

IN THE MATTER OF

METAGENICS, INC., ET AL.

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

Docket 9267. Amended Complaint, October 23, 1997--Decision, October 23, 1997

This consent order, among other things, requires a California-based company and its officer, the marketers of a calcium supplement known as "Bone-Builder," to possess scientific substantiation for any claim that their product or any food, drug or dietary supplement containing calcium will treat or prevent any disease, disorder or condition. The consent order also requires the respondents to possess scientific substantiation for superiority claims for such products and regarding the relationship between calcium and osteoporosis. In addition, the consent order prohibits the respondents from misrepresenting the existence or results of any test or study regarding such products.

Appearances

For the Commission: *Lesley Fair* and *C. Lee Peeler*.

For the respondents: *Robert Ullman, Bass & Ullman*, New York, N.Y.

AMENDED COMPLAINT

The Federal Trade Commission, having reason to believe that Metagenics, Inc., a corporation, doing business as Ethical Nutrients, and Jeffrey Katke, individually and as an officer of said corporation ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

PARAGRAPH 1. Respondent Metagenics, Inc., doing business as Ethical Nutrients, is a corporation organized, existing, and doing business under and by virtue of the laws of the State of California, with its principal office or place of business at 971 Calle Negocio, San Clemente, California.

Respondent Jeffrey Katke is an officer of Metagenics, Inc. Individually or in concert with others, he formulates, directs and controls the acts and practices of the said corporation, including the acts and practices alleged in this complaint. His business address is 971 Calle Negocio, San Clemente, California.

PAR. 2. Respondents have manufactured, advertised, offered for sale, sold and distributed an orally-ingested product containing microcrystalline hydroxyapatite ("MCHC"), minerals and protein, under the name Bone Builder (hereinafter "MCHC" or "Bone Builder"). Respondents also offer for sale and sell the MCHC product to other parties who market the product under their own brand names. Bone Builder is a food and/or drug, as the terms "food" and "drug" are defined in Sections 12 and 15 of the Federal Trade Commission Act.

PAR. 3. 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.

PAR. 4. Respondents have disseminated or have caused to be disseminated advertisements and promotional materials for Bone Builder, including but not necessarily limited to the attached Exhibits A through D. These advertisements and promotional materials contain the following statements:

1. The superior form of calcium proven to build bone. The latest research shows "microcrystalline hydroxyapatite" is the superior form of calcium that can build bone. We call this exciting Ethical Nutrient's [sic] product: BONE BUILDER. (Exhibit A).

2. Some calcium supplements can be worse than not taking anything at all. At best, others may slow bone loss, occasionally stopping it. But, BONE BUILDER can restore lost bone and has the clinical evidence to prove it! (Exhibit A).

3. A significant statement recurs in a number of reports: MCHC either reduces or totally eliminated bone pain, which was not found true of any other substance. (Exhibit A).

4. Only MCHC provides calcium in an "extremely bioavailable form" and the studies on it have "also indicated the superiority of the substance over traditional soluble calcium supplements." Of the substances used for experimentation to halt the progress of osteoporosis, only microcrystalline hydroxyapatite was considered to be totally free of "major potential hazard [sic]," which indicated its use for both "the treatment and prevention of osteoporosis." (Exhibit A).

5. These are just a few of the controlled clinical trials to be found in medical literature. The consensus of which is that microcrystalline hydroxyapatite halted bone loss, decreased pain and increased bone thickness when taken in adequate amounts over long periods of time, a record no calcium supplement could achieve. (Exhibit B).

6. Contains most absorbable kind of calcium. (Exhibit C).

7. BONE BUILDER is pure microcrystalline hydroxyapatite compound (MCHC), a substance which has been scientifically demonstrated to be the most effectively utilized source of calcium known. (Exhibit C).

8. Most importantly, no other product in the United States is as effective at preventing bone loss. (Exhibit C).

9. [R]esearch of the many common forms of calcium used in the trials demonstrated effectively that only one form of calcium was capable of preventing bone thinning and actually restoring bone strength, and that was "whole bone extract (microcrystalline hydroxyapatite concentrate)" (Exhibit D).

10. Where there is evidence that osteoporosis "runs in the family," and where there is evidence that calcium loss is already taking place, *i.e.* muscle spasms, receding gums, or loss of height, the ability of microcrystal-line hydroxyapatite [sic] (bone) concentrate places prevention as a matter of the individual sufferer's choice. This safe, reliable, inexpensive, scientifically-tested preventive is his/hers to take as they choose (Exhibit D).

