HEALTH OR HYPE?

A REPORT ON
UNUNITED SCIENCES OF AMERICA

American Council on Science and Health
1995 Broadway
New York, NY 10023
212-362-7044

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This special report was written by Stephen Barrett, M.D., Scientific and Editorial Consultant to the American Council of Science and Health (ACSH). His investigation was assisted by James J. Kenney, Ph.D., R.D., John H. Renner, M.D., Frederick J. Stare, M.D., Ph.D., and Diane Woznicki.

ACSH gratefully acknowledges the comments and contributions of the following individuals who reviewed this report:

Donald Austin, M.D., M.P.H.
Alfred E. Harper, Ph.D.
Victor Herbert, M.D., J.D.
William T. Jarvis, Ph.D.
David Kritchevsky, Ph.D.
Joseph F. Murphy, Esq.
Robert E. Olson, M.D., Ph.D.
Edward G. Remmers, Sc.D.
John H. Renner, Ph.D.
Sidney Shindell, M.D., LL.B.
Fredrick J. Stare, M.D., Ph.D.
Stephen S. Sternberg, M.D.
Elizabeth M. Whelan, Sc.D., M.P.H.

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Introduction

United Sciences of America, Inc. (USA, Inc.) is a multilevel marketing operation based in Dallas, Texas. Its corporate mission is "to provide all Americans with the potential of optimum health and vital energy through state-of-the-art nutrition" (1). Its products are dietary supplements which it suggested could help prevent cancer, heart disease, stroke and other ailments as diverse as AIDS and dandruff. The company began organizing in 1984 and officially began marketing its products in January 1986. Soon afterward, it projected gross sales of $150 million for 1986 and $1 billion for 1989, which would make it the fastest growing business in American history (2).

USA differed from other multilevel companies in at least four ways: 1) it claimed that prominent scientists had designed its products and endorsed them; 2) its marketing program was based on high-tech videotapes; 3) it was vigorously marketed to health professionals as well as to the general public; and 4) it promised extensive support for scientific research through grants and office-based clinical studies.

Despite its high-sounding goals, USA's activities were severely criticized by the scientific community and the news media (3-12). In the wake of this criticism, USA pledged drastic changes in its marketing program. But before they could be implemented, the company declared bankruptcy and was attacked by the FDA and three state attorneys general. This report examines what happened and advises consumers to be wary of similar promotions.

Company Management

USA's founder and chairman was Robert M. Adler II, a Dallas businessman who became wealthy by developing a computer that dials phone numbers and engages in interactive messages. USA's corporate brochure listed nine co-founders, including:

- Jerris Leonard, a former U.S. Assistant Attorney General, was USA's president.
- Joseph S. Ventura, who was an executive with Mr. Adler's telecommunications company, was USA's chief executive officer.
- Jeffrey A. Fisher, M.D., a pathologist with a master's degree in immunology, was USA's medical director and senior vice president and was president of the United Sciences of America Research Foundation. USA publications described him as a marathon runner and "a nationally recognized expert on preventive medicine." He hosts "The Life Extension Program," a talk show on radio station WOR, New York City.
- Lawrence J. Muno, USA's vice president for sports communications, is counselor and agent for many prominent athletes and has been president of the Association of Representatives of Professional Athletes.
- Mark Albion, Ph.D., an assistant professor of marketing at Harvard Business School, was an executive consultant to Mr. Adler and was said to have devised USA's marketing plan (2).
• Haydon Cameron, USA's vice president for marketing, is a former newspaper reporter who was a top sales leader for Cambridge International, marketers of the Cambridge Diet.

• Robert A. Good, M.D., Ph.D., was chairman of USA's Scientific Advisory Board. Former president of Sloan-Kettering Institute for Cancer Research, he is now chairman of the Department of Pediatrics and Professor of Microbiology and Immunology at the University of South Florida College of Medicine.

