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## **FDA APPROVES FIRST QUALIFIED HEALTH CLAIM FOR CHROMIUM PICOLINATE AND RISK OF TYPE 2 DIABETES**

### **FDA CONCLUDES THAT CHROMIUM PICOLINATE IS SAFE**

PURCHASE, N.Y., August 29, 2005, (Nutrition 21, Inc. Nasdaq: NXXI) -- The U.S. Food & Drug Administration (FDA) issued a favorable response to a qualified health claim petition filed by Nutrition 21, recognizing chromium picolinate as a safe nutritional supplement that may reduce the risk of insulin resistance and possibly type 2 diabetes. In a letter to the Company, the FDA's Center for Food Safety and Applied Nutrition concluded that there is credible evidence to support the following qualified health claim:

*"One small study suggests that chromium picolinate may reduce the risk of insulin resistance, and therefore possibly may reduce the risk of type 2 diabetes. FDA concludes, however, that the existence of such a relationship between chromium picolinate and either insulin resistance or type 2 diabetes is highly uncertain."*

The FDA declined to permit other qualified health claims that were proposed by the Company. "The FDA's initial response, while a starting point, is an important milestone in our Company's effort to communicate the health benefits of our products, said Gail Montgomery, President and CEO of Nutrition 21. "We expect several conclusive peer-reviewed studies to publish in the months ahead that should help build evidence to support additional health claims for chromium picolinate as the first recognized supplement that may reduce the risk of insulin resistance and possibly type 2 diabetes." Nutrition 21 holds the patent rights for those applications.

The study cited by the FDA was conducted by William Cefalu, MD, chief of the division of nutrition and chronic diseases at the Pennington BioMedical Research Center, Louisiana State University System. "Emerging research suggests that 200-1,000 mcg of chromium as chromium picolinate may play an important role in carbohydrate metabolism," said Cefalu.

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The FDA also concluded that chromium picolinate is safe, stating the following:

*“FDA concludes at this time, under the preliminary requirements of 21 CFR 101.14(b)(3)(ii), that the use of chromium picolinate in dietary supplements as described in the [approved] qualified health claims discussed in section IV is safe and lawful under the applicable provisions Act.”*

### **Insulin Resistance and Diabetes**

Insulin resistance is an epidemic condition that dramatically increases risk for type 2 diabetes, coronary heart disease and stroke, estimated to affect one in three Americans, according to The American College of Endocrinology (ACE) and the American Association of Clinical Endocrinologists (AACE).

“The FDA ruling confirms our strategic investments in clinical research to differentiate Chromax<sup>®</sup> and Diachrome<sup>®</sup> from other chromium supplements,” added Montgomery. “This qualified health claim should help health professionals and millions of consumers make better informed choices about reducing the risk of insulin resistance with chromium picolinate supplementation and possibly reducing the risk for type 2 diabetes.”

### **Health Claims for Dietary Supplements**

Because dietary supplements are under the "umbrella" of foods, FDA's Center for Food Safety and Applied Nutrition (CFSAN) is responsible for the agency's oversight of these products. Health claims describe a relationship between a food, food component, or dietary supplement ingredient, and reducing risk of a disease or health-related condition. By law, manufacturers may make three types of claims for their dietary supplement products: health claims, structure/function claims, and nutrient content claims.

The FDA will allow appropriately qualified health claims for dietary supplements as well as conventional foods, when the link between the substance's ability to reduce the risk of the disease does not meet the standard of "significant scientific agreement." According to the FDA's website, these qualified claims are based on the weight of the scientific evidence, i.e., there is more evidence for than against the relationship. In October 6, 2000, FDA published its updated strategy that describes when the agency will exercise enforcement discretion to allow qualified dietary supplement claims for nutrient/disease relationships.

<http://www.cfsan.fda.gov/~lrd/fr001006.html>.

### **About Nutrition 21, Inc.**

Nutrition 21 is a nutritional bioscience company and the maker of chromium-based supplements with health benefits substantiated by clinical research. The company markets Chromax<sup>®</sup> chromium picolinate (<http://www.chromax.com>), which is the most-studied form of the essential mineral chromium. The company also markets Diachrome<sup>®</sup> (<http://www.diachrome.com>). Nutrition 21 holds 36 patents for nutrition products, 27 of which are for chromium compounds and their uses. More information is available at [www.nutrition21.com](http://www.nutrition21.com).