PAR. 5. Through the use of the statements contained in the advertisements and promotional materials referred to in paragraph four, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A through D, respondents have represented, directly or by implication, that:

1. Post-menopausal women who have lost bone and who use Bone Builder or MCHC will experience no additional bone loss or bone thinning and will achieve a growth of new bone and increased bone thickness greater than the amount of bone lost;

2. Users of Bone Builder or MCHC will not experience bone loss, bone thinning, or osteoporosis;

3. Bone Builder or MCHC restores bone strength;

4. Bone Builder or MCHC reduces or eliminates pain associated with bone ailments; and

5. Bone Builder or MCHC is more bioavailable, more absorbable, or more effectively utilized by the body than other forms of calcium or is more effective than other forms of calcium in the prevention or treatment of bone ailments.

PAR. 6. Through the use of statements contained in the advertisements and promotional materials referred to in paragraph four, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A through D, respondents have represented, directly or by implication, that at the time they made the representations set forth in paragraph five, respondents possessed and relied upon a reasonable basis that substantiated such representations.

PAR. 7. In truth and in fact, at the time respondents made the representations set forth in paragraph five, respondents possessed and relied upon a reasonable basis to substantiate that: adequate calcium intake has many benefits and is one of the essential factors in the

body's ongoing process of removal of old bone and replacement by new bone; in conjunction with other factors, adequate calcium intake can play a significant role in reducing the rate of bone loss or bone thinning and in protecting bone strength; and individuals who do not consume adequate calcium are at greater risk of experiencing bone fractures than those who do. However, respondents did not possess and rely upon a reasonable basis that substantiated the representations in paragraph five. Therefore, the representation set forth in paragraph six was, and is, false and misleading.

PAR. 8. Through the use of the statements contained in the advertisements and promotional materials referred to in paragraph four, including but not necessarily limited to the advertisements and promotional materials attached as Exhibits A through D, respondents have represented, directly or by implication, that scientific research, including clinical tests, scientific papers and/or scientific studies, proves that:

1. Post-menopausal women who have lost bone and who use Bone Builder or MCHC will experience no additional bone loss or bone thinning and will achieve a growth of new bone and increased bone thickness greater than the amount of bone lost;
2. Users of Bone Builder or MCHC will not experience bone loss, bone thinning, or osteoporosis;
3. Bone Builder or MCHC restores bone strength;
4. Bone Builder or MCHC reduces or eliminates pain associated with bone ailments; or
5. Bone Builder or MCHC is more effectively utilized by the body than other forms of calcium or is superior to or more effective than other forms of calcium in the prevention or treatment of bone ailments.

PAR. 9. In truth and in fact, the representations set forth in paragraph eight have not been proven by scientific research, including clinical tests, scientific papers and/or scientific studies. Therefore, the representations set forth in paragraph eight were, and are, false and misleading.

PAR. 10. 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.

Commissioner Anthony not participating.

EXHIBIT A

Bea METAGENIC
EXHIBIT A

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are easily removed by the oxygen atoms through an orthoquinonoid polymer chain of excess of the resin and of absorption of stretching long term use or warpage in the

also indicated the superiority of the substance over traditional soluble calcium supplements.⁸ Of the

Line No.	Date	Amount
14-1053	1907	18
14-1054	1907	22

1970	1971	1972	1973
1.054	1.054	1.054	1.054

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EXHIBIT B

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WHY FOOL AROUND?

by Gene Birkeland

Recently on an interstate auto safari, my car broke down (as they are wont to do at the most critical times) and I was stuck for the night in a small town motel.

Since I was depressed with my circumstances, I flung myself on the bed, and began listening to the news.

A reporter came on with a story about osteoporosis. Now that really depressed me. Her story was superficial and badly researched, but what depressed me most was the thought of the thousands of people who might see it and believe this misinformation.

To illustrate her assertion that a simple elevation of calcium intake was the answer to osteoporosis, she'd taken several glasses of distilled white vinegar and dropped different brands of calcium tablets into them. This was supposedly an illustration of how they might dissolve in your stomach, and, of course, some of them didn't.

The one that dissolved most quickly was a well-known drug store product manufactured by a major pharmaceutical company containing a relatively small amount of calcium. What she didn't point out were the additives the product contained besides oyster shell powder (which is poorly absorbed in humans).

To bolster her story and give it credence, she threw in the name of a local medical doctor who confirmed her position that a high intake of calcium is the best way to prevent osteoporosis.

Nothing was said about the controversy which rages within scientific circle questioning whether calcium alone is the answer to osteoporosis.

For example, the prestigious British Medical Journal five years ago, in an article on the Non-hormonal Treatment Of Osteoporosis said, "Osteoporosis may be defined as the loss of bone accelerated beyond the normal

"physiological" rates, although this begs the question of what normal loss might be ... Its recognition, measurement, prevention and treatment were discussed at a recent symposium and the account of this emphasizes how opinion on these issues is still divided."

"... in osteoporosis it appears other factors are at work, not just an absence of sufficient calcium in the diet."