Scientific Advisory Board

USA's corporate brochure listed 14 scientific advisors in addition to Dr. Good:

• Julius Axelrod, Ph.D., Chief, Section on Pharmacology, Laboratory of Clinical Sciences, National Institute of Mental Health, and winner of the Nobel Prize in Medicine and Physiology in 1970

• Eugene Braunwald, M.D., Professor of Medicine, Harvard Medical School, and Physician-in-Chief, Brigham and Beth Israel Hospitals

• Peter Cerutti, M.D., Ph.D., Director of Carcinogenesis Research, Swiss Institute for Experimental Cancer Research

• Michael DeBakey, M.D., Chairman, Department of Surgery, Baylor College of Medicine

• Philip J. DiSaia, M.D., Professor and Chairman, Department of Obstetrics and Gynecology, University of California, Irvine Medical Center

• Maureen Henderson, M.D., Professor of Epidemiology and Medicine, University of Washington School of Medicine

• Rashida Karmali, Ph.D., Associate Professor of Nutrition, Rutgers University, and Associate Professor, Sloan-Kettering Institute for Cancer Research

• Alexander Leaf, M.D., Chairman, Department of Preventive Medicine and Clinical Epidemiology, Harvard Medical School

• Robert J. Morin, M.D., Professor of Pathology, Harbor-UCLA Medical Center

• Lester Packer, Ph.D., Professor of Physiology and Anatomy, University of California, Berkeley

• William A. Pryor, Ph.D., Professor of Chemistry and Biochemistry, Louisiana State University

• Andrew V. Schally, Ph.D., Chief, Department of Experimental Medicine, Tulane University, and winner of the Nobel Prize in Medicine and Physiology in 1977

• Eli Seifter, Ph.D., Professor of Biochemistry and Surgery, Albert Einstein College of Medicine

• C. Norman Shealy, M.D., Ph.D., Director, Shealy Pain and Health Rehabilitation Institute, and founder and past-president of the American Holistic Medical Association.
Most members of USA's Scientific Advisory Board were attracted by what they perceived as an opportunity to advance the cause of preventive medicine and the promise that more than $1 million a year in research funds would be made available to the scientific community. However, several members became upset that USA was using their presence on the board for marketing purposes. Between June and December 1986, Drs. Axelrod, Braunwald, Good, Henderson, Karmali, Leaf and Schally resigned. Some were upset about USA's marketing practices, while others were concerned about the unfavorable publicity the company was receiving.

According to Dr. Fisher, some of them and most of the remaining board members believed that supplements of the type promoted by USA could have valuable preventive health benefits—and most of them used one or more of the company's products (13). In August 1986, the Scientific Advisory Board issued a policy statement that "in deference to the universities and other institutions with which we are affiliated, it is appropriate for us to guide the development of but not endorse formally, these or any other commercial products" (14).

Most board members received annual stipends of $10,000 to $20,000 in return for attending one meeting a year and furnishing advice when requested. In line with USA's announced intention to generate nutrition-related scientific research, the USA Research Foundation awarded $100,000 grants for studies involving antioxidants or fish oils. The first 12 grants went to Drs. Leaf, Pryor, Cerutti, Good, Packer, DeBakey, Axelrod, and five other scientists who were not members of USA's Scientific Advisory Board.

Marketing structure

USA is similar in concept to Shaklee, Amway, and Herbalife. Its distributors are called "Independent Associates." Anyone can become an Independent Associate by completing an application and paying $24.50 for a Success System Kit and Manual. No knowledge of nutrition or medical care is required. Independent Associates are urged to use the products themselves and to persuade others to become Independent Associates who, in turn, use the products and recruit more Independent Associates. When sales volume is sufficient, distributors get a percentage of the sales in their "downline." During part of 1986, new customers were telephoned by a company representative who played a brief inspirational message from Dr. Good and asked whether they were using the products and how they liked them.

USA's sales manual suggested that "a successful Independent Associate is one who is committed to the USA Inc. Nutritional Plan—one who takes all four products every day." To make this convenient, kits containing a 1-month supply of the four products were available for $135.00 retail or $100.00 wholesale (the price to distributors).

Noting that "your most effective sales tool is always your own testimonial," the manual suggested starting by contacting family, friends, and close acquaintances. Then:

The USA, Inc. Nutritional Plan changes a person's image and outlook, building self-esteem and self-confidence.
The total plan enriches the lives of all who use it. Your customers will become so excited about the USA, Inc., formulas that they will want to refer friends to you for products. Referrals will lead to still more referrals because success breeds success . . .

