

FEDERAL TRADE COMMISSION DECISIONS

Findings, Opinions, and Orders

IN THE MATTER OF

NUTRITION 21, ET AL.

CONSENT ORDER, ETC., IN REGARD TO ALLEGED VIOLATION OF
SECS. 5 AND 12 OF THE FEDERAL TRADE COMMISSION ACT

Docket C-3758. Complaint, July 11, 1997--Decision, July 11, 1997

This consent order prohibits, among other things, the two California-based companies and their officer from making unsubstantiated advertising claims for their weight loss and health care products containing chromium picolinate and requires competent and reliable scientific evidence to substantiate any representation concerning the benefits, performance, efficacy or safety of any food, dietary supplement or drug they advertise or sell. The consent order also prohibits misrepresentations of the results of any study, test or research. In addition, the consent order requires the company to send its customers a notice of the Commission's allegations and a request to stop using sales materials that make the challenged claims.

Appearances

For the Commission: *Beth Grossman, Loren G. Thompson and C. Lee Peeler.*

For the respondents: *Stephen McNamara, Hymans, Phelps & McNamara, Washington, D.C.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Nutrition 21, a limited partnership; Selene Systems, Inc., a corporation and general partner of Nutrition 21; and Herbert H. Boynton, individually and as President of Selene Systems, Inc., a corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that this proceeding is in the public interest, alleges:

1. Respondent Nutrition 21 is a California limited partnership with its principal office or place of business at 1010 Turquoise St., Suite 335, San Diego, CA.
2. Respondent Selene Systems, Inc. is a California corporation and a general partner of Nutrition 21. Its principal office or place of business is the same as that of Nutrition 21.

3. Respondent Herbert H. Boynton is President of Selene Systems, Inc., a corporation. Individually or in concert with others, he formulates, directs, and controls the acts and practices of Nutrition 21 and Selene Systems, Inc., including the acts or practices alleged in this complaint. His principal office or place of business is the same as that of Nutrition 21.

4. Respondents have manufactured, advertised, offered for sale, sold, and distributed Chromium Picolinate for use in dietary supplements. Chromium Picolinate is a product subject to the provisions of Sections 12 and 15 of the Federal Trade Commission Act. The United States Department of Agriculture holds the patent on Chromium Picolinate, and Nutrition 21 holds the exclusive license to manufacture and sell Chromium Picolinate.

5. The acts and practices of respondents alleged in this complaint have been in or affecting commerce, as "commerce" is defined in Section 4 of the Federal Trade Commission Act.

6. Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for Chromium Picolinate, including but not necessarily limited to the attached Exhibits A-G. These advertisements and promotional materials contain the following statements:

A. Lose the Fat but Keep the Muscle . . .

Chromium Picolinate

At last there is a safe nutritional supplement that helps you lose unwanted fat more easily and quickly, while retaining vital muscle tissue. Now you can have a trimmer, firmer, leaner body.

LOSE THE FAT BUT KEEP THE MUSCLE

Most dieters who achieve significant weight loss lose far too much lean body mass (muscle and organ tissue). . . . Even worse, this lessened lean body mass lowers your metabolic rate, making it that much harder to keep the fat off permanently -- the yo-yo syndrome!

There is now excellent scientific evidence that Chromium Picolinate can accelerate fat loss while helping to preserve or even increase muscle.

CONVINCING NEW EVIDENCE

Overweight adults were recruited by a prominent San Antonio weight loss clinic to participate in a weight loss study. About half of the volunteers received supplemental Chromium Picolinate (200 or 400 micrograms chromium daily), while the others received placebos. Neither the participants nor the doctors evaluating them knew who was getting the chromium (a "double-blind" study). The volunteers were not placed on any specific diet or exercise regimen, although most of them were motivated to lose weight. After only 60 days, these were the impressive results:

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The changes in the placebo group were negligible. But the Chromium Picolinate group, on average, lost over 4 pounds of fat while gaining nearly a pound and a half of lean muscle for a Net Physique Enhancement of 5.6 pounds.

Another double blind-study was conducted in young off- season football players participating in a six-week weight-training program. The results were much the same: more muscle, less fat with Chromium Picolinate. Chromium Picolinate more than doubled the net benefits of exercise alone.

LEANER AND FIRMER

Because many people gain muscle with Chromium Picolinate, their weight loss in pounds doesn't accurately reflect the benefits of chromium. Most users report that event [sic] a modest weight loss as shown on the bathroom scale is accompanied by lost inches and smaller clothing sizes. They look and are leaner and firmer. Chromium Picolinate promotes fat loss, while enhancing the muscle that assures a trim athletic physique.

HOW DOES CHROMIUM PICOLINATE WORK?