Guy Abraham, MD., an internationally recog-

ADDITIVES CONTAINED IN A POPULAR DRUG STORE CALCIUM SUPPLEMENT

Corn Syrup Solids	Talc	Hydroxypropyl	Methyl cellulose
Corn Starch	Sodium Starch Glycolate	Calcium Stearate	Polysorbate 80
Pharmaceutical Glaze	Titanium Dioxide	Vitamin D	Methylpropyl Paraben
Polyvinylpyrrolidone	Carnauba Wax	Polyethylene Glycol	D & C Yellow #10 Dye
Acetylated Monoglyceride	Edetate Di-sodium	FD & C Blue #1 Dye	Simethicone Emulsion

EXHIBIT B

nized authority on the endocrinology of obstetrics and gynecology, in a conversation with me, as well as in public speeches, has pointed out that no country in the world has set calcium requirements as high as the United States — and no country has more bone problems. Dr. Abraham has been the recipient of at least two international awards for his work, part of which stemmed from his research while heading ob-gyn endocrinology research at UCLA's Harbor General Hospital in Los Angeles, CA.

There, Dr. Abraham had found that women with severe premenstrual tension had too much dairy food in their diets, and too high a calcium intake relative to their magnesium intake. As he pointed out, animals such as elephants and gorillas grow huge skeletons eating only green plants, which have twice as much magnesium as calcium. Dr. Abraham took the women off dairy products to reduce calcium intake, while upping their consumption of vegetable greens to increase magnesium intake. The result? No more premenstrual tension.

In osteoporosis, it appears other factors are at work, not just an absence of sufficient calcium in the diet. And, at least a quarter century has passed since calcium retention was shown not to be adequate without a modicum of estrogen to enhance the calcium uptake — or it is merely excreted in the urine. Only a medical doctor can prescribe estrogen, but the enterprising TV reporter never mentioned the importance of the relationship.

No doubt many people were likely to believe her over-simplification. Yet osteoporosis is still a major health problem, which to some extent continues to baffle the medical research world. Research project reports on possible causes and potential cures for osteoporosis are frequently published to this day in the medical literature.

The only positive reports on halting the devastation and crippling of osteoporosis have come through the medical administration of small, care-

"... micro-crystalline hydroxyapatite halted bone loss, decreased pain and increased bone thickness when taken in adequate amounts over long enough periods of time, a record no other form of calcium could achieve."

fully monitored quantities of estrogen along with calcium, or through the administration of a product little known in the United States, but widely used in Europe and England: microcrystalline hydroxyapatite.

In a clinical trial in England, for example, a group of women with bone disease were divided into 3 matched groups. The result was "Over the 14-month follow-up, there was a significant loss of cortical bone in controls, a significant increase in cortical bone thickness in the MCHC (microcrystalline hydroxyapatite) group, and no change in the CG (calcium gluconate) group." The MCHC group had a net cortical bone gain of 11.6%. (Cortical bone is the outer bone)

The research team from the Royal Free Hospital in London, described the substance they were testing: "MCHC powder is prepared from bovine bone and provides both the organic and inorganic constituents occurring in normal bone. The powder contains hydroxyapatite microcrystals, calcium, trace metals (including zinc, silicon and iron), protein, amino acids and aminoglycans."

Another advantage the research team noted was the low sodium content of MCHC compared to calcium gluconate which was of advantage in "long-term treatment of patients with cirrhosis or other diseases complicated by salt retention."

The prevention of osteoporosis follows that old adage that "an ounce of prevention is worth a pound of cure" as most adults lose bone steadily throughout their lives. This loss is accelerated in women after the menopause, a situation which led to British researchers to advise, "the only way to prevent osteoporosis is to make sure that the subject starts his or her aging process with well-mineralized bones." (emphasis added)

Too often, however, nothing is done until a fracture occurs either crushing the trabecular (inner) bone in the spine which causes pain as well as

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height loss, or the fracture of a long bone. Some studies show a trend toward "fracture of the wrist at 60, of the shoulder at 70, and the neck at 80," though such fractures are seldom attributed to osteoporosis.

In fact, one research team has stated: "The perceived frequency of osteoporosis is unrealistically low and usually the diagnosis is made only when

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osteoporosis at all!"***

crush fractures of the vertebral bodies occur and consequently lead to loss of height."

In another clinical trial, 10 grams of MCHC containing approximately 1,500 mgs of cal-

cium was used over a period of nine months on patients who were in severe pain, had recent fractures and were on analgesics (pain killers). The majority reported less bone pain with a subsequent decrease of intake of analgesics and an increase in plasma calcium.

In another trial group of individuals aged 70 to 98, the whole bone extract was used because "the proportions of the mineral content correspond to the presumed physiological needs of the organism since they are those of bone itself ... it was found that the whole-bone extract significantly increased absorption of the tracer suggesting it is a valuable medium for calcium administration in metabolic bone disease." In this latter test the research team also concluded, as had others before and since, that the whole bone extract was better than calcium gluconate which they had checked out at the same time.