The video presentations will make the sales for you, and at the same time, will show your friends how easy it is to do the same with their friends.

Earnings could accrue both from retail sales and from sales by the people one sponsors. "Every new retail customer represents an approximately 30% return on your product investment," said the manual. "Start one new customer a day for the next 12 months and your profit on retail sales will compound to a very handsome income." (If all of these customers stayed on the 4-product retail program, the profit would exceed $1,000 for the first month and $80,000 for the year. However, anyone with any business sense taking the 4-product program would become a distributor to buy it wholesale—which would reduce the sponsor's earnings from $35/month per person to $4/month per person.)

To illustrate how sponsoring can pyramid income, the manual illustrated how sponsoring three distributors who each sponsor three more who in turn sponsor three more (for a total of 39 people in the downline) will yield a bonus of $114 per month if all parties involved purchase $100 worth of products. To remain eligible for downline commissions, distributors would have to buy at least $100/month of products from the company. However, those with significant downlines would have to buy larger amounts to qualify for maximum bonuses.

USA's earliest distributors, Robert and Brenda McIntyre, of Plano, Texas, acquired more than 60,000 people in their downline. The McIntyres, who began sponsoring people in December 1985, published a newsletter and developed promotional aids of their own. In their Marketing Plan Video, Robert claimed that "within the next 10 to 15 years, more than half of all the products moved in the United States will go through network marketing." He also said there are 500,000 millionaires in the United States today, 20% of whom have come through the industry of network marketing.

In this videotape, McIntyre illustrated the potential profits that could accrue by sponsoring five people who sponsor five more who sponsor five more who sponsor five more—who sponsor five more—for a downline total of 3,903. He also stated how much he and his wife have earned (despite company policy against doing this). Copies of their April 1986 sales report and cancelled check were widely circulated by some members of his downline. From December 1985 through April 1986 their commissions were $523, $13,512, $35,593, $69,235, and $108,316.

Business Building Basics, a sales manual sold by the McIntyres, gave three more Profit Plan illustrations: a 2x2x2 $100/person downline would yield $40/month; a 4x4x4 $100/person downline would yield $672/month; and a 6x6x6 $100/person downline would yield $2,580/month. The book noted, however:

The illustrations in no way represent typical or actual historical growth or achievement by specific USA Associate
groups nor are they intended to suggest that an achievement of this type will be easy or even possible for some USA Associates (15).

USA's products

The company's press packet stated:

At the heart of United Sciences of America, Inc.'s broad-based nutrition program lies its products, four state-of-the-art nutritional formulations that are based on over 50,000 published research and clinical studies interpreted by some of the world's foremost research scientists... to come up with the right amounts of nutrients to promote optimal health without any risk whatsoever of toxicity. Moreover the [Scientific Advisory] Board will continue to analyze the data as it comes in—at the rate of 1,300 new research papers a month—with an eye to additional changes as necessary (16).

The four products were: 1) the Master Formula of vitamins, minerals, and antioxidants; 2) Formula Plus, a marine lipid concentrate rich in omega-3 fatty acids; 3) Fiber Energy Bar, containing nine grams of fiber; and 4) Calorie Control Formula, a high-fiber protein powder mix for use as a meal substitute. Their ingredients are listed in Appendix 1. A weight management program and a chewable nutritional formula for children ages 6 to 14 were being developed.

Marketing aids

USA and its products were promoted with videotapes and brochures that contained many questionable claims:

- **Company Overview** (1985). This 20-page document described USA's purposes, scientific advisory board, research base, products, research goals, and marketing strategy. The company is described as "a major new entity with a revolutionary health concept." Its corporate mission was "to provide all Americans with the potential of optimum health and vital energy through state-of-the-art nutrition." The company was said to have established "the world's largest computerized data base in clinical nutrition" in the following manner:

  USA's team of Ph.D. researchers searched and reviewed the collective data of more than 5 million references in 14,200 medical and scientific journals covering 150 countries... From this powerful body of clinical evidence came USA's own in-house index of 30,000 scientific studies covering 250,000 pages of documented research which was condensed to 10,000 pages of categories and studies... Never before has a nutritional information base so complex been assembled by a single company."

