

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

a long time that chromium helps build muscle. What is new is that scientists now have measured, during a clinical study, the actual gains that chromium produces.

It no longer makes any difference what people "think" about chromium or about the different forms of chromium because the facts are in -- facts determined by clinical tests conducted according to acceptable scientific standards. And they have shown that one form of chromium --Chromium Picolinate--does accelerate muscle growth. (Exhibit E)

F. Lose The Fat; Keep The Muscle With Chromium Picolinate.

Here's Why You Need Chromium Picolinate.

Like iron, calcium, and zinc, chromium is a nutritionally essential mineral. Its most biologically available form, Chromium Picolinate, can have nutritionally helpful effects on your health and fitness. Combining it with a lifestyle of low-fat eating and everyday exercise can improve both health and fitness.

Lose Fat and Keep Muscle with Chromium Picolinate.

Nine confirming scientific studies with humans and animals demonstrate a significant reduction in body fat when Chromium Picolinate is added to the diet. These studies also show a consistent trend toward increased lean muscle. Muscle burns calories, fat merely stores calories.

Chromium Picolinate Helps Maintain A Normal Healthy Metabolism.

Insulin has very important functions: It maintains the normal nutritional metabolism of protein (muscle building), carbohydrate (major energy source), and fat (energy storage). It also influences appetite control and calorie-burning. Insulin simply can't perform normally without an adequate supply of chromium.

Chromium is Undersupplied in 90% of Adult Diets.

The National Academy of Sciences recommends 50 to 200 micrograms of chromium daily. U.S. Department of Agriculture studies show that men get only 33 micrograms and women get only 25 micrograms, on average, from their food. So, help yourself stay lean and healthy. Choose low-fat meals; choose exercise that you enjoy; and choose Chromium Picolinate to supplement your daily diet. Do it for the healthy edge. Do it for life!

(Exhibit F)

G. "Lose the Fat; Keep the Muscle" with Chromium Picolinate. Millions of Americans are trying to lose weight and many succeed -- but only temporarily.

Typically, up to 30% of lost weight is muscle. This lowers your metabolic rate and slows calorie burning. Muscles burn calories even while you sleep; fat merely stores calories. This lowered metabolic rate makes it hard to keep lost pounds from creeping back. Result: the "yo-yo" syndrome in which weight is repeatedly lost and then regained. After each lose-gain cycle the proportion of fat increases. This can result in a permanently depressed metabolic rate, persistent overweight. . . and utter frustration.

To break this vicious cycle it is important to lose only fat while maintaining, or even increasing muscle.

Most diet plans not only don't work, they're counterproductive. Permanent weight loss requires a permanent commitment. Steps 1, 2, and 3 in the box [below] are endorsed by nearly all weight loss experts. Studies show that optimal chromium nutrition, Step 4, is also an effective part of long-term fat loss programs. Chromium is in short supply in 9 out of 10 American diets and it's absolutely essential for normal insulin function. Normal insulin activity is crucial for hunger control and

calorie-burning. Studies show that 200-400 micrograms of chromium daily, as Chromium Picolinate, results in significant fat loss while muscle tissue is maintained or even increased. Dr. Gil Kaats of San Antonio reports, "During six weeks on Chromium Picolinate, overweight volunteers lost more than four pounds of fat, while muscle increased by nearly a pound and a half."

FOUR STEPS TO A LEANER FIRMER BODY

1. Reduce Dietary Fat Consumption to No More Than 20% of Calories--Eating Fat Makes You Fat
 2. Increase Dietary Fiber--Low in Calories; High in Nutrients
 3. Get Regular Aerobic Exercise--and Burn Fat Calories!
 4. Take Chromium Picolinate Daily--Lose the Fat; Keep the Muscle
- (Exhibit G)

7. Through the means described in paragraph six, respondents have represented, expressly or by implication, that:

- A. Chromium Picolinate significantly reduces body fat.
- B. Chromium Picolinate causes significant weight loss.
- C. Chromium Picolinate causes significant weight loss without dieting or exercise.
- D. Chromium Picolinate causes long-term or permanent weight loss.
- E. Chromium Picolinate increases lean body mass and builds muscle.
- F. Chromium Picolinate significantly increases human metabolism.
- G. Chromium Picolinate controls appetite and craving for sugar.
- H. Chromium Picolinate significantly reduces total and LDL serum cholesterol.
- I. Chromium Picolinate significantly lowers elevated blood sugar levels.
- J. Chromium Picolinate is effective in the treatment and prevention of diabetes.
- K. Ninety percent of U.S. adults do not consume diets with sufficient chromium to support normal insulin function, resulting in increased risk of overweight, heart disease, elevated blood fat, high blood pressure, and diabetes.

8. Through the means described in paragraph six, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in paragraph seven, at the time the representations were made.

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9. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in paragraph seven, at the time the representations were made. Therefore, the representation set forth in paragraph eight was, and is, false and misleading.

10. Through the means described in paragraph six, respondents have represented, expressly or by implication, that scientific studies demonstrate that Chromium Picolinate:

- A. Significantly reduces body fat.
- B. Causes significant weight loss.
- C. Causes significant weight loss without dieting or exercise.
- D. Causes long-term or permanent weight loss.
- E. Increases lean body mass and builds muscle.
- F. Significantly reduces total and LDL serum cholesterol.
- G. Significantly lowers elevated blood sugar levels.
- H. Is effective in the treatment and prevention of diabetes.

11. In truth and in fact, scientific studies do not demonstrate that Chromium Picolinate:

- A. Significantly reduces body fat.
- B. Causes significant weight loss.
- C. Causes significant weight loss without dieting or exercise.
- D. Causes long-term or permanent weight loss.
- E. Increases lean body mass and builds muscle.
- F. Significantly reduces total and LDL serum cholesterol.
- G. Significantly lowers elevated blood sugar levels.
- H. Is effective in the treatment and prevention of diabetes.

Therefore, the representations set forth in paragraph ten were, and are, false or misleading.

12. The acts and practices of respondents as alleged in this complaint constitute unfair or deceptive acts or practices, and the making of false advertisements, in or affecting commerce in violation of Sections 5(a) and 12 of the Federal Trade Commission Act.

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EXHIBIT 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.*



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EXHIBIT A

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EXHIBIT A

LOSE THE FAT BUT KEEP THE MUSCLE

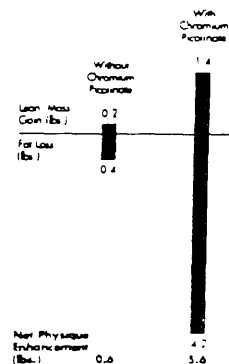
Most dieters who achieve significant weight loss lose far too much lean body mass (muscle and organ tissue). This not only diminishes strength and agility but also affects appearance. With less muscle, pleasing curves flatten, chests sink, arms and legs look spindly. Even worse, this lessened lean body 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 (1). 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:

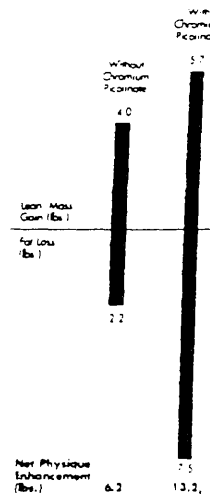
The changes in the placebo group were negligible. But the Chromium Picolinate group, on average, lost over 4 pounds of fat while gaining nearly a pound and a half of lean muscle for a Net Physique Enhancement of 5.6 pounds.



The effect in men alone was even more striking, with an average fat loss of 7.7 pounds. Interestingly, the greatest enhancement of muscle mass was seen in the older subjects, those above age 40, who gained 2.1 pounds of muscle while losing 4.4 pounds of fat. This is especially important since muscle tissue typically declines with age.

Another double-blind study was conducted in young off-season football players participating in a six-week weight-training program (2). The results were much the same: *more muscle, less fat* with Chromium Picolinate. Chromium Picolinate more than doubled the net benefits of exercise alone.

These findings are also confirmed by animal studies. Scientists at Louisiana State University recently reported that young pigs receiving Chromium Picolinate achieved 70% more muscle with 21% less body fat as compared to pigs on an identical diet *not* receiving Chromium Picolinate (3).



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EXHIBIT A

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 even 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.

WHAT IS CHROMIUM PICOLINATE?

