant to Section 403(r)(5)(D) of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. 343(r)(5)(D)) with respect to certain claims about the relationship between chromium picolinate and 1) insulin resistance, 2) cardiovascular disease when caused by insulin resistance, 3) abnormally elevated blood sugar levels, 4) cardiovascular disease when caused by abnormally elevated blood sugar levels, 5) type II diabetes, 6) cardiovascular disease when caused by type II diabetes, 7) retinopathy when caused by abnormally high blood sugar levels, and 8) kidney disease when caused by abnormally high blood sugar levels. You submitted this petition on behalf of Nutrition 21, Inc.

Because your petition is complete, it is undergoing initial FDA review. In accordance with Section 403(r)(4)(A)(i) of the Act (21 U.S.C. 343(r)(4)(A)(i)) and 21 CFR 101.70(j)(2), within 100 days of receipt of a petition, the petition will either be filed for comprehensive review or denied. A denial may be by either FDA action within the 100-day period, which ends on March 28, 2004, 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.

2004 Q-0144

ACK 1

Page 2 – Jonathon W. Emord

If you have any questions, please feel free to contact me in the Nutrition Programs and Labeling Staff at 301-436-1694.

Sincerely yours,

A handwritten signature in black ink that reads "Julie Schrimpf". The signature is written in a cursive style with a large initial "J" and a long, sweeping underline.

Julie Schrimpf, PhD, RD  
Nutrition Programs and Labeling Staff  
Office of Nutritional Products, Labeling and Dietary Supplements  
Center for Food Safety and Applied Nutrition