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**VIA EMAIL** *Julie.moss@fda.gov*

**AND UPS GROUND**

Dr. Julie Schrimpf Moss  
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:

This letter amends Petitioner Nutrition 21, Inc.'s (Nutrition 21's) health claim petition for chromium picolinate. In accordance with 21 C.F.R. § 101.70(f), Nutrition 21 submits the attached article Gunton, J.E. et al, Brief Report: Chromium Supplementation Does Not Improve Glucose Tolerance, Insulin Sensitivity, or Lipid Profile, *Diabetes Care* 2005 Mar;28(3):712-3. In the attached self titled brief report, the authors reach the conclusion that their study showed "no beneficial effect of chromium supplementation in the treatment of people with impaired glucose tolerance (IGT) despite increases in serum chromium levels, which suggested an adequate dosage regimen." Nutrition 21 has evaluated the report and concludes that the study is flawed.

The authors failed to recognize that the chromium picolinate product administered at 800 mcg per day yielded a daily dose of 100 mcg per day of elemental chromium. 100 mcg a day is half of the recognized amount (200 mcg) of elemental chromium previously shown to have an effect on glucose levels. Cefalu, W.T., *Role of Chromium in Human Health and in Diabetes*, *Diabetes Care* 2004 Nov; 27(11):2741-2751, 2745.<sup>1</sup> Thus, the Gunton study showed no beneficial effect because it used half of the amount of elemental chromium previously shown to produce a physiological effect.

It appears the authors erroneously believed that 800 mcg of the compound chromium picolinate would yield 800 mcg of elemental chromium. Gunton at 712.

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<sup>1</sup> The authors' misconception is revealed in their statement, "...the chromium dose (at 800 mcg /day) was at the higher end of the ranges used in previous studies." In fact, the chromium dose was 100 mcg/day and was at the lower end of the ranges used in previous studies. Id.

Bullivants Natural Health Products, the supplier of the chromium picolinate product identified, has confirmed that 800 mcg of their product yields 100 mcg of elemental chromium (two doses of 400 mcg of chromium picolinate at 50 mcg of elemental chromium each).<sup>2</sup> The lack of a beneficial effect from 100 mcg of elemental chromium a day is not only understandable but is expected.

Sincerely,

Jonathan W. Emord  
Andrea G. Ferrenz

Attachment

Cc: FDA, Dockets Management Branch, fdadockets@oc.fda.gov

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<sup>2</sup> Australia limits the amount of elemental chromium to 50 mcg per day.