The **Company Overview** stated that media interviews with scientists and superstar athletes, combined with articles in major publications "are expected to elevate USA Inc.'s extraordinary concept into a new national MOVEMENT." USA's Profit Plan was "designed to encourage all product-users to go into business for themselves—with a minimal financial investment and without risk." It also offered "a vital new life—and financial freedom for all who become involved."
In response to a complaint from Dr. Fredrick J. Stare, Dr. Fisher stated:

I would like to apologize for the material that somehow found its way into your hands. This original "company overview" was poorly written, completely unsophisticated and essentially a piece of marketing "hype." It was not intended to be circulated but mistakenly several copies were . . .

I assure you that USA, Inc., has no intention of sponsoring flim-flam men as this original overview may have suggested . . . USA's President and General Counsel, Jerris Leonard, is a former U.S. Assistant Attorney General and Federal Prosecutor. He has set down strict prohibitions against distributors in the field making false claims and assures me that anyone violating these prohibitions will be terminated as a distributor. I would like to point out, however, that this is a merger between science and business and, in order to generate revenue for research and education purposes, business must be served. Therefore there has to be a marketing plan (17).

Despite this disclaimer, the Company Overview was widely circulated (probably to thousands of prospective distributors) during 1986, and USA, Inc., never notified distributors to stop utilizing it as a recruiting tool.

- Corporate Brochure (1986). This was a sophisticated, beautifully illustrated, 20-page booklet similar in scope to the Company Overview. According to this brochure, USA "has developed a preventive health program that incorporates every nutritionally related breakthrough from the world's most prestigious hospitals and research institutes." Dr. John Wise, USA Vice President of Science and Data Information, was pictured in a very large room filled with computers. (Though no indication was given, the computers belong not to USA but to Dialog Information Services, of Palo Alto, California, a company that maintains massive computerized files in many fields.) The marketing message stated that "a perfect blend of philosophy, products, and programs help make it possible for all USA Inc. Associates to succeed." The brochure contained pictures of ten athletes and stated:

Many of the world's finest and most visible athletes support the USA, Inc. quest for excellence. These superstars use and endorse the USA, Inc nutritional formulas and are actively involved in the USA business opportunity. Many of their family members, friends and teammates are USA, Inc. Associates.

The ten athletes were: Joe Montana (San Francisco 49ers); Gary Carter (New York Mets); Chris Evert Lloyd (tennis star); Bill Rodgers (marathon runner); Steve Garvey (San Diego Padres); Tony Dorsett (Dallas Cowboys); Steve Watson (Denver Broncos); Nolan Ryan (Houston Astros); Bobby Beathard (general manager, Washington Redskins); and John Mengelt (former professional basketball player). According to an article in Advertising Age, Montana and Evert Lloyd were to promote USA's products nationally while the others were to promote them regionally. The athletes were recruited by USA co-founder Larry Muno and Matt Mertola,
who heads his own New York-based sports celebrity organization (18). Newsweek has reported that Chris Evert Lloyd will receive one percent of USA's 1986 nationwide revenues (19).

- **Nutritional Plan (1985, 1986).** This 2-page flyer described the company's products and listed its scientific advisory board. According to the flyer, Harvard's Dr. Alexander Leaf called USA's products "the most complete nutritional program I have ever analyzed." (Dr. Leaf denies making this statement or giving approval for its release. Dr. Fisher insists that he did. Regardless, the idea that a "nutritional program" can be complete without any consideration of food is absurd.) The flyer also quoted Dr. Morin: "The scientific and clinical evidence supporting the USA Inc. formulas is overwhelming and I strongly recommend them."

- **Success System Manual (1986).** This plush 64-page looseleaf manual provided information about USA's profit plan, how to build a business, and various company policies. The manual claimed that USA's products "represent the basic elements of a highly effective program for optimal health" and were "the finest nutritional program ever developed." One page of the manual stated that "USA Inc. products are food supplements which are meant to be used solely for dietary purposes. They are not intended to be cures for any diseases or ailments." But another page called personal testimonials "your most effective sales tool." A list of authorized promotional statements included: "This nutritional plan was developed and endorsed by some of the world's most respected medical experts." Suggestions for telephone prospecting included: "Are you serious about getting a new car? I know a way to help you get it."