These are just a few of the controlled clinical trials to be found in medical literature. The consensus of which is that microcrystalline hydrox-

yapatite halted bone loss, decreased pain and increased bone thickness when taken in adequate amounts over long enough periods of time, a record no calcium supplement could achieve.

The product has been available in Europe and England for years and is now available in the United States under the name Bone Builder (formerly Ethical).

REFERENCES

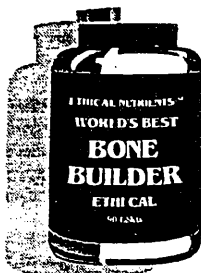
- Dixon, et al, Osteoporosis: a multidisciplinary problem, London, Royal Society of Medicine, Academic Press.
- Vitamin D, Hydroxyapatite, and Calcium Gluconate in Treatment of Cortical Bone Thinning in Postmenopausal Women With Primary Biliary Cirrhosis, Epstein, et al, Amer. J. of Clin. Nutr. 9/82.
- Estimation of True Calcium Absorption, Harvey, M.D., et al, Creighton University School of Medicine, Annals of Internal Medicine, 1985:103:316-321.
- Treatment of Spinal Osteoporosis in Postmenopausal Women, Nordin, Hovman, et al, Mineral Metabolism Unit, General Infirmary, Leeds, British Medical Jnl, 10 Feb. 1980.
- Bone Loss in the Elderly, Rowe, Ph.D., Univ. of Iowa, Jnl of Prosthetic Dentistry.
- Effect of Milk Supplements on Calcium Metabolism, Bone Metabolism and Calcium Balance, Recker, MD, & Heaney, MD, Am. Jnl. Clin. Nutrition, 41:Feb. 85.
- Bone Mineral Content of Amenorrheic and Eumenorrheic Athletes, Drinkwater, Ph.D., Wilson, M.D., et al, New England Jnl of Med., Vol 311, No. 5, 8-2-84.
- Action of Zinc on Bone Metabolism in Rats, Yamaguchi, Yamaguchi, Shimokata College of Pharmacy, Suzuka, Japan, Biochemical Pharmacology, Vol 35, No. 5.
- Intestinal Absorption of Calcium from Three Commercial Calcium Preparations in Man, Bergsted, Jorgensen, et al, NEJM 9-2-82.
- Long Distance Running, Bone Density and Osteoarthritis, Lane, MD, Bloch Ph.D., et al, JAMA, 3-7-86.
- Histological Osteomalacia due to Dietary Calcium Deficiency in Children, Marie, Ph.D., Pussifor, MB, et al, NEJM, 9-2-82.
- Calcium and Phosphorus Nutritional Status of Lacto-ovo-vegetarian and Omnivore Students, Neakem, Kiza, McEndree, Univ. of Neb., Nutrition Reports International, Feb. 84.
- Calcium and Hypertension, Annals of Internal Medicine, Vol 203, No. 6, 12-85.
- Harvard Medical School Health Letter, April 1987.
- Calcium Bioavailability from Ca Carbonate and Ca Citrate, MJ Nizar, C Pak, Jnl of Clin Endocrinology and Metabolism, 1985.
- CALCIUM: Where it Should Be and Shouldn't Be: Bland, Complementary Medicine, May/June 1986.
- Vitamin D, Hydroxyapatite, and Calcium Gluconate in Treatment of Cortical Bone Thinning in Postmenopausal Women With Primary Biliary Cirrhosis, Epstein, MRCP, Kato, MD, Dick FRCP, Sherlock, FRCP, Amer. Jnl of Clin. Nutrition 9/82.
- Non-hormonal Treatment of Osteoporosis, Brit Med Jnl, March 1983.
- Treatment of Osteoporotic Patients, Dunston, Parnon, et al, Clinical Trials Jnl, No. 3, 1973.
- Effect of Whole Bone Extract on Calcium Absorption in the Elderly, Windsor, Munn, et al, Age and Aging, 1973 2, 220.

EXHIBIT C

METAGENICS
EXHIBIT C

WORLD'S BEST BONE BUILDER

- ✓ All necessary bone building nutrients in one tablet
- ✓ Formulated by nature
- ✓ Processed using breakthrough technology
- ✓ Completely safe



- ✓ Successfully tested and used in Europe for over 10 years
- ✓ Available for first time in U.S.
- ✓ Contains most absorbable kind of calcium
- ✓ Not to be confused with bone meal or ordinary hydroxyapatite

THE PROBLEM: Osteoporosis is an enormous public health problem, responsible for at least 1.2 million fractures in the United States each year. One third of women over sixty-five will have vertebral fractures. By extreme old age, one of every three women and one of every six men will have had a hip fracture. Hip fracture is fatal in 12-20% of cases and it results in long term nursing home care for half the patients who survive. More women die from the complications of fractures yearly than the combined deaths resulting from cancer of the cervix and breast. The direct and indirect costs of osteoporosis are estimated at 6.1 billion dollars annually in the United States. Furthermore, the gradual loss of bone results in disfigurement, wrinkling, decreasing mobility and the deposition of calcium in soft tissue (kidney, arteries, joints, etc.) leading to further complications.