Chromium Picolinate is an exceptionally bioactive source of the essential mineral chromium. Chromium plays a vital role in "sensitizing" the body's tissues to the hormone insulin. Weight gain in the form of fat tends to impair sensitivity to insulin and thus, in turn, makes it harder to lose weight (4).

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.

"Saves" Protein Insulin directly stimulates protein synthesis and retards protein breakdown in muscles (5, 6). This "protein-sparing" effect of insulin tends to fall off during low-calorie diets as insulin levels decline, resulting in loss of muscle and organ tissue. 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 (4).

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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.

MORE IMPORTANT DIET ADVICE

Excellent chromium nutrition is an essential component of weight control. Here are other important keys to a trimmer body:

Avoid Dietary Fat. Remember this *fat makes you fat*. Dietitians traditionally have recommended overall calorie restrictions for weight control, but it's now clear that fat calories should be specifically avoided (9, 10). Why? Most ingested fat is quickly stored in your adipose (fat) tissue. Once absorbed, it doesn't provide feedback control to "tell" you that you're not hungry. That's because it isn't directly available as an energy source for the brain. And, unlike carbohydrate or protein, it doesn't trigger the insulin-dependent thermogenic mechanisms that produce a compensatory, and therefore fat-reducing, increase in your metabolic rate.

In contrast, complex carbohydrates (as in bread, potatoes, fruits and vegetables) provide good feedback control of hunger while stimulating an increased metabolic rate - mechanisms that are enhanced by Chromium Picolinate.

For best results, keep dietary fat below 20% of total calories consumed. Olives, avocados, nuts, vegetable oil, and margarine are all extremely high in fat. However most other foods (not of animal origin) are quite low in fat and are great for dieters. Among animal foods, skinless white meat poultry and fish (prepared without frying) are good, as are non-fat and low-fat yogurt and cottage cheese, skim and 1% milk, and egg whites (not yolks). When you must use oil, use it very sparingly.

Regular Exercise. Most people believe that the weight control benefits of exercise result merely from calories burned during exercise. But in fact, exercise also produces a compensatory increase

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Complaint

EXHIBIT A

your metabolic rate that is quite important for weight control (11). (12) Chromium Picolinate helps this effect because insulin plays an important role in increasing the metabolic rate (12). Regular aerobic exercise is best for enhancing metabolism and burning fat while weight-lifting has a beneficial effect on metabolism by increasing muscle mass. Muscle cells use energy; fat cells merely store it.

Calorie Restriction with Adequate Protein.

By avoiding fatty foods, getting regular exercise, and supplementing with Chromium Picolinate, some people can lose fat and substantially improve their physiques, even without any special effort to control their calorie intake. However, people who want to lose weight quickly, or who have a lot of fat to lose, or who have slow metabolisms, may wish to accelerate the process by restricting their calorie intake (that is, going on a diet). If you do substantially reduce your calorie intake, make sure that you get ample protein by including high-protein/low-fat foods in your diet - this is important along with Chromium Picolinate for minimizing loss of muscle. If you are severely restricting calories for weeks at a time, a doctor's supervision is essential. Remember that "quick fix" diets aren't likely to do you any permanent good unless you follow up with an abiding commitment to low-fat foods and exercise.

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. Now they're enthusiastic about low-fat eating plus exercise and are ever-so-proud of their beautiful new bodies! When your efforts are rewarded by good results, you're more likely to keep trying.

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.

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EXHIBIT B



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

In his syndicated column *Nutrition News* dated October 16, 1991, the eminent nutritionist Dr. Jean Mayer states,

"Evidence shows that the amount of fat stored in the body increases with each cycle of up-and-down dieting. When a person loses weight, both fat and muscle tissue are shed. When the weight is put back, however, it tends to be made up of a greater proportion of fat and less muscle, leaving the person 'fatter' than ever.

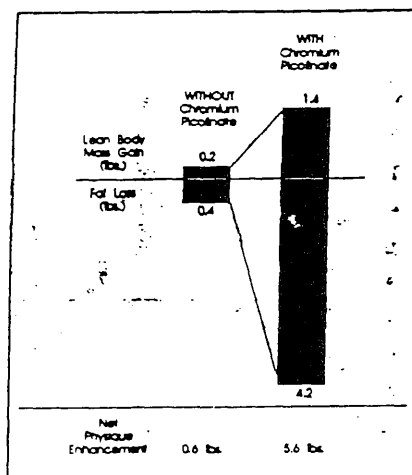
"Consider a 5-foot-5 woman weighing 145 pounds, of which 51 pounds are fat, or 35 percent of her total body weight. After dieting for a few months, she loses 20 pounds — 13 in the form of fat and the rest as muscle tissue and water. She now weighs 125 pounds, including 38 pounds (30 percent) of fat. During the next six months, however, all the lost weight creeps back. But the regained weight is composed of 17 pounds of fat and only three pounds of muscle tissue and water. Thus, the woman weighs what she did originally, but she's carrying more fat—55 pounds, or 38 percent. Each time the cycle is repeated, she's likely to become 'fatter'."

CLEARLY, THE KEY TO BREAKING THIS DISCOURAGING CYCLE OF EVER MORE FAT, EVER LESS MUSCLE, IS LOSING FAT WHILE PRESERVING—OR EVEN INCREASING—MUSCLE. (A more accurate term is lean body mass which includes not only muscle, but also organ tissue such as heart, liver, kidney, etc.)

This is precisely what Dr. Gilbert Kaats and his colleagues achieved in a recently completed study that was reported on October 11 at the annual meeting of the American Aging Association.

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. Neither the volunteers nor their doctors knew who was getting the chromium which made it a "double-blind" study. 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! A Net Physique Enhancement of 5.6 pounds.

The older people in this study (average age 55) did even better than the younger people (average

Continued on page 3

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EX B

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EXHIBIT B

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ATLANTA

--- FEDERAL TRADE

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2 Chromium Picolinate and Diabetes / Journal Reviews Studies / Pigs Slim Down

NOTED PHYSICIAN
RECOMMENDS CHROMIUM
PICOLINATE FOR DIABETIC
PATIENTS

"I advise my diabetic patients to supplement their diet with a 200 microgram a day tablet of chromium picolinate, a supplement available at health food stores and pharmacies. It may help make it easier to control sugar levels."

With those words, Isadore Rosenfeld, M.D., joined the growing list of medical authorities who endorse the health benefits of Chromium Picolinate. The quote is from his new book, *THE BEST TREATMENT* (Simon & Schuster — 1991).

Dr. Rosenfeld is a clinical professor of medicine at the New York Hospital-Cornell Medical Center. He was a commentator on the long-running, popular, nationally syndicated television series "Hour Magazine" and author of several top-selling books on nutrition and health.

Other authors who endorse the superior qualities of biologically active Chromium Picolinate include Jeffrey Fisher, M.D., *THE CHROMIUM PROGRAM* (Harper & Row Publishers—1990); Sheldon Saul Hendler, M.D., Ph.D., *THE DOCTORS' VITAMIN AND MINERAL ENCYCLOPEDIA* (Simon & Schuster—1990); Edwin Hellinjak, M.D., *THE PRINCETON PLAN* (St. Martin's Press—1990); Ronald Hoffman, M.D., *THE DOCTORS BOOK OF HOME REMEDIES* (Rodale Press—1990); Julian M. Whitaker, M.D., *HOW TO LOSE WEIGHT WITHOUT DIETING and 99 SECRETS FOR A LONGER HEALTHIER LIFE* (Phillips Publishing—1991); and Richard A. Passwater, Ph.D., *THE NEW SUPERNUTRITION* (Pocket Books—1991).

NUTRITION JOURNAL
REVIEWS CHROMIUM
PICOLINATE

THE JOURNAL OF APPLIED NUTRITION presented an extensive review of the clinical studies with Chromium Picolinate in its October issue (Vol. 43, No. 1, 1991). The Journal is the official publication of the International Academy of Nutrition and Preventive Medicine.

This publication is of special importance to the health food industry because it is the first scientific journal dedicated to the concept that increased dietary intakes of nutritional factors are efficacious against numerous human diseases.

Dr. Brian Leibovitz, editor, says, "The new focus of *THE JOURNAL OF APPLIED NUTRITION* is on supplementary macro- and micro-nutrients in the prevention and treatment of disease as well as in the maintenance of optimal health. An enormous, and ever-increasing volume of data supports this concept."

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.

Because of its ability to enhance the activity of insulin, the article in the Journal suggests that additional clinical applications for Chromium Picolinate might be found, such as:

- improved wound healing
- improved immune response
- improved brain function
- reduced risk of heart disease.