- **Company Introduction Videotape (1985).** This videotape was narrated by William Shatner (Captain Kirk of Star Trek) and included scenes of a space rocket launching, a giant computer bank, scientific laboratories, prominent medical institutions, and medical journals. Shatner alleged that "our food, water and air are becoming contaminated" by chemicals ("toxic killers"), that cancer is on the rise, that our soil is being depleted of "vital, life-giving nutrients and important earth minerals," that one out of every three families will be stricken with some form of cancer, and that two out of five people will die of heart disease or stroke. Then he described how USA's founder, Robert Adler, developed a "brain trust of medical and scientific experts who have pioneered one of the most dramatic programs in the history of nutritional science ... Their mission is clear: to develop a complete nutritional program to protect us from the growing dangers that are threatening the health of our nation." Shatner also suggested that investing in USA's program would result in "looking your best, feeling maximum physical energy and mental well-being, enjoying total health." Appendix 2 contains the full text of this tape.

- **Business Opportunity Videotape (1985).** This message was combined with the Company Introduction into a 26-minute videotape. William Shatner explained multilevel marketing and stated that "the potential profits are staggering because the growth is geometric." Mark Albion suggested that anyone using USA's marketing package properly would be successful, and "with a medical and scientific credibility, United Sciences, Inc. is destined to become the IBM of nutrition." And Joe
Montana, Gary Carter, Chris Evert Lloyd, Bill Rodgers and Steve Garvey invited viewers to "join USA's winning team."

- Video Update (1986). This 20-minute videotape was narrated by William Shatner, who stated: "When used as a supplement to a sensible, high-fiber, low-fat dietary plan and exercise, the four USA formulas constitute a comprehensive nutritional program incorporating every key nutritional supplement which will benefit our health according to existing scientific data." Dr. Robert Good said, "I'm convinced that the program being advocated and promulgated by USA of regular exercise, of calorie restriction, and appropriate nutrition, well-balanced nutrition, can carry us a long way toward preventing these diseases associated with aging, and in that way maximizing health." Dr. Robert Morin said: "The USA formulas when used as a supplement to a high-fiber, low-calorie diet may well prove to be our best defense against the known, as well as the unknown, pathology of aging." Shatner stated: "The USA clinical advisory board of over 250 highly respected physicians and scientists from all across the United States is currently conducting and planning broad-based human nutritional studies." Chris Evert Lloyd stated: "I've been on the USA nutritional program for almost a year now and there's no doubt in my mind that my energy level has really improved... I meet people in my travels, and it always amazes me whether I meet them on the streets or at airports or at tennis tournaments, they all come up to me and say how much these products have enhanced and improved their lives." And Joe Montana stated: "Since I've been on the program, I've felt a noticeable difference, especially in overall endurance. I don't get that end-of-the-day sluggish feeling that I used to get all the time."

- Medical Library Videotape (1986). During this 90-minute tape, Dr. Fisher answered about 100 questions about USA's products and the relationship of nutrients to disease. According to the tape's narrator:

[This videotape] represents a major breakthrough in medical communications. United Sciences of America is dedicated to accumulating and translating the vast amount of new medical data that is emerging daily from the world's major hospitals, research institutes and laboratories. Contained within this explosion of medical research is information that can have a powerful impact on all our lives. Nutritional science is expanding so rapidly that only a company with USA's state-of-the-art computer technology and USA's advisory boards, comprised of world-leading medical doctors and Ph.D. researchers can properly inform the public. Education is the most important goal of United Sciences of America. It is USA corporate policy to continually update our public information and our nutritional program. By doing so, USA intends to improve the quality of health care for millions of Americans.

When asked why people should follow the USA program, Dr. Fisher responded:

You may feel healthy, you may look good, but optimal health is more than just an absence of disease. Many studies, including a large study conducted by the federal government, have shown widespread deficiencies in most Americans of at least one
essential nutrient. In addition to that, we are being barraged all the time with an increasing number of pollutants and cellular toxins. The Master Formula is designed to help correct these deficiencies and help protect us against these cellular toxins and pollutants through the use of antioxidants that we have synergistically blended through all our research studies into this Master Formula . . .