THE SOLUTION: Regular exercise, a whole foods diet, smoking cessation, and adequate absorption of micro-nutrients will end the current rapid bone loss epidemic in the United States population.

GREAT NEWS! A COMPLETE, NATURE-MADE, BONE FOOD IS NOW AVAILABLE. THIS BONE FOOD IS BONE BUILDER (formerly ETHI CAL).

THE BONE BUILDER STORY: BONE BUILDER is a pure microcrystalline hydroxyapatite compound (MCHC), a substance which has been scientifically demonstrated to be the most effectively utilized source of calcium known. This highly useful substance is distinguished by its unusual ability to be absorbed into the bloodstream. For example, studies have demonstrated it to be absorbed at twice the rate of calcium gluconate. Hydroxyapatite is a complex calcium salt which forms the basis of bone. It has an ideal calcium/phosphorus ration of 2:1.

A considerable number of laboratory and clinical studies have been undertaken to understand the nature and value of MCHC. Using animal studies, researchers have demonstrated a lack of both acute and chronic toxicity. Thus, we know MCHC to be completely safe.

Clinically, MCHC has been shown to be highly effective. For example, in one study of postmenopausal women a comparison was made between MCHC, calcium gluconate and a control group. Over a 14 month period, the control group experienced a 5.5% bone loss, the calcium gluconate group a 1.5% bone gain, while



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the MCHC group experienced a 6.1% bone gain. Positive calcium balances were reported in other clinical studies using MCHC to treat osteomalacia (bone softening). In yet another study the author states "... we have demonstrated that MCHC dramatically reduces skeletal pain in patients developing osteoporosis, and have also presented strong evidence that this symptomatic improvement is associated with both favorable biochemical and radiological bone changes".

BONE BUILDER SOURCE: The MCHC contained in BONE BUILDER has been derived solely from the bones of healthy animals raised in an environment free from pesticides, insecticides, growth hormones and other environmental contaminants. It has been processed by an exclusive technique which preserves the natural qualities inherent in the raw substance. This is in marked contrast to the preparation of bone meal, which is an ashed residue, devoid of life, having been subjected to considerable heat, and washed with chemical solvents. This harsh processing causes the protein matrix to cross-link, altering the value of the collagen, and considerably reducing the effectiveness of the subsequent preparation. Also, bone meal often contains an unacceptably high amount of lead. BONE BUILDER does not. In essence, BONE BUILDER may be considered a minimally-processed, complete nature-made food for the bone.

CHEMICAL PROPERTIES OF MICROCRYSTALLINE HYDROXYAPATITE: MCHC is a complex salt in which 3 molecules of calcium phosphate are associated with 1 molecule of calcium hydroxide. Hydroxyapatite occurs as hexagonal needles arranged as rosettes. These are embedded in a protein matrix. Its chemical name is decacalcium dihydroxide hexakis-(orthophosphate).

Apart from calcium and phosphorus, other major minerals present in MCHC are sodium, magnesium and potassium. Unlike commercial soluble calcium supplements, the sodium content is low (0.65%), a factor of importance for some consumers.

The main trace minerals present are zinc, silicon, and iron. Others include rubidium, caesium and platinum, as well as many others.

MCHC contains 14% collagen and 4% other proteins, as well as hydroxyproline. Other amino acids present in relatively high amounts including glycine and glutamic acid. Also included are glucosaminoglycan, citrate, flouride (0.008%) and water.

SUMMARY: BONE BUILDER consists of microcrystalline hydroxyapatite which, itself being from bone, is a complete bone food. BONE BUILDER is not merely another calcium supplement, although it happens to be the most highly absorbable form of calcium known. BONE BUILDER is hypoallergenic, palatable and cost-effective. Most importantly, no other product in the United States is as effective at preventing bone loss.

REFERENCES: Available upon request. Please ask for "MCHC scientific references".



For FREE Literature Pack Contact: Ethical Nutrients • 23180 Del Lago • Laguna Hills, CA • 92653

1-800-692-9400 (Nationwide)

1-800-833-9526 (In California)

EXHIBIT D

METAGENICS
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STRONG BONES -- YOU NOW HAVE A CHOICE

by Gene Birkeland

You may be able to remember a book, "Life Begins at Forty." Fortunately, I don't, so you're much older than I—I only remember the title, which has become almost cliché, and while many other things may also begin at forty, some of them are not so great.

Forty may well be the time for a good many of us when the sins and errors of our youth begin to show up, creating situations in our bodies for which we never bargained, and are quite often at a loss to understand.