Controls Hunger Many people report that Chromium Picolinate helps to control appetite, especially sugar cravings. It is believed that chromium sensitizes the "glucostat" in the brain that monitors blood sugar availability and "tells" you when you're hungry or not hungry.

"Spare" Protein . . . By "sensitizing" muscle to insulin, Chromium Picolinate helps to preserve muscle in dieters so that they "burn" more fat and less muscle. Preservation of lean body mass has an important long-term positive effect on metabolic rate, helping dieters keep off the fat they've lost.

Stimulates Metabolism It promotes efficient metabolism by aiding the thermogenic (heat producing) effects of insulin. Insulin levels serve as a rough index of the availability of food calories, so it's not at all surprising that insulin stimulates metabolism.

HOW MUCH CHROMIUM PICOLINATE SHOULD I TAKE FOR OPTIMAL WEIGHT LOSS?

Clinical trials with 200 to 400 micrograms of chromium daily produced significant benefits. Larger individuals and those engaged in strenuous work or exercise may see better results with higher levels -- up to a maximum of 400 micrograms daily.

PUTTING IT ALL TOGETHER

The best thing about Chromium Picolinate is that it makes other sensible weight control efforts more effective. Many people report that they have tried diet and exercise before, but say that they didn't get good results until they added Chromium Picolinate. . . .

Chromium Picolinate, all by itself, isn't likely to make a fat person thin. But it can be the decisive component of an overall strategy for long-term weight control and, in the bargain, make an important contribution to good health.

(Exhibit A) (references omitted)

B. WEIGHT LOSS, FAT LOSS AND MUSCLE LOSS
or "How to Break the String of Yo-Yo Diets"

CLEARLY, THE KEY TO BREAKING THIS DISCOURAGING CYCLE OF EVER MORE FAT, EVER LESS MUSCLE, IS LOSING FAT WHILE PRESERVING--OR EVEN INCREASING--MUSCLE. . . .

This is precisely what Dr. Gilbert Kaats and his colleagues achieved in a recently completed study

One hundred fifty men and women were asked to join in a weight loss study. Roughly half were given supplemental Chromium Picolinate (200 or 400 micrograms chromium daily), while the others got a placebo. They were not placed on any specific diet or exercise regimen, although most were trying to lose weight. . . . After 72 days, these were the impressive results:

The changes in the placebo group were insignificant. However the Chromium Picolinate group, on average, lost over 4 pounds of fat while gaining nearly a pound and a half of lean muscle!

The review of clinical trials reported that supplementation with Chromium Picolinate:

- reduced total serum cholesterol and LDL, the "bad" cholesterol
- reduced elevated blood sugar levels and glycosylated hemoglobin in diabetics
- significantly reduced body fat and increased muscle in exercising individuals.

Chromium is an essential nutrient that is in short supply in 90% of typical U.S. diets. . . .

CHROMIUM PICOLINATE: Take daily, 200 to 400 micrograms to preserve muscle while you lose weight

Chromium Picolinate has other important attributes:

- preserving or enhancing muscle; it maintains or increases the metabolic rate making weight loss easier.
- significantly lowering elevated serum cholesterol
- significantly lowering elevated blood sugar
- helping to control appetite. A great many people report reduced appetite, especially sugar cravings.

(Exhibit B)

C. CHROMIUM PICOLINATE:

The yeast-free BioActive Chromium with Important Clinically Proven Benefits

Chromium is vitally important to good health because it is essential to the efficient function of the hormone insulin. Poor responsiveness to insulin is very common and is linked with increased risk for overweight, heart disease, elevated blood fat, high blood pressure, and diabetes.

Yet chromium's nutritional status in the U.S. is very poor: 90% of American diets provide less than the minimal amount recommended by the National Academy of Sciences, and most nutritional forms of chromium are poorly absorbed.

Chromium Picolinate is well absorbed and highly bioactive. In clinical trials at major hospitals and universities it has been shown to:

- significantly reduce body fat
- help build lean, strong muscles
- lower elevated cholesterol
- reduce elevated blood sugar in diabetics

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By mechanisms that are not yet fully understood nutritional (trivalent) chromium is absolutely essential to the function of insulin.

A great many U.S. adults have poor insulin function. They produce normal or even elevated amounts of insulin, but their body's tissues are relatively insensitive to it. Indeed, recent studies show that at least one in four adults has reduced sensitivity to insulin.

The majority of these people don't become overtly diabetic because their pancreas compensates by secreting increased amounts of insulin. In these people, insulin insensitivity is a "silent" problem that can be diagnosed only by observing increased blood insulin levels and/or modest impairments of glucose tolerance.