Also, a lot of very, very comprehensive studies by most major research institutions in this country, including the National Cancer Institute, the National Institute of Health, the American Heart Association, the American Cancer Society, have recommended that Americans cut calories and increase fiber. The USA programs—the Calorie Control Formula and the Fiber Energy Bar—are meant to accomplish this painlessly, safely and permanently.

The Formula Plus is a really unique combination of the fish oils, EPA and DHA. A lot of you may have been hearing in the media lately that we should be eating more fish. This comes from studies on the Eskimos and Japanese compiled in research data not only in this country but in Europe that these fish oils can have a really positive impact on our cardiovascular system. It can do things like lower the blood fats, cholesterol and triglycerides, reduce the risk of forming blood clots in our arteries, and also can even help lower blood pressure.

Later he added:

The USA formulas are a type of insurance policy to help protect you against the numerous nutritional deficiencies in the American diet and the wide variety of cellular pollutants and toxins that occur in our environment. Therefore we recommend that you make the USA formulas an integral part of your daily life . . .

The main reason to take the USA formulas is for long-term results and to maximize your health. In many cases you may note a feeling of increased energy, vitality and well being.

When asked whether he was on the USA program, Dr. Fisher replied, "Of course I am. How do you think I got so healthy looking?"

Throughout the tape, Dr. Fisher referred to nutrition research which he relates to the prevention and treatment of heart disease, breast and colon cancer, arthritis, diabetes, intestinal problems, premenstrual syndrome, acne, osteoporosis, and other health problems. For example:

- To help prevent AIDS, "it makes good sense to strengthen your immune system as much as possible. This can be done by the nutrients zinc, vitamin A, vitamin C and and Vitamin E, and also eating a diet with reduced calories and fat and high in fiber."

- "Although there's no solid evidence that one particular nutrient can reduce stress, there is a great deal of well documented evidence that stress reduces the functioning of the immune system . . . So if
you're under stress, not only should you plan a good stress-management program, but you should also try to stimulate your immune system. And you can do this through certain nutrients, such as zinc, vitamin A, Vitamin C and vitamin E."

• "Dandruff can be due primarily to a free radical reaction in your scalp. Free radicals are very reactive chemicals that are produced in our cells due to many environmental pollutants, such as cigarette smoke, alcohol, radiation, inflammation, and eating the wrong foods. These free radicals can be responsible for such mundane problems as dandruff and serious conditions like cancer. Free radical diseases can be helped and prevented by taking supplemental nutrients called antioxidants—things like beta-carotene, vitamin A, vitamin C, vitamin E, the minerals zinc and selenium, and the sulfur-containing amino acids cystine, methionine and glutathione."

Staff members and advisors of the American Council on Science and Health who observed this tape believe it is a mixture of facts and misinterpretations that no layperson could sort out. When presented with the idea that laypersons are already spreading misinformation based on their perceptions of the tape, Dr. Fisher replied, "The reason I made the tape is so that people wouldn't do that. We made it to help them not have to rely on their own lack of knowledge to present the facts" (13).

• Awards Banquet Videotape (1986). This covered the ceremonies at a banquet on June 21, 1986, when over 600 of the company's officers and successful distributors gathered for a dinner celebration. Master of ceremonies William Shatner stated:

USA's Scientific Advisory Board was formed in response to the critical need for solutions, the need to develop a total approach to state-of-the-art nutrition. The board has achieved its goal of designing a plan which eliminates the guesswork for a concerned and questioning public. The USA nutritional program embodies the latest clinical findings which indicate that in order to maintain your health, we must enhance key nutritional elements in our bodies to counteract the damage from megatoxins, poor eating habits and mounting environmental stress. We must reduce our daily intake of fat, sugar and calories and replace them with a scientifically balanced nutritional plan rich in fiber, antioxidants and micronutrients. What makes this total approach so unique is that the USA nutritional program is being continuously updated as new scientific information is discovered.