One of these incomprehensible conditions, now occurring on a fairly large scale, is osteoporosis, in which abnormal mineral loss over a long period of time causes weakened bones susceptible to sudden breakage and/or a painful shrinkage of the spine.

From personal experience I know that the average physician does not understand the chemistry involved in this painful condition, but I also have the words of some of the doctors themselves as they discussed this problem in a symposium in England not too long ago.

These research specialists concluded, "Early diagnosis is difficult because osteoporosis is asymptomatic until it is advanced far enough to cause structural failure of bone." And, continues the specialists, "opinion is still divided on the recognition, measurement, prevention and treatment" of osteoporosis.

This is true. I have observed the slow disintegration of my mother from a woman of slim build and average height to a very short statured dowager. Over these last ten years she has shrunk some 5 and 1/2 inches, and the only remedy her busy Hollywood-star struck physician has offered is an occasional cortisone shot to alleviate the pain.

Her situation is not unique. When the pain began in her back (the result of a vertebrae fracturing and compressing the disc), I drove her to the doctor's office, telling her to ask him if this was not related to a loss of calcium.

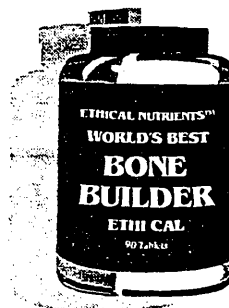
Emerging from his office later, she said, "You were right! He said he saw x-rays of my spine three years ago which showed calcium loss even then." I looked at her in amazement and consternation. "Are you telling me he's known this for three years and hasn't told you about it or advocated any sick remedy?" "Well, what could he do?" she said.

Even at that time he could have taken the known medical steps to prevention of further loss which consisted of small daily quantities of conjugated estrogens accompanied by calcium supplementation. He happens, however, to belong to that school of medicine which scorns all supplements and still believes all estrogens are carcinogenic.

His management of the condition was to dispense occasional shots of cortisone without regard that long-term use of steroids causes further mineral loss, as does inactivity and complicating major disease conditions.

Ten years later, Mother is restricted to the use of canes and walker and is relatively inactive.

So prevalent is this type of situation that the British doctor who reported on the symposium, Allan St. J. Dixon (Royal National Hospital for Rheumatic Diseases), stated, "Osteoporosis thus appears to join diabe-



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tes, gall stones, and diverticulosis as one of the diseases of affluence."

"The perceived frequency of osteoporosis," says Dr. Dixon, "is unrealistically low and usually the diagnosis is made only when crush fractures of the vertebral bodies occurs and consequently lead to loss of height."—yet, continues Dr. Dixon, studies show the condition leads to "fractures of the wrist at 60, of the shoulder at 70, and the femoral neck at 80."

Even though men are also victims of the bone-thinning process and some evidence of it usually shows up by age 70, women are by far the predominant sufferers which begins at least as early as the menopause—whether surgically or naturally occurring.

Dr. Dixon has observed that in the United States even well-fed women had an average intake of calcium of 660 mg per day.—"Well below the recommended daily intake of 800 mg"—a figure, he says, "which many nutritionists would still regard as being too low."

As a result, Dr. Dixon concluded, "calcium seems to be the forgotten nutrient of Western society, and it seems that a failure to consume enough of it must inevitably lead to loss of bone mineral."

There needs to be an alternative, says Dr. Dixon, (and there is) which is safe, effective, inexpensive and may be continued over years without harm, especially as bone rebuilding and strengthening cannot be expected to take place rapidly.

He has reviewed all the alternatives which have been the object of studies by his colleagues, such as the use of many varieties of calcium supplements in conjunction with other substances. All were found wanting.

Dixon's research of the many common forms of calcium used in the trials demonstrated effectively that only one form of calcium was capable of preventing bone thinning and actually restoring bone strength, and that was "whole bone extract (microcrystalline hydroxyapatite concentrate) (which) is well absorbed and does not have the disadvantages of the former preparations."

"Dixon cited hospital trials of the substance (in which) . . . microcrystalline hydroxyapatite concentrate did restore bone."

Microcrystalline hydroxyapatite concentrate contains the bone minerals calcium, phosphorus and magnesium together with trace amounts of zinc, copper, manganese, and other trace and ultratrace elements in the normal physiological proportions.

Dixon cited hospital trials of the substance making a comparison of it to calcium gluconate which "halted the bone loss but did not restore it, whereas microcrystalline hydroxyapatite concentrate did restore bone."

Concluding his remarks, Dr.

Dixon added, "Nothing can restore the spinal posture to normal in those people whose spines have already shrunk because of osteoporosis, (but) there is good evidence to suggest that preventative treatment is very effective."

Where there is evidence that osteoporosis "runs in the family," and where there is evidence that calcium loss is already taking place, i.e., muscle spasms, receding gums, or loss of height, the ability of the microcrystalline hydroxyapatite (bone) concentrate places prevention as a matter of the individual sufferer's choice. This safe, reliable, inexpensive, scientifically-tested preventive is his/hers to take as they choose and not dependent upon the whim of another.

