

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

In the Matter of)	
)	
NUTRITION 21,)	
a limited partnership,)	
)	File No. 932 3282
SELENE SYSTEMS, INC.,)	
a corporation and general)	AGREEMENT CONTAINING
partner of Nutrition 21, and)	CONSENT ORDER
)	
HERBERT H. BOYNTON,)	
individually and as President)	
of Selene Systems, Inc., a)	
corporation.)	
)	

The Federal Trade Commission has conducted an investigation of certain acts and practices of 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 (“proposed respondents”). Proposed respondents, having been represented by counsel, are willing to enter into an agreement containing a consent order resolving the allegations contained in the attached draft complaint. Therefore,

IT IS HEREBY AGREED by and between Nutrition 21 and Selene Systems, Inc., by their duly authorized officers, and Herbert H. Boynton, individually and as President of Selene Systems, Inc., and counsel for the Federal Trade Commission that:

- 1a. Proposed respondent Nutrition 21 is a California limited partnership with its principal office or place of business located at 1010 Turquoise Street, Suite 335, San Diego, CA 92109.
- 1.b.. Proposed respondent Selene Systems, Inc. is a California corporation and a general partner of Nutrition 21. Its address is the same as that of Nutrition 21.
- 1.c. Proposed respondent Herbert H. Boynton is President of Selene Systems, Inc. Individually or in concert with others, he formulates, directs and controls the policies, acts, or practices of Selene Systems, Inc. and Nutrition 21, and his address is the same as that of Nutrition 21.
2. Proposed respondents admit all the jurisdictional facts set forth in the draft complaint.
3. Proposed respondents waive:

- a. Any further procedural steps;
- b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law; and
- c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft complaint, will be placed on the public record for a period of sixty (60) days and information about it publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify proposed respondents, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision in disposition of this proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by proposed respondents that the law has been violated as alleged in the draft complaint, or that the facts as alleged in the draft complaint, other than the jurisdictional facts, are true.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to proposed respondents: (1) issue its complaint corresponding in form and substance with the attached draft complaint and its decision containing the following order in disposition of the proceeding, and (2) make information about it public. When so entered, the order shall have the same force and effect and may be altered, modified, or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery of the complaint and the decision and order to proposed respondents by any means specified in Section 4.4 of the Commission's Rules shall constitute service. Proposed respondents waive any rights they may have to any other manner of service. The complaint may be used in construing the terms of the order. No agreement, understanding, representation, or interpretation not contained in the order or in the agreement may be used to vary or contradict the terms of the order.

7. Proposed respondents have read the draft complaint and consent order. They understand that they may be liable for civil penalties in the amount provided by law and other appropriate relief for each violation of the order after it becomes final.

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 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. 20580.

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. 20580.

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 twenty (20) years from the date of its issuance, 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.

Signed this _____ day of _____, 199__.

NUTRITION 21

By: _____
VICTOR MORENO
President

SELENE SYSTEMS, INC.

By: _____
HERBERT H. BOYNTON
President

HERBERT H. BOYNTON, individually
and as President of Selene Systems, Inc.

STEPHEN H. McNAMARA
Hyman, Phelps & McNamara, P.C.
Attorney for respondents

BETH GROSSMAN
Counsel for the Federal Trade Commission

LOREN G. THOMPSON
Counsel for the Federal Trade Commission

APPROVED:

C. LEE PEELER
Associate Director
Division of Advertising Practices

JOAN Z. BERNSTEIN
Director
Bureau of Consumer Protection

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.

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

**UNITED STATES OF AMERICA
FEDERAL TRADE COMMISSION**

In the Matter of)	
)	
NUTRITION 21,)	
a limited partnership,)	
)	
SELENE SYSTEMS, INC.,)	
a corporation and)	DOCKET NO.
general partner of Nutrition 21,)	
and)	
)	
HERBERT H. BOYNTON,)	
individually and as President)	
of Selene Systems, Inc., a)	
corporation.)	
)	

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 92109.
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:

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

* * * *

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 ~~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 ***those 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 6, 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 6, respondents have represented, expressly or by implication, that they possessed and relied upon a reasonable basis that substantiated the representations set forth in Paragraph 7, at the time the representations were made.

9. In truth and in fact, respondents did not possess and rely upon a reasonable basis that substantiated the representations set forth in Paragraph 7, at the time the representations were made. Therefore, the representation set forth in Paragraph 8 was, and is, false and misleading.

10. Through the means described in Paragraph 6, 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 10 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.

THEREFORE, the Federal Trade Commission on this _____ day of _____, 199__, has issued this complaint against respondent.

By the Commission.

Donald S. Clark
Secretary

SEAL:

[Exhibits A-G attached to paper copies of complaint, but not available in electronic format.]

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement to a consent order from Nutrition 21, a limited partnership, Selene Systems, Inc., a general partner of Nutrition 21, and Herbert H. Boynton, President of Selene Systems, Inc. (“respondents”).

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement or make final the agreement’s proposed order.

This matter concerns chromium picolinate, a nutrient patented by the United States Department of Agriculture. Respondents hold the exclusive license to manufacture and sell chromium picolinate in the United States. The Commission’s proposed complaint alleges that the respondents represented without a reasonable basis in their advertisements that chromium picolinate: a) significantly reduces body fat; b) causes significant weight loss; c) causes significant weight loss without diet or exercise; d) causes long-term or permanent weight loss; e) increases lean body mass and builds muscle; f) significantly increases human metabolism; g) controls appetite and reduces cravings for sugar; h) significantly reduces total and LDL serum cholesterol; i) significantly lowers elevated blood sugar levels; and j) is effective in the treatment and prevention of diabetes. The proposed complaint also alleges that respondents represented without a reasonable basis that ninety percent of adults in the United States 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. Finally, the proposed complaint alleges that respondents falsely represented that a number of those claims were supported by scientific studies.

The proposed consent order contains provisions designed to prevent the respondents from engaging in similar acts and practices in the future. Part I of the proposed order prohibits respondents from making the challenged representations for chromium picolinate or any other food, dietary supplement, or drug unless they possess and rely upon competent and reliable scientific evidence that substantiates the representations.

Part II of the proposed order prohibits respondents from making any representation about the benefits, performance, efficacy, or safety of chromium picolinate or any other food, dietary supplement, or drug unless they possess and rely upon competent and reliable scientific evidence that substantiates the representation.

Part III of the proposed order prohibits respondents from misrepresenting the existence, contents, validity, results, conclusions, or interpretations of any test, study, or research.

Part IV of the proposed order requires respondents to send notification letters to past,

current, and future purchasers for resale of chromium picolinate. The letter describes the Commission's allegations and the terms of the order, and advises recipients to stop using promotional materials making the challenged claims.

Parts V through IX of the proposed order relate to respondent's obligation to maintain records, distribute the order to current and future officers and employees, notify the Commission of changes in corporate structure or in the individual's employment, and file compliance reports with the Commission. Part X provides that the order will terminate after twenty years under certain circumstances.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.