There is increasing evidence that this "silent" insulin insensitivity is in fact a serious medical problem.

But there is now evidence that insulin insensitivity may itself lead to weight gain, owing to an impairment of "dietary thermogenesis. . . ."

Insulin insensitivity almost certainly also impairs the development of muscle.

Diabetes As noted, most people can compensate for modest impairments of insulin sensitivity by producing more insulin. But in some people, as insulin sensitivity continues to decline, the pancreas is unable to keep up with the increased need for insulin, and "adult-onset" (Type II) diabetes results. In this syndrome, there is a significant net reduction in insulin activity, resulting in persistent elevations of blood sugar even after an overnight fast. Adult-onset diabetes . . . is responsible for a tremendous toll in premature death and disability. Long-term diabetes can lead to heart disease, arterial disease (often requiring leg amputation), blindness, kidney failure, and nerve damage.

POOR CHROMIUM NUTRITION AND METABOLISM

Diets that are too high in fats and too low in fiber-rich unrefined foods, inadequate exercise, as well as overweight, are all major factors contributing to poor insulin responsiveness. Poor chromium nutrition also plays a vitally important role.

Refined American diets are very poor sources of chromium. The National Academy of Sciences has recommended a daily chromium intake of 50 to 200 micrograms. Yet studies by the U.S. Department of Agriculture indicate that 90% of Americans receive less than 50 micrograms daily--and 25% receive less than 20 micrograms!

This problem is compounded because most sources of chromium are not efficiently absorbed. . . .

In addition, there is evidence that many people may have defective chromium metabolism. . . . Diabetics also tend to have lower chromium levels.

In brief, impaired insulin sensitivity is very prevalent and is associated with increased risk for overweight, heart disease, diabetes, and high blood pressure.

Chromium, which is crucial for proper insulin function, is in short supply in most American diets, is often inefficiently absorbed, and may not be efficiently metabolized by many people.

THE SOLUTION: BIOACTIVE CHROMIUM

These considerations emphatically suggest the desirability of dietary chromium supplementation. But not all chromium supplements are equally effective. In clinical studies, inorganic chromium (*e.g.* chromic chloride) has been beneficial for mild impairments of glucose tolerance, but has not proven useful in overt diabetes or for lowering elevated cholesterol. In contrast, large intakes of brewer's yeast, a rich source of organically bound chromium, have been found useful for treating diabetes and high cholesterol. . . .

The most likely explanation is that some organic chromium complexes are more readily taken up by cells than is inorganic chromium.

CHROMIUM PICOLINATE

Scientists at the U.S. Department of Agriculture have developed an excellent, perhaps an ideal organic complex of chromium. . . . Chromium Picolinate thus proves exceptionally effective for achieving intestinal absorption and intracellular uptake of chromium.

(Exhibit C) (references omitted)

D. CHROMIUM PICOLINATE -- THE CLINICAL PROOF. . .

The initial studies with Chromium Picolinate have yielded exciting results:

Physique Enhancement for Athletes

Young male athletes engaged in an exercise program at Bemidji State University (Minnesota) received daily doses of Chromium Picolinate (200 micrograms chromium) or a matching placebo. After 6 weeks, the chromium group gained 44% more lean body mass than the placebo group. Even more striking, the chromium group lost 23% of its body fat as compared to only 7% in the placebo group. These differences were highly statistically significant.

A similar study has been conducted at Louisiana State University with men and women beginning weight-training students. A preliminary report indicates that Chromium Picolinate accelerated the increase in muscle size in both men and women, and, in the women, nearly doubled the increase in lean body mass.

Cholesterol Reduction In a double-blind crossover study conducted by the medical staff of San Diego's Mercy Hospital, people with elevated cholesterol received a daily dose of Chromium Picolinate providing 200 micrograms chromium, alternating with a matching placebo. After 6 weeks of chromium, LDL cholesterol . . . had dropped 10% Inorganic chromium has not been reported to lower elevated cholesterol.

Adult-Onset Diabetes A similar double-blind crossover trial was conducted at Mercy Hospital with Type II (adult-onset) diabetics. After 6 weeks of Chromium Picolinate (200 micrograms of chromium), fasting blood sugar was lowered by 18% . . .

This is the first time that a nutritional intake of chromium *per se* has been reported to improve glucose metabolism in overt diabetes. (Exhibit D) (references omitted)

E. Chromium Picolinate --The Results Speak For Themselves

Two well designed, well executed studies prove that Chromium Picolinate accelerates muscle growth and reduces body fat. Such a statement cannot be made for any other chromium compound.

A recent issue of *MUSCLE & FITNESS* presented an article calling attention to the newly proven anabolic role of chromium. Body builders have believed for

