



United States Department of Agriculture
Research, Education, and Economics
Agricultural Research Service

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17 May 2004

U. S. Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket 2004Q-0144 Health Claim Petition, Chromium Picolinate

Dear Sir or Madame:

I wish to express my support for qualified health claims for chromium picolinate as a dietary supplement to reduce the risk of Type II or non-insulin dependent diabetes (NIDDM) and associated health conditions.

Judicious supplementation of chromium picolinate coupled with moderate, achievable changes in diet and exercise habits can prevent the development of NIDDM in virtually everyone with impaired glucose tolerance. Consumers need access to reliable information in order to make informed choices that could result in the prevention of a chronic and serious debilitating disease. There is no better, faster, or cheaper means to provide this information to all Americans than to allow a qualified health claim.

At this time NIDDM must be considered a major public health crisis, consuming 10% of all US healthcare costs and 25% of Medicare expenditures. The forecast is for this disease to become far worse in the next decade, due mainly to record-breaking levels of obesity in the North American population. Ten years ago, few foresaw the increase in NIDDM cases that would be associated with increasing obesity and inactivity. A decade ago, NIDDM was a disease of mature adults, but now it is diagnosed in elementary school children. Obesity is the leading cause of NIDDM and cardiovascular disease, and we are entering a new millennium in which life expectancy in Western countries will fall, not rise, if we do not intervene on a public health crisis scale.

I have worked in the research field of natural products for NIDDM treatment and prevention for ten years. I have contributed to and published research on chromium picolinate,

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other forms of chromium supplementation, cinnamon extracts, various phytochemicals, and n-3 polyunsaturated fatty acids and their use for treating diabetes and roles in development of the disease. I am very familiar with the body of scientific research on chromium picolinate.

Chromium picolinate research makes a compelling argument for reducing the risks for insulin resistance, abnormally elevated blood sugar, NIDDM, and diabetes:

- Since chromium absorption is generally less than 1%, it is essential to make claims for a supplement which can be shown to be bioavailable for the majority of consumers. At this time, only chromium picolinate meets this standard.
- Only chromium picolinate has been proven to lower fasting glucose and glycated hemoglobin in large, double-blind, dose-response clinical trials.
- Only chromium picolinate has been consistently effective in reducing insulin resistance in pre-diabetics.
- Only chromium picolinate has been tested on and shown effective for gestational and steroid-induced diabetes. While these conditions are not as significant as NIDDM in terms of number of cases, such studies illustrate the apparent fundamental ability of chromium picolinate to normalize glucose homeostasis.
- In head-to-head comparisons in laboratory animals, chromium picolinate was the best absorbed commercially available supplement.

I have also had the opportunity to regularly communicate to consumers, disseminating information on natural approaches for NIDDM prevention and treatment. In this vein, I have given many lectures and written hundreds of magazine and newsletter articles. In 1999, I authored "Diabetes: Prevention and Cure" (Kensington Publishing). Correct and safe chromium supplementation protocols are a cornerstone of my book, and I have seen, first-hand, how consumer access to *reliable, understandable* information on the diabetes-risk-reducing effects of chromium picolinate can literally change lives.

Although there are genetic predispositions for development, NIDDM is a disease caused almost exclusively by diet and lifestyle choices--unfortunately the rather poor choices being made by many Americans today. The good news is that the risk of NIDDM can be *to a large degree reduced* by reversing those diet and lifestyle choices. I believe that intervention by all means possible is crucial today.

Now is not the time to hold back on health claims for supplements such as chromium picolinate that have two decades of research proving their essentiality and efficacy in controlling blood sugar and preventing NIDDM. Withholding FDA endorsement of this information will contribute to the emergence of millions more NIDDM cases in the next few years and cannot be considered sound public policy.


Sincerely,



Dr. C. Leigh Broadhurst, Ph.D.

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Please note that these statements reflect my opinion as a scientist and do not reflect the official position of USDA - ARS or imply any endorsement, commercial or otherwise, on their part.



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