Probably just like you, I get fed up with swallowing supplements. Yet I have only to visit my mother to see the alternative which inadequate attention to prevention has created: being condemned to hobbling around in continual pain supported by cane or walker, or just sitting.

The supplement which I have been discussing, microcrystalline hydroxyapatite concentrate, is not merely bone meal, but is instead specially selected portions of the bones of animals raised in the absence of pesticides and insecticides. These bone sections are carefully processed (ground up) at less than 98° to preserve the essential microcrystalline structure as it exists in raw bone. It has been available in Europe and England for some years and is now available in the United States under the name Bone Builder (formerly Ethical Cal), and is sold exclusively by Ethical Nutrients of Laguna Hills, CA.



For FREE Literature Pak Contact: Ethical Nutrients • 23180 Del Lago • Laguna Hills, CA 92653
(714) 855-1718 (Local) • 800-833-2956 (In California) • 800-592-9400 (Nationwide).

DECISION AND ORDER

The Commission having heretofore issued its complaint charging the respondents named in the caption hereof with violation of Section 5 of the Federal Trade Commission Act, as amended, and the respondents having been served with a copy of that complaint, together with a notice of contemplated relief; and

The respondents, their attorney, and counsel for the Federal Trade Commission having thereafter executed an agreement containing a consent order, an admission by the respondents of all the jurisdictional facts set forth in the 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 jurisdictional facts, are true and waivers and other provisions as required by the Commission's Rules; and

The Secretary of the Commission having thereafter withdrawn this matter from adjudication in accordance with Section 3.25(c) of its Rules; and

The Commission having considered the matter 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 comment filed thereafter by an interested person pursuant to Section 3.25 of its Rules, now in further conformity with the procedure described in Section 3.25(f) of its Rules, the Commission hereby makes the following jurisdictional findings and enters the following order:

1. Respondent Metagenics, 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 located at 971 Calle Negocio, San Clemente, California.

Respondent Jeffrey Katke is an officer of said corporation. He formulates, directs and controls the policies, acts and practices of said corporation and, and his office and principal place of business is located at the above stated address.

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

3. 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 3.25(f) of the Commission's Rules, the Commission may, without further notice to respondents: (1) issue its amended complaint corresponding in form and substance with the draft of amended complaint attached hereto and its decision containing the following order to cease and desist in disposition of the proceeding; and (2) make information public in respect thereto. When so entered, the order to cease and desist 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 by the U.S. Postal Service of the amended complaint and decision containing the agreed-to order to proposed respondents' address as stated in this agreement shall constitute service. Proposed respondents waive any right they may have to any other manner of service. The amended complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

ORDER

I.

It is ordered, That respondents Metagenics, Inc., a corporation, doing business as Ethical Nutrients, or under any other name, its successors and assigns, and its officers, and Jeffrey Katke, individually and as an officer of said corporation, and respondents' agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Bone Builder or any food or dietary supplement, food, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall not represent, in any manner, directly or by implication, that:

1. Post-menopausal women who have lost bone and who use such product will experience no additional bone loss or bone thinning or will achieve a growth of new bone or increased bone thickness greater than the amount of bone lost;

2. Users of such product will not experience bone loss or bone thinning;
3. Such product restores bone strength;
4. Such product reduces or eliminates pain associated with bone ailments; or
5. Such product is more bioavailable, more absorbable, or more effectively utilized by the body than other forms of calcium, or is superior to or more effective than other forms of calcium in the prevention or treatment of bone ailments,

unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation. For purposes of this order, "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.

II.

It is further ordered, That respondents Metagenics, Inc., a corporation, doing business as Ethical Nutrients, or under any other name, its successors and assigns, and its officers, and Jeffrey Katke, individually and as an officer of said corporation, and respondents' agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Bone Builder or any food or dietary supplement, food, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall not misrepresent, in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

III.

It is ordered, That respondents Metagenics, Inc., a corporation, doing business as Ethical Nutrients, or under any other name, its successors and assigns, and its officers, and Jeffrey Katke,

individually and as an officer of said corporation, and respondents' agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of Bone Builder or any food or dietary supplement, food, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, insofar as said respondents make any representation, in any manner, directly or by implication, regarding the relationship between calcium and osteoporosis:

A. Shall limit any such representation to the health claims authorized by the Food and Drug Administration for calcium and osteoporosis as set forth in Section 101.72 of Title 21 of the Code of Federal Regulations, 58 Fed. Reg. 2665 (1993), and any amendments thereto; or

B. At the time of making such representation, shall possess and rely upon competent and reliable scientific evidence that substantiates the representation.

IV.