PIGS ON CHROMIUM
PICOLINATE LOSE FAT AND
GAIN MUSCLE

Chromium Picolinate supplemented piglets had 21% less carcass fat and 7% more muscle than unsupplemented pigs according to a report delivered to the American Association of Animal Science in August. All other factors were the same. Same breed of pigs. Same feed. Same living conditions. And, yes, they all ate like pigs. The Chromium Picolinate supplemented piglets also had lower cholesterol levels than controls. (*Journal of Animal Science*, Vol. 69, Supp. 1)

Dr. Lee Southern, Tim Page, and T.L. Ward conducted the study of carcass characteristics at the Department of Animal Science at Louisiana State University. In the trial they used chromium chloride, picolinic acid, and Chromium Picolinate. Only those animals supplemented with Chromium Picolinate showed favorable results.

Three separate carefully controlled studies have now been conducted with piglets, two at Louisiana State University and one at Oregon State University. It is reassuring to know that virtually the same beneficial effects demonstrated for humans are confirmed in animal studies.

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Complaint

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EXHIBIT B

Diabetes: Chippewa Indians Benefit from Chromium Picolinate

3

DRAMATIC IMPROVEMENT IN TYPE II DIABETICS

American Indians are especially vulnerable to Type II diabetes. The incidence of the disease has increased dramatically during the past 50 years.

Because Chromium Picolinate reduced elevated blood sugar in clinical studies at Mercy Hospital in San Diego, Dr. Gary Evans conducted an informal trial with five Chippewa Indians in northern Minnesota. Normal non-diabetic blood sugar readings range between 60 and 120 milligrams/deciliter. Supplementation with 200 micrograms a day of chromium from Chromium Picolinate produced these impressive results:

The potential health benefits are so striking that a full scale study will be undertaken in January. The results of the preliminary study are scheduled for publication in *WESTERN JOURNAL OF MEDICINE* in November.

IMPORTANT NOTE: Since Chromium Picolinate may reduce the requirement for insulin or diabetic drugs, all diabetics, whether Type I or Type II, should take Chromium Picolinate **ONLY** under the direction of their physician.

SEX	BLOOD SUGAR (mg/dl)		BENEFICIAL CHANGE	PERCENT CHANGE
	START	END		
Male	245	197	- 48	19.5%
Female	268	212	- 56	20.8%
Female ^a	357	137	220	61.6%
Female ^b	136	89	- 47	34.5%
Female ^c	282	203	- 79	28.0%

a) This subject was a diabetic taking 50 units of insulin in the morning and 25 units more later in the day. Her insulin intake has been adjusted downward.

b) This subject has been taking a diabetic drug which has now been discontinued.

c) This subject had dropped to 147 after two weeks. She predicted this reading would be high because she had been "eating a lot of coolies."

BREAKING THE STRING OF YO-YO DIETING

(continued from page 1)

age 36) which is why this study was reported at the American Aging Association meeting.

Chromium is an essential nutrient that is in short supply in 90% of typical U.S. diets. So try these simple rules to break the yo-yo syndrome:

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

FAT: Stop storing it . . . by cutting daily consumption to less than 20% of daily calories

FAT: Start burning it . . . by exercising at least 30 minutes per day at least four days per week

CARBOHYDRATE: Eat fresh fruits, vegetables and whole grain products high in dietary fiber. Cut way down on foods that contain sugar.

PROTEIN: Eat moderate amounts but make sure it's very low fat or no fat as in skim milk or non-fat yogurt.

Although preserving muscle is of overriding importance in solving the yo-yo diet problem, 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.

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EXHIBIT B

4

Promotional Materials Available

CHROMIUM PICOLINATE***Lose the Fat;
Keep the Muscle***

Three new "point-of-sale" promotional pieces are now available to distributors and retailers of Chromium Picolinate products:

1. A vivid yellow-and-black shelftalker that proclaims **CHROMIUM PICOLINATE—*"Lose the Fat Keep the Muscle"***
2. A "Weight Loss" folder that picks up the theme of "Lose the Fat but Keep the Muscle." Designed to fit into a regular business envelope or literature rack, the folder explains how Chromium Picolinate works to help reduce body fat while retaining and building muscle.
3. A "Muscle" folder describes the scientific tests that show significant gains in muscle mass result from supplementation with Chromium Picolinate. With the continuing concern about health hazards of anabolic steroids, a safe and effective nutrient is an important asset to athletes or anyone interested in maintaining a strong, lean physique. The folders and shelftalker are available in reasonable quantities free from Nutrition 21.

Chromium Picolinate is a biologically active form of trivalent chromium that is patented by the U.S. Department of Agriculture. It is licensed exclusively to Nutrition 21.

*Lose the Fat
but Keep the
Muscle...*

**Chromium
Picolinate**

It's not zero it's safe
muscle supplement
that keeps you lean
and strong for more
health and quickly while
retaining your muscle
mass. You can have
a stronger, firmer
leaner body.

Scientifically proven
to promote a

firmer

leaner

stronger

physique

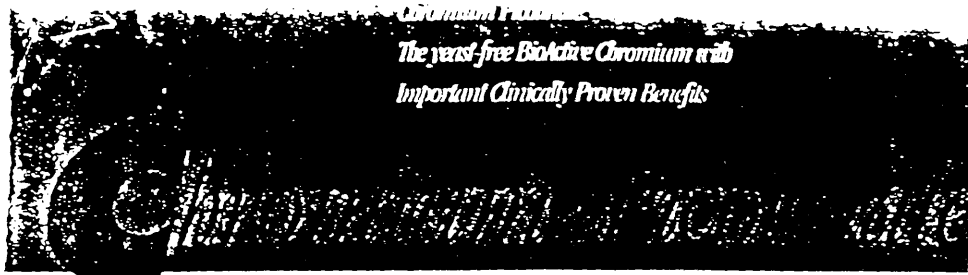
**Chromium
Picolinate**

With all the claims about
muscle supplements,
it's hard to know who or
what to believe. That's
why the proven scientific
data for Chromium
Picolinate really
stands out.

Information in the Nutrition 21
NEWSLETTER is compiled from
the most reliable available data on
health subjects. It is not intended
as medical advice. Its inclusion is
solely informational and educational.
Please consult a physician or
health professional should the need
for one be indicated.

NUTRITION 21
1010 Turquoise, Suite 335
San Diego, CA 92109

EXHIBIT C



Chromium is vitally important to good health because it is essential to the efficient function of the hormone insulin. Poor responsiveness to insulin is even asymptomatic 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 such that 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 is the active ingredient in clinical trials at major hospitals and universities which have shown it:

- significantly reduce need for
- help build strong muscles
- lower elevated cholesterol
- reduce elevated blood sugar in diabetes

No other chromium supplement has shown these benefits. Chromium Picolinate is patented by Dr. J. R. Department of Nutrition and is distributed under an exclusive license by Nutrition 21.

THE INSULIN-CHROMIUM CONNECTION

To identify chromium's crucial role in maintaining the efficient function of the hormone insulin, insulin must be examined. It is the essential mediator of all important food energy sources — carbohydrates, protein, and fat. It is secreted by the pancreas in response to absorption of these nutrients and enables the body tissues to take up blood sugar, glucose, as an energy source. It also stimulates protein synthesis and retains protein reserves in skeletal muscle and other tissues. In effect, it enables the body to store and use the carbohydrates energy available to support brain, heart, and muscular activity.

When insulin action is seriously impaired, whether by a reduced insulin secretion or reduced tissue responsiveness, the resulting syndrome is known as diabetes. This is characterized by persistent elevation of blood sugar and increased body fat stores, insulin resistance, and damage to the kidney, heart, and retina. As a result, the efficiency of insulin function results in chronic overeating, obesity, and a host of other health problems, including atherosclerosis, high blood pressure, and heart disease.

By means of a series of clinical studies, we have shown that chromium picolinate is the most effective form of chromium in restoring

deficient insulin sensitivity and leads to glucose tolerance as well as other effects typically seen in clinical diabetes: increased fat stores, impaired growth, and increased risk for elevations of blood sugar, cholesterol, normal or even elevated in these animals, so impaired tissue response to insulin is clearly to blame.

