DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

APR 7 2004

1303 '04 APR -8 P1:22

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

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 (Docket No. 2004Q-0144)

Dear Mr. Emord:

This letter acknowledges receipt on March 24, 2004 by the Food and Drug Administration (FDA) of your letter by email of the same date regarding the above referenced chromium picolinate petition that you submitted on December 19, 2003 on behalf of Nutrition 21, Inc. We understand that the petitioner has elected to have their health claim petition reviewed under the new process for qualified health claims rather than under the standard health claim review process described in Section 403(r)(5)(D) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 343(r)(5)(D)) and 21 C.F.R. § 101.70. We will therefore follow the interim procedures for qualified health claims described in the FDA guidance entitled "Interim Procedures for Qualified Health Claims in the Labeling of Conventional Human Food and Human Dietary Supplements" that published on July 10, 2003. (http://www.cfsan.fda.gov/~dms/nuttf-e.html)

Accordingly, today we are filing the qualified health claims for chromium picolinate and its relationship to the conditions described in the claims. However, the agency advises that it has not yet reached a final decision as to whether these claims fall within the framework established by Congress for health claims. For example, the agency has not determined whether all the claims are claims to reduce the risk of a disease or health-related condition. The petition is posted on Dockets web page (Http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm ) and we are requesting comment on it for 60 days. Interested persons may submit comments until June 7, 2004. Within 225 days of the filing date, we will notify you of our final decision regarding the requested qualified health claims. We have calculated that date to be November 18, 2004.

2004Q-0144

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Please feel free to contact Dr. Julie Schrimpf at 301-436-2031 if you have any questions concerning this petition.

Sincerely yours,

Laura Tarantino

Laura Tarantino, Ph.D.
Acting Director
Office of Nutritional Products, Labeling
and Dietary Supplements
Center for Food Safety
and Applied Nutrition