It is further ordered, That respondents Metagenics, Inc., a corporation, doing business as Ethical Nutrients, or under any other name, its successors and assigns, and its officers, and Jeffrey Katke, individually and as an officer of said corporation, and respondents' agents, representatives, and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of:

A. Bone Builder or any food or dietary supplement, food, or drug containing calcium, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall not make any representation, in any manner, directly or by implication, that any such product will treat, cure, alleviate the symptoms of, prevent, or reduce the risk of developing any disease, disorder, or condition; or

B. Any food or dietary supplement, food, or drug, as "food" and "drug" are defined in Section 15 of the Federal Trade Commission

Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, shall not make any representation, in any manner, directly or by implication, that any such product is more effective than any other product in treating, curing, alleviating the symptoms of, preventing, or reducing the risk of developing any disease, disorder, or condition,

unless, at the time of making such representation, respondents possess and rely upon competent and reliable scientific evidence that substantiates the representation.

V.

Nothing in this order shall prohibit respondents from making any representation that is specifically permitted in labeling for any such product by regulations promulgated by the Food and Drug Administration pursuant to the Nutrition Labeling and Education Act of 1990.

VI.

Nothing in this order shall prohibit respondents from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

VII.

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

A. Any advertisement making any representation covered by this order;

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

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

representation, including complaints from consumers, and complaints or inquiries from governmental organizations.

VIII.

It is further ordered, That respondent Metagenics, Inc., or its successors and assigns, shall:

A. Within thirty (30) days after the date of issuance of this order, provide a copy of this order to each of its operating divisions, subsidiaries, principals, officers, directors, managers and distributors, and to each of its employees, agents, and representatives engaged in the preparation, placement, or dissemination of advertisements, promotional materials, product labels, or other such sales materials covered by this order; and

B. For a period of five (5) years from the date of issuance of this order, provide a copy of this order to each of its principals, officers, directors, managers and distributors, and to all employees, agents, and representatives engaged in the preparation, placement, or dissemination of advertisements, promotional materials, product labels, or other such sales materials covered by this order within three (3) days after the person commences his or her responsibilities.

IX.

It is further ordered, That respondent Metagenics, Inc., its successors and assigns, shall notify the Commission at least thirty (30) days prior to any change in the corporation 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 the acts or practices subject to this order; the proposed filing of a bankruptcy petition; or a change in the corporate name or address. Provided, however, that, with respect to any proposed change in the corporation about which the respondent learns less than thirty (30) days prior to the date such action is to take place, respondent shall notify the Commission as soon as 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.

X.

It is further ordered, That for a period of five (5) years from the date of issuance of this order, respondent Jeffrey Katke shall provide written notice to the Federal Trade Commission within thirty (30) days of:

- A. Any change in his business or employment that may affect compliance obligations arising out of this order;
- B. The discontinuance of his business or employment; and
- C. His affiliation with any new business or employment; each such notice to include his business address and telephone number, home address, and a statement describing the nature of the business or employment and his duties and responsibilities.

XI.

This order will terminate on October 23, 2017, or twenty 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 paragraph in this order that terminates in less than twenty 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 paragraph.

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 paragraph 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.

XII.

It is further ordered, That respondents shall, within sixty (60) days after service upon them of this order, and at such other times as the 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.

Commissioner Anthony not participating.

IN THE MATTER OF

MID-SOUTH PCM GROUP, P.C., ET AL.

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

Docket C-3773. Complaint, November 5, 1997--Decision, November 5, 1997

This consent order prohibits, among other things, the Tennessee-based corporations and its officer from claiming that PCM ortho-k or any substantially similar service provides a cure for vision deficiencies; that all people can achieve normal vision without eyeglasses or contact lenses on a permanent basis if they wear devices used with such services occasionally or at night; that the four academic studies prove PCM ortho-k is safe and effective in correcting nearsightedness, farsightedness, and astigmatism; and that PCM ortho-k has been approved by the FAA and all branches of the military. In addition, the consent order requires reliable scientific evidence for any future success or efficacy claims.

Appearances

For the Commission: *Christa Vecchi, Matthew Daynard and Dean Graybill.*

For the respondents: *John L. Ryder, Apperson, Grump, Duzane & Maxwell, Memphis, TN. and Michael Evangelisti, Black, Babango & Morgan, Memphis, TN.*

COMPLAINT

The Federal Trade Commission, having reason to believe that Mid-South PCM Group, P.C., Eye and Vision Clinic, P.C., and International Computerized Orthokeratology Society, Inc., corporations, and J. Mason Hurt, O.D., individually and as an officer of the corporations ("respondents"), have violated the provisions of the Federal Trade Commission Act, and it appearing to the Commission that a proceeding by it in respect thereof would be in the public interest, alleges:

1. Respondent Mid-South PCM Group, P.C. ("Mid-South") is a corporation formed under the laws of the state of Tennessee, with its principal office or place of business located at 2865 Summer Oaks Drive, Bartlett, TN.