THE "GLUCOSE TOLERANCE FACTOR"

Clinical studies in the early 1970s led to the conclusion that there was a specific "glucose tolerance factor" which was the result of chromium and the insulin receptor protein and receptor activation. However, decades of subsequent research have failed to substantiate this "glucose tolerance factor" (GTF) theory with an extensive research program. In fact, the chromium picolinate has been shown to be effective in restoring insulin sensitivity and the number of active insulin receptors in people with poor insulin sensitivity.

THE PROBLEM — INEFFICIENT INSULIN FUNCTION

A great many U.S. adults have poor insulin function. They produce normal or even elevated amounts of insulin, but their body tissues are relatively unresponsive to it. Indeed, recent studies show that at least one in four adults has reduced sensitivity to insulin.¹

The majority of these people do not become overtly diabetic because their pancreas is capable of secreting increased amounts of insulin. In these people, insulin resistance is a chronic problem that can be diagnosed even by the increased blood insulin levels and/or modest elevations of blood sugar levels.

There is a strong evidence that this "silent" insulin resistance is a major risk factor for diabetes.

Overweight/Poor Physiology — People get a chronic disease called insulin resistance. But there's a new wonder drug called chromium picolinate which can help. It's an important new health product. It's the only one that's been shown to be effective in restoring insulin sensitivity and the number of active insulin receptors in people with poor insulin sensitivity. It's the only one that's been shown to be effective in restoring insulin sensitivity and the number of active insulin receptors in people with poor insulin sensitivity. It's the only one that's been shown to be effective in restoring insulin sensitivity and the number of active insulin receptors in people with poor insulin sensitivity.

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EXHIBIT C

Insulin insensitivity almost certainly also impairs the development of muscle. Efficient insulin action promotes protein synthesis and retards protein degradation in skeletal muscle and other tissues. Muscle wasting is a prominent feature of diabetes. Thus, efficient insulin function is important for optimal anabolic activity.

Heart Disease. A growing number of studies show that impaired insulin sensitivity, even in the absence of overt diabetes, is associated with a significantly increased risk for cardiovascular disease and premature death (7-10). Insulin insensitivity is an independent risk factor (not dependent on correlations with cholesterol, blood pressure, etc.), and is often associated with elevated triglycerides and high blood pressure (Reaven's syndrome). Since it usually doesn't cause symptoms that lead to its diagnosis, it is truly a silent killer.

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 by far the most common type of diabetes in the Western world, and 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.

Hypertension. Essential hypertension (the most common type of high blood pressure) is often associated with impaired insulin sensitivity (5,11). It is not yet known whether this impaired sensitivity is in fact a contributing cause of hypertension. But it is interesting to note that many measures which improve insulin sensitivity — weight loss, exercise, and high-fiber diets — also tend to lower elevated blood pressure.

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 vital, important role.

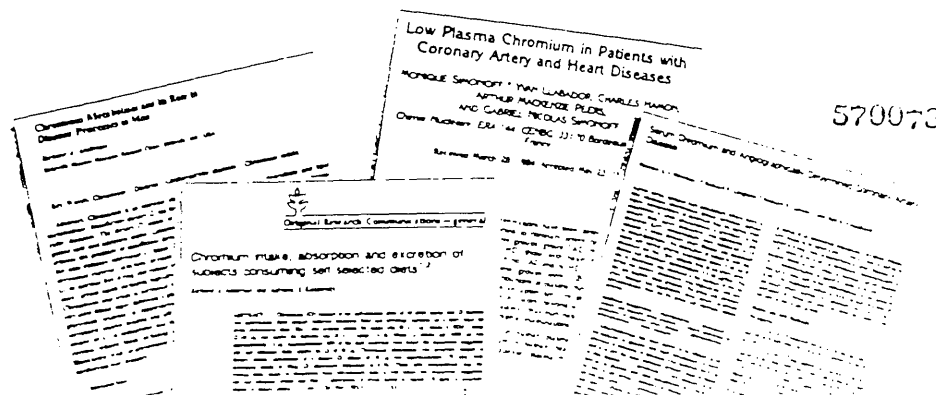
Refined American diets are very poor sources of chromium. The National Academy of Sciences has recommended a daily chromium intake of 50 to 200 micrograms. Yet studies by the U.S. Department of Agriculture indicate that 90% of Americans receive less than 50 micrograms daily — and 13% receive less than 20 micrograms (12).

This problem is compounded because most sources of chromium are not efficiently absorbed. The trivalent chromium ion, in its inorganic, unbound form, as in chromic chloride (the form most commonly used in supplements and clinical studies) has a strong positive electrical charge and does not readily pass through biological membranes. Within the nutritional range of 50 to 200 micrograms, only about 1/2 of 1% of chromic chloride is absorbed (4), and intracellular uptake of the free chromic ion is poor.

In addition, there is evidence that many people may have defective chromium metabolism. Studies show that people with coronary artery disease have significantly lower serum chromium levels than those with healthy arteries (13,14). The observed differences are too large to be explained by dietary differences alone; evidently there is a flaw in the metabolism of chromium in these people — perhaps associated with a defect in intestinal absorption and/or intracellular transport of chromium. Diabetics also tend to have lower chromium levels (15).

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.



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EXHIBIT C

THE SOLUTION: BIOACTIVE CHROMIUM

These considerations emphasize the need for the development of chromium supplementations. But the chromium supplement must be effective. In clinical studies, inorganic chromium (e.g., chromium chloride) has been beneficial for mild impairment of glucose tolerance, but has not proved useful in overt diabetes or for lowering elevated cholesterol (16, 17). In contrast, three studies of brewer's yeast, a rich source of organically bound chromium, have been found useful for treating diabetes and high cholesterol (18-20). The greater effectiveness of the organic chromium complexes found in yeast may account for these beneficial results.

Inorganic chromium (chromium chloride) does not readily pass across the lipid membranes. However, when organically bound in chelated forms, chromium has much greater membrane permeability because the neutralization of the positive charge of the chromium and the more fat soluble "chelate" has been studied. The effects of chromium compounds on insulin function in chromium-deficient rat tissue slices; they reported that many organic complexes of chromium were more effective than inorganic chromium in promoting insulin action (21). The most likely explanation is that some organic chromium complexes are more readily taken up in cells than is inorganic chromium.

While brewer's yeast is a good source of bioactive chromium, yeast-chromium is not ideal as a supplemental source because of the large volume of yeast required, and because of the possibility of yeast allergy. That's why an effective yeast-free organic chromium complex is an attractive alternative.

CHROMIUM PICOLINATE

Scientists at the U.S. Department of Agriculture have developed an excellent, perhaps an ideal organic complex of chromium, Chromium Picolinate. Picolinic acid is a natural metabolite produced in the human liver and kidney. Because of its unique chemical structure, it forms strong chelates with transition metals such as zinc, manganese, and chromium (22). In addition, so being very stable even in acidic gastric juice, which breaks down most chelates, these picolinate complexes are electrically neutral, no positive charge, and fat soluble, which means that they can pass through cell membranes efficiently. Chromium Picolinate thus proves exceptionally effective for achieving intestinal absorption and intracellular uptake of chromium.

THE REMARKABLE SAFETY OF CHROMIUM PICOLINATE

One typical of the many nutrients which is marketed and thus renders chromium amounts which are safe and found in nutritional supplements is provided in the last of our FDA document entitled "Dietary of THE ESSENTIAL MINERALS" which states that the adult single dose of chromium complex of chromium was 4,000-600 micrograms (extrapolated from human) compared to the recommended 50 to 200 micrograms. Test animals fed approximately 2,500 micrograms of inorganic chromium daily throughout their entire lifespan experienced no adverse effects.