USA president Jerris Leonard said:

[Those present] provide the living proof that this company is not hype, it's not front, it is indeed a reality . . . an entity whose purpose is driven by a cause. And the cause is not greed, and the cause is not money, and the cause is not ego. The cause is to bring a better sense of well being and fitness and health and better nutrition . . . maybe even a few more years of life to all those people who will listen, who will receive this message, and who will become a part of this cause. Now that doesn't mean that you don't have a right to
make an honest buck by being involved in this cause. But the cause comes first . . . You can bring better health to millions of Americans if you will stay with it, if you will believe in the credibility of this program . . . you will in fact make a change in the health and well being of the people in this country . . . hopefully in the entire world.

Dr. Fisher added:

This company is really based on scientific credibility . . . There is no hype involved. Sales does not necessarily have to involve hype. That's what we've been trying to tell ourselves all along, and I think that you've finally gotten the message—that you don't have to hype this. This is for real. There really is scientific evidence that the stuff that we are telling you can increase the length and the quality of your lives.

¢ Display Systems. For use at "trade shows, medical offices, conventions and business lobbies," USA offered four display systems ranging in price from $608 for the 6-foot tabletop model to $12,240 for the 25-foot system.

Clinical Advisory Board

USA's Clinical Advisory Board was described on company letterheads as a group of "America's most distinguished physicians specializing in a preventive approach to medicine."

Actually, any physician could join the board by completing a simple application. Many of its members were recruited by soliciting subscribers to The Townsend Letter for Doctors, a newsletter for "holistic" doctors (20). Others were recruited through Independent Associates, all of whom were asked to submit doctors' names. Hospital residents as well as office-based physicians were solicited to join the Clinical Advisory Board and also to sell USA products. Some doctors were told they could earn commissions by having their patients order products through a toll-free telephone number.

When the company received a doctor's name, it sent an information kit that included the Company Introduction videotape, the Medical Library videotape, an audio cassette tape, and applications to join as a Research Member or a Physician Affiliate of the Clinical Advisory Board. The audiotape stated that the Clinical Advisory Board was formed for three purposes:

1. To help make health professionals more aware of nutritional science—with regular updates and critiques of pertinent nutritional preventive medical literature.

2. To serve as a national referral base for USA associates who desire general medical care and advice and/or who have specific questions about the formulas.

3. To aid in the monitoring of patients in clinical studies on the USA formulas. According to Dr. Fisher, "One of the goals of USA, Inc. is to conduct the largest group of clinical trials ever attempted on nutritional supplements (20)."
Applicants for the Clinical Advisory Board were asked to specify their medical training and focus of practice, and to provide two references. The Research Membership application asked, "Having studied the USA Nutritional Program, do you recommend it?" and authorized USA to publish the applicant's name, medical school, specialty and office address in USA medical research literature, printed materials and audio visual productions. The Research Affiliate application asked how many patient referrals the applicant could accommodate and whether the applicant supported USA's corporate philosophy and recommended its nutritional program. Research Members were expected to conduct research on their patients. Research Affiliates were merely placed on a mailing list for medical reports.

Dr. Fisher said that about 500 doctors had signed up as of mid-December, with slightly more than half interested in Research Membership. But to receive referrals or participate in USA's clinical studies, they would have to take a nutrition course and pass an open book exam which the company was still preparing (13).

Clinical Advisory Board members received a letter of welcome from Dr. Good stating:

It is our intention to modify the way physicians evaluate and treat their patients. By conducting an extensive array of human nutrition studies and having them published in peer-reviewed journals, our goal is to make the medical community more aware of important, new information in nutritional science.

USA also intended to use its Clinical Advisory Board for political purposes. After the company was criticized in The New England Journal of Medicine, Dr. Fisher asked the Clinical Advisory Board to send rebuttal letters to the journal's editor (21). In another mailing, he said:

The Food and Drug Administration is currently entertaining a motion to bar medical claims from nutritional products, [which] could affect USA, Inc's ability to promote the attributes of our preventive health program . . . The FDA must be informed and educated about the value and necessity of nutritional supplements in general, and USA Inc's products and goals in particular. Please contact the FDA in writing and underscore the merits of the concepts and products marketed by our company. In the future, we may request that you personally call the FDA in a combined effort to strongly communicate our position on this issue. If this damaging initiative is pursued, you will be informed of a date and time to contact the administration (22).

