



**Emord** & Associates, P.C.

1800 ALEXANDER BELL DRIVE, SUITE 200  
RESTON, VA 20191

1050 SEVENTEENTH STREET, N.W., SUITE 600  
WASHINGTON, D.C. 20036  
202.466.6937 • FAX 202.466.6938  
www.emord.com

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**VIA UPS GROUND**

Julie Schrimpf Moss, Ph.D., R.D.  
FDA, CFSAN, ONPLDS, DNPL  
5100 Paint Branch Parkway  
Room 4A032, HFS-830  
College Park MD 20740

***Re: Nutrition 21, Inc., Health Claim Petition for Chromium Picolinate***

Dear Dr. Moss:

Nutrition 21 hereby submits three additional documents to the docket that may be relevant to the agency's review of Nutrition 21's petition for chromium picolinate. The three attachments were published after the petition was submitted.

**Attachment A**

Attached is a copy of a recent letter to the editor, by Gunton et al. entitled, "Chromium supplementation does not improve glucose tolerance, insulin sensitivity, or lipid profile: a randomized, placebo-controlled, double-blind trial of supplementation in subjects with impaired glucose tolerance: response to Komorowski and Juturu." *Diabetes Care*. 2005 Jul;28(7):1842-3. Nutrition 21 submitted Gunton et al.'s brief report on March 22, 2005. In her letter, Dr. Gunton confirms that she used 100 mcg of elemental chromium in her study. That dose is significantly lower than the chromium dose of 800 mcg originally reported in the brief report entitled "Chromium supplementation does not improve glucose tolerance, insulin sensitivity or lipid profile" by Gunton JE et al published in *Diabetes Care* 2005 Mar 28 (3): 712-3. As previously stated in Nutrition 21's letter to the editor, the 100 mcg chromium dose of chromium picolinate is far below the level shown to effect a reduction in blood sugar levels. A dose of at least 200 mcg of chromium is required to produce that reduction effect. (*J Am Coll Nutr*. 1998 Dec;17(6):548-55 and *Diabetes Care* 2004 Nov 27(11): 2741-2745).

**Attachment B**

Attached is a copy of Vrtovec et al, “Chromium supplementation shortens QTc interval duration in patients with type 2 diabetes mellitus,” American Heart Journal, 149 N. 4, 632-636 (2005). Vrtovec et al. is a study of human subjects diagnosed with type 2 diabetes and is being submitted in support of Petitioners claims “Chromium picolinate may reduce the risk of cardiovascular disease when caused by abnormally elevated blood sugar levels” and “Chromium picolinate may reduce the risk of cardiovascular disease when caused by insulin resistance.”

### **Attachment C**

Attached is a copy of Mati et al. Biol Trace Elem Res 105(1-3):229-248. A study of type 2 diabetic mice strongly suggests that chromium supplementation reduces the symptoms of hyperglycemia and improves renal function by recovering renal chromium concentrations. Urinary albumin concentrations, creatinine clearance rates and serum ratios of BUN to creatinine were significantly lower in diabetic mice than controls. The number of tubular vacuolations in the kidney sections was lower in diabetic mice supplemented with chromium as chromium picolinate. Mati et al. found that supplementation with chromium picolinate preserves or restores renal function in type 2 diabetic mice and found no renal toxicity after prolonged feeding with chromium picolinate.

Sincerely,

/s/

Jonathan W. Emord  
Andrea G. Ferrenz

### Attachments

A - “Chromium supplementation does not improve glucose tolerance, insulin sensitivity, or lipid profile: a randomized, placebo-controlled, double-blind trial of supplementation in subjects with impaired glucose tolerance: response to Komorowski and Juturu.” Diabetes Care. 2005 Jul;28(7):1842-3) and Komorowski and Juturu – comments to Gunton et al – Diabetes Care July 2005.

B – Vrtovec et al, Chromium supplementation shortens QTc interval duration in patients with type 2 diabetes mellitus, American Heart Journal, 149 N. 4, 632-636 (2005).

C - Mati et al. Biol Trace Elem Res 105(1-3):229-248