PRESENT KNOWLEDGE OF CHROMIUM DEFICIENCY (23) states that the recommended daily intake of chromium is about 100 to 200 RECOMMENDED DIETARY ALLOWANCES (RDA) (24) (25) (26) (27) (28) (29) (30) (31) (32) (33) (34) (35) (36) (37) (38) (39) (40) (41) (42) (43) (44) (45) (46) (47) (48) (49) (50) (51) (52) (53) (54) (55) (56) (57) (58) (59) (60) (61) (62) (63) (64) (65) (66) (67) (68) (69) (70) (71) (72) (73) (74) (75) (76) (77) (78) (79) (80) (81) (82) (83) (84) (85) (86) (87) (88) (89) (90) (91) (92) (93) (94) (95) (96) (97) (98) (99) (100) (101) (102) (103) (104) (105) (106) (107) (108) (109) (110) (111) (112) (113) (114) (115) (116) (117) (118) (119) (120) (121) (122) (123) (124) (125) (126) (127) (128) (129) (130) (131) (132) (133) (134) (135) (136) (137) (138) (139) (140) (141) (142) (143) (144) (145) (146) (147) (148) (149) (150) (151) (152) (153) (154) (155) (156) (157) (158) (159) (160) (161) (162) (163) (164) (165) (166) (167) (168) (169) (170) (171) (172) (173) (174) (175) (176) 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EXHIBIT D

Chromium Picolinate:
The vast free BioActive Chromium with
Important Clinically Proven Benefits

CHROMIUM PICOLINATE — THE CLINICAL PROOF

Since so little is known about chromium's metabolism and transport in the body, the only reasonable way to evaluate the merits of any chromium supplement is by observing its effects in properly controlled clinical studies. The initial studies with Chromium Picolinate have yielded exciting results...

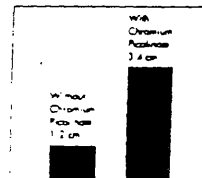
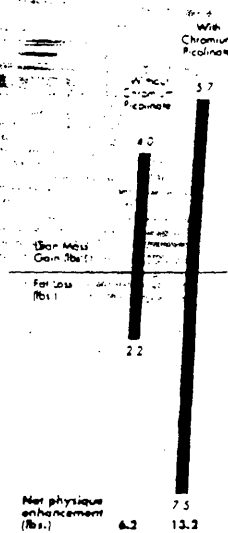
Physique Enhancement for Athletes

Young male athletes engaged in an exercise program at...

Bernard State University (Minnesota) received daily doses of Chromium Picolinate (200 micrograms chromium) or a matching placebo. After 6 weeks, the chromium group gained 34% 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 (23).

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.



Increase of Chest + Arm + Thigh Measurements

For Animals Scientists at USU have reported that Chromium Picolinate added to diets of growing pigs at 100-200 ppm chromium, made animals with 21% less fat and 18% larger pork chops (24). Studies are now underway on other types of livestock. Chromium Picolinate may offer an effective natural alternative to the use of anabolic hormones in the livestock industry.

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EXHIBIT D

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 (the dangerous kind) had dropped 10%, apolipoprotein B (a component of LDL) dropped 16%, while apolipoprotein A₁ (a component of protective HDL) rose 11% (24). Apolipoprotein B correlates with increased heart risk, whereas increased apolipoprotein A₁ is associated with lower risk. Thus, all of the observed changes suggest a lessened risk for heart disease. Inorganic chromium has not been reported to lower elevated cholesterol.



Total and low-density lipoprotein cholesterol of 14 subjects given placebo followed by chromium picolinate supplements. The values depicted with the open squares are for total cholesterol and the units are on the left vertical axis. The values depicted with the closed squares are for low-density lipoprotein (LDL) cholesterol and the units are on the right vertical axis.

Reports from Consumers A great many users of Chromium Picolinate report a marked reduction of sugar cravings. Many note an enhancement of mental energy levels. Others have noted improved gum health. These remarks are frequent enough that we believe they represent genuine effects. These possibilities will be addressed in future clinical studies; they are credible owing to the fact that insulin influences the function of most of the body's tissues.

Cell Culture Studies The insulin-potentiating action of Chromium Picolinate has also been documented in cell cultures. When rat muscle cells are pre-incubated with Chromium Picolinate, insulin-stimulated uptake of glucose and amino acids increases dramatically, as does insulin binding. Preincubation with chromium picolinate or chromic chloride has no statistically significant effect on insulin function in these studies (26).

Uptake of Glucose and Leucine into Skeletal Muscle Cells Cultured with Various Forms of Chromium

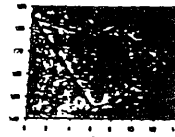
Substrate	Chromium Compound in Culture Medium			
	None	Chloride	Nicotinate	Picolinate
Glucose	11.2 ± 2.1	24.2 ± 3.4	37.2 ± 3.0	74.2 ± 6.6
Leucine	1.2 ± 0.2	11.2 ± 1.1	15.2 ± 1.0	32.2 ± 4.0

Effect of Various Chromium Compounds on Total Receptor-Bound Insulin

Total receptor-bound insulin (CPM)	Chromium Compound in Culture Medium			
	None	Chloride	Nicotinate	Picolinate
	1.2 ± 0.2	1.1 ± 0.1	1.3 ± 0.2	1.4 ± 0.3

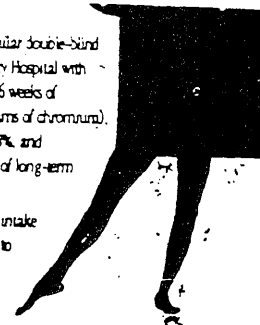
Adult-Onset Diabetes A similar double-blind crossover trial was conducted at Mercy Hospital with Type II (adult-onset) diabetes. After 6 weeks of Chromium Picolinate (200 micrograms of chromium), fasting blood sugar was lowered by 18%, and glycosylated hemoglobin (a measure of long-term glucose control) dropped 10% (23).

This is the first time that a nutritional intake of chromium per se has been reported to improve glucose metabolism in overt diabetes.

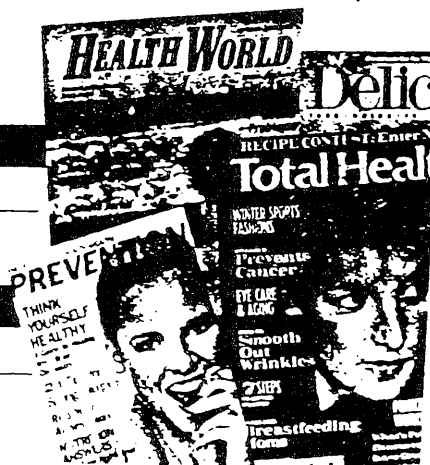


Fasting blood glucose of eleven adult-onset diabetics during supplementation with chromium picolinate and placebo. The values depicted with the solid squares were obtained with the patients who started the study with placebo. The values depicted with the open squares were obtained with the patients who started the study with chromium picolinate (CrPic).

Additional exciting clinical and animal studies with Chromium Picolinate—including one at a major diet center—have been completed or are in progress. The results of these studies must be kept confidential until they can be published in appropriate biomedical journals.



Clinical trials conducted by Deborah Menden, award-winning bodybuilder and doctoral candidate at Louisiana State University, confirmed the physique-enhancing effect of Chromium Picolinate.



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EXHIBIT D

CHROMIUM PICOLINATE IN THE MEDIA

The results of these extensive studies with Chromium Picolinate have been widely reported in the press.

Books: Chromium Picolinate has been recommended as the optimum supplement of choice in recent books by leading physicians and scientists.

The Doctors' Vitamin and Mineral Encyclopedia — Sheldon Saul Hendler, M.D., Ph.D. (Simon & Schuster)

The Chromium Program — Jeffrey A. Fisher, M.D. (Harper & Row)

The Princeton Plan — Edwin Heleniak, M.D. (St. Martin's Press)

The Doctors' Book of Home Remedies —

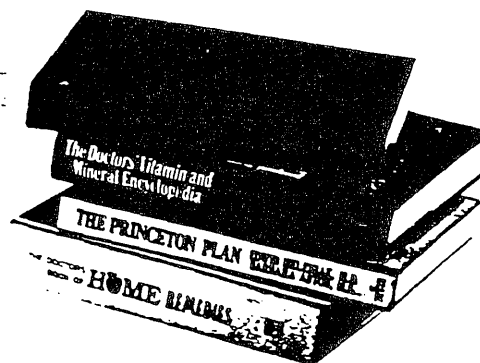
Ronald Hoffmann, M.D. (Roddale Press)

The Purification Prescription —

Sheldon Saul Hendler, M.D., Ph.D. (William Morris & Co.)

The New Super Nutrition —

Richard Passwater, Ph.D. (Simon & Schuster)



Magazines: The three million readers of *Cosmopolitan* (May 1981) read a discussion of Chromium Picolinate's value for dieters under the headline "A Miracle Mineral?" The cholesterol-reducing effect of Chromium Picolinate was highlighted in *The Ladies Home Journal*. *Longevity* has praised Chromium Picolinate as a safe alternative to anabolic steroids. *American Druggist* ran a similar article, while *Drug Store News* reported the findings on diabetes. Numerous publications for athletes and for health food shoppers have run feature articles on Chromium Picolinate, including *Prevention*, *Better Nutrition*, *Whole Foods Today*, *Living Total Health*, *Muscular Development*, *Runner's World*, and *Velo News*.



Newspapers: Many of the nation's most respected and widely read newspapers have devoted articles to Chromium Picolinate including LOS ANGELES TIMES, WASHINGTON POST, USA TODAY, SAN DIEGO UNION, SAN DIEGO TRIBUNE, SAN FRANCISCO CHRONICLE, DETROIT FREE PRESS, PHOENIX GAZETTE, and HOUSTON POST.

The tide of publicity should continue to roll as additional provocative clinical findings are published in the months and years to come.

This widespread favorable media attention translates into a broad and growing market for Chromium Picolinate products.



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EXHIBIT D

SOME FREQUENTLY ASKED QUESTIONS

Q: Is Chromium Picolinate "GTF"?

A: As previously noted, there is no good evidence for the existence of a specific chromium complex, i.e., GTF that mediates chromium's physiological effects. However, certain organic chromium complexes might reasonably be said to have "GTF activity" in the sense that they are more efficient than inorganic chromium in achieving intestinal absorption, intracellular uptake and insulin potentiation. Chromium Picolinate certainly has superb "GTF activity" in this sense. However, to avoid confusion we prefer to refer to Chromium Picolinate as "Bioactive Chromium."

It is interesting to note that brewer's yeast cells make picolinic acid. Perhaps picolinic acid is a constituent of the highly bioactive chromium complexes found in brewer's yeast.

Q: Isn't picolinic acid toxic?

A: When administered in very high doses to experimental animals, picolinic acid *per se* can exert toxic effects, possibly including a nutrient antagonism effect. This has no relevance whatever to any amounts of picolinic acid complexed with nutritional amounts of essential metals. An effective level of Chromium Picolinate providing 200 micrograms chromium is complexed to only 1.4 milligrams of picolinic acid — far less than the quantity which makes even dogs sick. As noted earlier, picolinic acid is a natural protein metabolite produced in the human liver and kidney. Furthermore, it should be noted that the characteristics and physiological effects of mineral picolinate complexes will be distinct from those of the picolinic acid. Neither we nor anyone else advocates the use of free picolinic acid as a nutritional supplement.

In pharmacological doses, picolinic acid (nicotinic acid) leads to unwanted side effects and sometimes induces liver failure. But it would be unfair and certainly ridiculous to use this fact to call into question the safety of nutritional doses of chromium nicotinate. By the same token, the effects of high-dose picolinic acid clearly have no bearing on the safety of nutritional doses of Chromium Picolinate.

Q: I've heard that some forms of chromium are toxic. What about Chromium Picolinate?

A: Hexavalent chromium is an unstable form of chromium that is extremely active as an oxidizing agent in living cells. Hexavalent chromium damages DNA and other vital components.

In contrast, trivalent chromium—the nutritional form of chromium—is very stable and is also used virtually routinely even in amounts far beyond the nutritional range. Chromium Picolinate contains only the trivalent nutritional form of chromium. It is a safe substance and would not be expected to be

of Chromium Picolinate that could feasibly be administered (many thousands of times higher than the nutritional dose) without any discernible adverse effects.

Q: Why haven't we heard more about chromium?

A: Chromium is one of the newer essential trace elements. Unlike iron and iodine which have been known to be essential for over 140 years, the essentiality of chromium was discovered barely 30 years ago. Nevertheless, it is even *more* important as iron, iodine, or zinc for proper nutrition and good health.

Most previous clinical studies with chromium have used chromium chloride which isn't very well absorbed or utilized. Now that Chromium Picolinate is available as a much more bioactive supplemental source, you will be hearing a lot about chromium in coming years.

Q: Why is chromium underutilized in typical American diets?

A: Most minerals and trace elements that are essential for humans are also essential for plants; plants will contain adequate levels of these minerals because otherwise they couldn't grow. But iodine, selenium, and chromium are *not* required by plants, and crops grown in soils depleted of these minerals will supply minimal amounts.

The refinement of flour strips it of much of this chromium content. The prominence of high calorie low nutrition junk foods in typical American diets also dilutes daily chromium intake.

This brochure is intended solely for the information of nutritional manufacturers and distributors and is not intended for the general public. Nutritional supplement distributors are advised to consult their own legal counsel before using any of the information in this brochure or promote products made with Chromium Picolinate.



NUTRITION 21

1010 Turquoise Street, Suite 555

San Diego, CA 92109-6194 • (619) 594-2800 • FAX (619) 594-2800

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Complaint

EXHIBIT D

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NUTRITION 21

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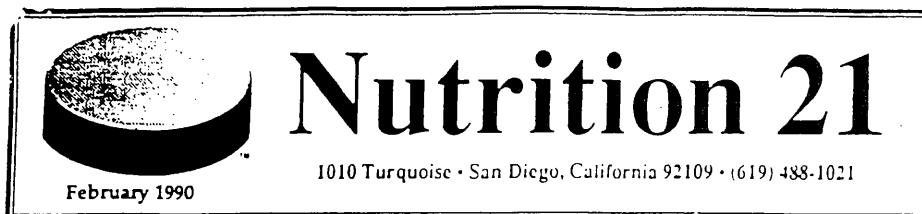
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EXHIBIT E



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.

by Richard Passwater, Ph.D.

A recent issue of **MUSCLE & FITNESS** presented an article calling attention to the newly proven anabolic role of chromium. Body builders have believed for a long time that chromium helps build muscle. What is new is that scientists now have measured, during a clinical study, the *actual* gains that chromium produces.

It no longer makes any difference what people "think" about chromium or about the different forms of chromium because the *facts are in*—facts determined by clinical tests conducted according to acceptable scientific standards. And they have shown that one form of chromium—Chromium Picolinate—does accelerate muscle growth.

This article will discuss the studies showing that Chromium Picolinate is specifically effective for building muscle and promoting fat loss.

THE FIRST STUDY

Two clinical studies examined the effects of Chromium Picolinate on body composition in young male athletes. They were conducted recently at Bemidji (Minnesota) State University under the direction of Dr. Muriel Gilman and Guy Otte. Ten male students enrolled in a weight training course were randomly divided into two groups of five each. All of them worked out for 40 minutes twice a week.

One group received Chromium Picolinate (200 micrograms of chromium daily) while the other got a placebo, a similar looking capsule but without any active ingredients. It was a "double-blind" study. That is, the supple-

ments were coded so neither the students nor the scientists evaluating them knew who was getting the chromium. Body content of fat and muscle, as well as biceps and calf circumferences, were recorded at the start of the study and again after two weeks and six weeks of supplementation.

At the end of the study the changes in the students' muscle size and body fat were measured. Then the code was broken and the scientists learned for the first time which of the students had been taking Chromium Picolinate and which had received placebos.

In six weeks, the Chromium Picolinate group gained an average of 3.5 pounds of lean body mass, compared to only 1/10 of a pound in the placebo group. This difference was highly statistically significant.

When the researchers analyzed all the differences between the two groups, they felt the results warranted further study with a larger number of participants.

THE SECOND STUDY

The second study involved 31 football players during the off-season. They all engaged in a weight training program, four times a week, one hour per session. The athletes were divided randomly into two groups: one received Chromium Picolinate and the other a placebo. Again, it was a double-blind study. Body composition was determined before and after six weeks of supplementation.

When the study was completed, it was found that the group taking Chromium Picolinate gained an average of 5.7 pounds of

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Chromium Picolinate—The Results Speak for Themselves

lean body mass, compared to 3.9 pounds in those getting a placebo. This 44% greater increase is statistically very significant.

BODY FAT LOSS

Even more intriguing was the effect on body fat. The group that had been taking Chromium Picolinate averaged a fat loss of 7.5 pounds. That was 22% of their total body fat. The other group lost an average of 2.2 pounds, only 6% of their total body fat. This difference also had a very high statistical significance.

The anabolic effect of good chromium nutrition can readily be attributed to the known anabolic effects of the hormone insulin. But the fat burning result with Chromium Picolinate, as demonstrated in Dr. Gilman's study, is not so readily predictable.

A likely possibility is that Chromium Picolinate enhances metabolism in "brown fat". This type of adipose tissue is found on the back and near many internal organs. It is activated after a carbohydrate-rich meal by a chain of events that requires insulin action on a portion of the brain known as the hypothalamus. Probably Chromium Picolinate makes the hypothalamus more sensitive to insulin.

Activated brown fat raises the metabolic rate by rapidly burning fatty acids and generating heat. Thus, Chromium Picolinate may promote fat burning while aiding the synthesis and retention of protein in muscle—certainly an ideal state of affairs for body builders!

HOW IT WORKS

Picolinic acid is a mineral binder—a chelator—that is produced in the human body from protein. It is exceptionally effective for promoting the absorption and cellular uptake of minerals such as zinc, iron, manganese, and chromium. Dr. Gary Evans, formerly a research scientist for the United States Department of Agriculture and now a chemistry professor at Bemidji State University, is primarily responsible for demonstrating the superb nutritional value of mineral picolates.

Chromium Picolinate is of special interest. Inorganic sources of chromium such as chromic chloride are very poorly absorbed, only about 1/2 of 1% of an oral dose. Animal studies conducted by Dr. Evans showed that Chromium Picolinate was five to 10 times better absorbed *and* retained than other forms of chromium tested.

The Chromium Picolinate molecule is highly stable and passes across cell membranes much more readily than inorganic chromium. This is in contrast to the compound of chromium and niacin which Dr. Walter Mertz has reported to be unstable. Animal studies also show that Chromium Picolinate is exceptionally safe. Fears that Chromium Picolinate might prove toxic because of an antagonism between niacin and picolinic acid are groundless. The standard daily dose of Chromium Picolinate provides only 1.4 milligrams of picolinic acid—less than 1/10 of the amount produced in the human body every day!

Weight Control Results With Chromium Picolinate

The sharp reduction in body fat noted in the Bemidji State study was remarkable and unanticipated, and suggests that Chromium Picolinate may have value as a diet aid. The following outstanding and unequivocal case results were reported by Julia Ross, Executive Director of Recovery Systems:

L——: Mid-thirties, with a long history of obesity. She weighed 250 lbs. most of her adult life. She was not a dieter although she did Weight Watchers seriously three times.

(1) Refined carbohydrates and fats were the mainstays of her diet.

(2) She went on massive and frequent binges.

High alcohol and tobacco consumption as an adult. These symptoms worse before meals.

(3) She had a long history of clinical hypoglycemia with associated severe and chronic headaches, dizziness and sugar cravings. These symptoms persisted even during the past nine years of stable weight loss (through the Overeaters Anonymous program) and a protein and vegetables (only) diet.

The first dose of Shape-Up (Chromium Picolinate) eliminated the headaches within 26 minutes. Within three days, the shakiness before meals was gone at 200 mcg. in A.M. and 200 mcg. in P.M.

Continued on last page

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EXHIBIT F

Lose The Fat; Keep The Muscle With Chromium Picolinate.



Here's Why You Need Chromium Picolinate.

Like iron, calcium and zinc, Chromium is a nutritionally essential mineral. Its most biologically available form, Chromium Picolinate, can have nutritionally helpful effects on your health and fitness. Combined with a lifestyle of low-fat eating and even-day exercise can improve both health and fitness.

Lose Fat and Keep Muscle with Chromium Picolinate.

Nine confirming scientific studies with humans and animals demonstrate a significant reduction in body fat when Chromium Picolinate is added to the diet. These studies also show a consistent trend toward increased lean muscle. Muscle burns calories; fat merely stores calories.

Chromium Picolinate Helps Maintain A Normal Healthy Metabolism.

Insulin has very important functions. It maintains the normal nutritional metabolism of protein (muscle building), carbohydrate (major energy source) and fat (energy storage). It also influences appetite control and calorie-burning. Insulin simply can't perform normally without an adequate supply of chromium.

Chromium is Undersupplied in 90% of Adult Diets.

The National Academy of Sciences recommends 50 to 200 micrograms of chromium daily. U.S. Department of Agriculture studies show that men get only 33 micrograms and women get only 25 micrograms on average from their food. So, help yourself stay lean and healthy. Choose low-fat meats, choose exercise that you enjoy, and choose Chromium Picolinate to supplement your daily diet. Do it for the healthy edge. Do it for life!

CHROMIUM PICOLINATE

Call or write Nutrition 21 for a FREE brochure, "Hidden Fat in the American Diet". Nutrition 21, 1010 Turquoise Street-Pp2, San Diego, CA 92104. (619) 488-7423.

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DECISION AND ORDER

The Federal Trade Commission, having initiated an investigation of certain acts and practices of the respondents named in the caption hereof, and the respondents having been furnished thereafter with a copy of a draft of the complaint which the Bureau of Consumer Protection proposed to present to the Commission for its consideration and which, if issued by the Commission, would charge respondents with violation of the Federal Trade Commission Act; and

The respondents, their attorney, and counsel for the Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the aforesaid draft of complaint, a statement that the signing of said agreement is for settlement purposes only and does not constitute an admission by respondents that the law has been violated as alleged in such complaint, or that the facts as alleged in such complaint, other than the jurisdictional facts, are true, and waivers and other provisions as required by the Commission's Rules; and

The Commission having thereafter considered the matter and having determined that it had reason to believe that the respondents have violated the said Act, and that a complaint should issue stating its charges in that respect, and having thereupon accepted the executed consent agreement and placed such agreement on the public record for a period of sixty (60) days, and having duly considered the comments received, now in further conformity with the procedure described in Section 2.34 of its Rules, the Commission hereby issues its complaint, makes the following jurisdictional findings and enters the following order:

1. Respondent Nutrition 21 is a limited partnership organized, existing, and doing business under and by virtue of the laws of the State of California with its office and principal place of business at 1010 Turquoise St., Suite 335, San Diego, CA.

2. Respondent Selene Systems, Inc. is a corporation organized, existing, and doing business under and by virtue of the laws of the State of California with its office and principal place of business at 1010 Turquoise St., Suite 335, San Diego, CA. It is a general partner of Nutrition 21.

3. Respondent Herbert H. Boynton is President of Selene Systems, Inc., a corporation. He formulated, directed, and controlled the acts

and practices of Nutrition 21 and Selene Systems, Inc. His address is the same as that of Nutrition 21.

4. The Federal Trade Commission has jurisdiction of the subject matter of this proceeding and of the respondents, and the proceeding is in the public interest.

ORDER

DEFINITIONS

For the purposes of this order:

1. "*Competent and reliable scientific evidence*" shall mean tests, analyses, research, studies, or other evidence based on the expertise of professionals in the relevant area, that has been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

2. "*Purchaser for resale*" shall mean any purchaser or other transferee of Chromium Picolinate, or of the right or license to sell Chromium Picolinate, either as Chromium Picolinate or as an ingredient of any other product, other than respondents, who sells, or who has sold, Chromium Picolinate, either as Chromium Picolinate or as an ingredient of any other product, to other purchasers or to consumers.

3. Unless otherwise specified, "*respondents*" shall mean Nutrition 21, a limited partnership, Selene Systems, Inc., a corporation, their successors and assigns and their officers; and Herbert H. Boynton, individually and as an officer of Nutrition 21 and Selene Systems, Inc.; and each of the above's agents, representatives, and employees.

4. "*Commerce*" shall mean as defined in Section 4 of the Federal Trade Commission Act, 15 U.S.C. 44.

I.

It is ordered, That respondents, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Chromium Picolinate or any food, dietary supplement, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting

commerce, shall not make any representation, in any manner, expressly or by implication, that:

- A. Such product reduces body fat;
- B. Such product causes weight loss;
- C. Such product causes weight loss without dieting or exercise;
- D. Such product causes long-term or permanent weight loss;
- E. Such product increases lean body mass or builds muscle;
- F. Such product increases human metabolism;
- G. Such product controls appetite or craving for sugar;
- H. Such product reduces serum cholesterol;
- I. Such product lowers elevated blood sugar levels;
- J. Such product is effective in the treatment or prevention of diabetes; or

K. Ninety percent or any number or percentage of U.S. adults do not consume diets with sufficient chromium to support normal insulin function, resulting in increased risk of overweight, heart disease, elevated blood fat, high blood pressure, diabetes, or any other adverse effect on health, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

II.

It is further ordered, That respondents, directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Chromium Picolinate or any food, dietary supplement, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, shall not make any representation, in any manner, expressly or by implication, regarding the benefits, performance, efficacy, or safety of such product, unless, at the time the representation is made, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

III.

It is further ordered, That respondents directly or through any corporation, partnership, subsidiary, division, or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any product or program, in or

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Decision and Order

affecting commerce, shall not misrepresent, in any manner, expressly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

IV.

It is further ordered, That respondents shall send by certified mail, return receipt requested, a copy of the attached Exhibit A to:

A. Each purchaser for resale of Chromium Picolinate with whom respondents have done business since January 1, 1993, within thirty (30) days of the date this order becomes final, to the extent that such purchasers are known to respondents through a diligent search of their records, including but not limited to computer files, sales records, and inventory lists. The mailing shall not include any other documents; and,

B. For a period of three (3) years following service of this order, each purchaser for resale with whom respondents do business after the date of service of this order who has not previously received the notice. Such notices shall be sent no later than the earliest of: (1) the execution of a sales or licensing agreement or contract between respondents and the prospective purchaser for resale; (2) the receipt and deposit of payment from a prospective purchaser for resale of any consideration in connection with the sale or licensing of chromium picolinate; or (3) the date on which respondents first ship chromium picolinate to the purchaser for resale.

V.

It is further ordered, That respondents, and their successors and assigns, shall, for five (5) years after the last date of dissemination of any representation covered by this order, maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All advertisements and promotional materials containing the representation;

B. All materials that were relied upon in disseminating the representation; and

C. All tests, reports, studies, surveys, demonstrations, or other evidence in their possession or control that contradict, qualify, or call into question the representation, or the basis relied upon for the

representation, including complaints and other communications with consumers or with governmental or consumer protection organizations.

VI.

It is further ordered, That respondents shall notify the Federal Trade Commission at least thirty (30) days prior to any proposed change in the partnership or corporation(s), that may affect compliance obligations arising under this order, including but not limited to a dissolution, assignment, sale, merger, or other action that would result in the emergence of a successor corporation; the creation or dissolution of a subsidiary, parent, or affiliate that engages in any acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the partnership or corporation name or address. Provided, however, that with respect to any proposed change in the corporation about which respondents learn less than thirty (30) days prior to the date such action is to take place, respondents shall notify the Commission as soon as is practicable after obtaining such knowledge. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C.

VII.

It is further ordered, That respondents shall deliver a copy of this order to all current and future principals, partners, officers, directors, and managers, and to all current and future employees, agents, and representatives having responsibilities with respect to the subject matter of this order, and shall secure from each such person a signed and dated statement acknowledging receipt of the order. Respondents shall deliver this order to current personnel within thirty (30) days after the date of service of this order, and to future personnel within thirty (30) days after the person assumes such position or responsibilities.

VIII.

It is further ordered, That respondent Herbert H. Boynton, for a period of ten (10) years after the date of issuance of this order, shall notify the Commission of the discontinuance of his current business

or employment or of his affiliation with any new business or employment. The notice shall include respondent's new business address and telephone number, and a description of the nature of the business or employment and his duties and responsibilities. All notices required by this Part shall be sent by certified mail to the Associate Director, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Washington, D.C.

IX.

It is further ordered, That respondents shall, within sixty (60) days after the date of service of this order, and at such other times as the Federal Trade Commission may require, file with the Commission a report, in writing, setting forth in detail the manner and form in which they have complied with this order.

X.

This order will terminate on July 11, 2017, or twenty (20) years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the order, whichever comes later; provided, however, that the filing of such a complaint will not affect the duration of:

A. Any Part in this order that terminates in less than twenty (20) years;

B. This order's application to any respondent that is not named as a defendant in such complaint; and

C. This order if such complaint is filed after the order has terminated pursuant to this Part.

Provided further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the order, and the dismissal or ruling is either not appealed or upheld on appeal, then the order will terminate according to this Part as though the complaint was never filed, except that the order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

ATTACHMENT A

[To be printed on Nutrition 21 Stationery]

BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED

[Date]

Dear [purchaser for resale]:

This letter is to inform you that Nutrition 21 recently entered into a consent agreement with the Federal Trade Commission ("FTC") concerning certain claims we made for chromium picolinate, which the FTC has alleged to be deceptive. Although Nutrition 21 does not admit the FTC's allegations, we have agreed to have substantiation for any future claims about the effectiveness of chromium picolinate at the time we make those claims, and to stop making claims that scientific studies demonstrate the effectiveness of chromium picolinate unless those claims are true.

As a part of our settlement with the FTC, we also agreed to send this letter notifying our distributors, wholesalers and others to whom we sell chromium picolinate to stop using or distributing advertisements or promotional materials containing the challenged claims.

The FTC alleged that we made unsubstantiated claims relating to the effectiveness of chromium picolinate. Specifically, the FTC alleged that we did not have a reasonable basis for claims that:

- Chromium Picolinate significantly reduces body fat;
- Chromium Picolinate causes significant weight loss;
- Chromium Picolinate causes significant weight loss without dieting or exercise;
- Chromium Picolinate causes long-term or permanent weight loss;
- Chromium Picolinate increases lean body mass and builds muscle;
- Chromium Picolinate significantly increases human metabolism;
- Chromium Picolinate controls appetite and craving for sugar;
- Chromium Picolinate significantly reduces total and LDL serum cholesterol;
- Chromium Picolinate significantly lowers elevated blood sugar levels;
- Chromium Picolinate is effective in the treatment and prevention of diabetes; and
- Ninety percent of U.S. adults do not consume diets with sufficient chromium to support normal insulin function, resulting in increased risk of overweight, heart disease, elevated blood fat, high blood pressure, and diabetes.

The FTC considers a reasonable basis for these types of claims to consist of competent and reliable scientific evidence.

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In addition, the FTC alleged that we falsely claimed that scientific studies demonstrated many of the above claims about chromium picolinate.

We request your assistance by asking you to discontinue using, relying on or distributing any advertising or promotional materials for chromium picolinate that make any of the above claims unless and until you possess competent and reliable scientific evidence that substantiates the claims. Please also notify any of your retail or wholesale customers that they should follow the same procedures.

Thank you very much for your assistance.

Very truly yours,

HERBERT H. BOYNTON
Chairman of the Board
Nutrition 21

Modifying Order

124 F.T.C.

IN THE MATTER OF

COLUMBIA/HCA HEALTHCARE CORPORATION

MODIFYING ORDER IN REGARD TO ALLEGED VIOLATION OF
SEC. 7 OF THE CLAYTON ACT AND SEC. 5 OF THE
FEDERAL TRADE COMMISSION ACT*Docket C-3619. Consent Order, Oct. 3, 1995--Modifying Order, July 14, 1997*

This order reopens a 1995 consent order -- that permitted Columbia/HCA and Healthtrust, Inc., to merge and required the divestiture of the lease agreement -- and this order modifies the consent order by terminating Columbia/HCA's obligation to divest a commercial lease (the Infusamed Lease) for office space in a building in Utah.

ORDER REOPENING AND MODIFYING ORDER

On February 18, 1997, Columbia/HCA Healthcare Corporation ("Columbia") filed its Petition Of Columbia/HCA Healthcare Corporation To Reopen And Modify Order ("Petition") pursuant to Section 5(b) of the Federal Trade Commission Act, 15 U.S.C. 45(b), and Section 2.51 of the Commission's Rules of Practice and Procedure, 16 CFR 2.51. Respondent asks that the Commission reopen the proceeding in Docket No. C-3619 and modify the order to terminate the requirement that Columbia divest the commercial lease identified in Item 6 of Part II of Section A of Schedule B of the order ("the Infusamed Lease"). The Petition was placed on the public record for thirty days, until March 24, 1997, and no comments were received. For the reasons discussed below, the Commission has determined to grant Columbia's Petition.

Columbia states that this Petition is the second step of two procedural steps to remedy a minor error in the order. On December 5, 1995, Columbia filed a petition to reopen and modify the order to terminate the Utah Hold Separate requirements upon its completion of the divestiture of the Part I assets listed on Schedule B of the order, *i.e.*, the Utah hospitals themselves. The Part II assets listed on Schedule B consist of certain assets and businesses that were identified by Columbia during consent negotiations with Commission staff as being related to each of the listed Utah hospitals,¹ and included the Infusamed Lease. On May 15, 1996, the Commission

¹ The only distinction that the order expressly makes between the Part I and Part II assets is that the acquirer of a divested Part I hospital need not give the Commission prior notification of the re-sale of a Part II asset to anyone who also owns a hospital in the relevant market. *See* order, paragraph IV.F.