A nurses advisory board was also formed, whose purposes included: 1) recommendations for research; 2) developing strategies with which nurses could interact with physicians in promoting USA formulas; and 3) recommending ways to interest nurses in marketing USA products (23).

USA publications

USA published three periodicals:
USA Update. A bimonthly subscription magazine to provide distributors with "the most up-to-date nutritional, marketing and lifestyle news, packaged with unprecedented sophistication." The first issue, which had 36 pages, discussed USA's four formulas, its pending weight management program, the work of Dr. Good, the success story of Robert McIntyre, pointers on fitness and food labels, and answers to questions about USA products. It also contained a testimonial by a customer who said that his program of exercise, proper eating and USA products had saved him from cardiac surgery.

Express. This was a monthly news report for distributors, which was published in June, July/August, and September. Each issue listed USA's top 100 distributors and provided information about USA's products, policies, and procedures. Photographs of USA officials, distributors, and company activities also appeared.

Journal. This 12-page booklet was sent monthly for three months beginning in July 1986 by the USA Research Foundation to interested health professionals. Each issue consisted of two articles written in technical language and referenced. The topics discussed were: dietary selenium; drinking water and cancer; nutrition and brain function; health risks of passive smoking; garlic, blood disorders and cancer; and stress and immunity.

Public relations

In September 1986, USA hired the public relations firm of Cunningham & Walsh, 260 Madison Avenue, New York, NY 10016. Its press packet stated:

In just a few short months, this rapidly growing firm has emerged as an undisputed leader in assembling a massive amount of research data on nutrition and health, translating that knowledge into the most nutritionally complete and advanced product formulations possible with today's research and technology, and marketing them with a unique strategy and distribution system.

"USA, Inc., is going to shift the emphasis on health care from drugs and treatment to prevention and nutrition," declares Robert M. Adler, the company chairman and founder . . . Using sophisticated computer technology and advisory boards, our goal is to educate physicians and the public to improve the quality of health for millions of Americans.

Advertising by distributors

USA distributors advertised widely in publications and by direct mail. Some excerpts:

- "This company and its products have been endorsed by some of the world's most renowned medical professionals, including 2 Nobel Prize winners . . . It is being said by people across America that we offer the greatest part time job in America and the greatest full time business opportunity." [Flyer, Allentown, Pa.]

- "Presenting: A Life Extension Program . . . Many product testimonials are in regarding weight loss, increased energy, positive
effects for diabetics, lowered blood pressure, lowered cholesterol and triglyceride levels, and reduced PMS symptoms. We just heard a strong testimony regarding Meniere's disease, an inner ear imbalance problem." [Flyer, Allentown, Pa.]

- "Achieve optimal health and financial freedom selling nutritional and weight control products endorsed by Nobel Prize winning physicians and world class athletes." [Classified ad in American Health]

- "Anyone who makes a concerted effort can produce in 9 to 10 months an organization with sales of $100,000 per month." [Mailing from a Wisconsin dentist to other dentists.]

- "Be Your Own Boss--20% of new millionaires made it due to ground floor multilevel marketing opportunities!!" [Flyer from Massachusetts]

- "Top commission checks already exceed $30,000 monthly." [Flyer announcing meeting in Suffern, New York.]

- "Cancer is winning . . . and, 2 out of 5 Americans will die of heart disease . . . United Sciences of America, Inc., is a major new entity with a revolutionary new concept involving documented scientific breakthroughs now emerging in nutrition and health . . . This company has produced the most professional recruiting and marketing tool ever created in multilevel marketing. A Spielberg type high budget video narrated by one of Hollywood's most respected actors. This video will be available in continuous play for use in your waiting rooms and as an educational tool for your patients. This company has designed a lucrative marketing plan which will generate larger bonus checks than have ever been seen in this industry." [Full-page ad in The American Chiropractor]

- "... The powerfully professionally produced videos are convincing up to 90% of the people who see them to become customers, distributors, or both." [Promotional letter, Allentown, Pa.]

- "MLM GOLDMINE. Dynamic new nutritional company. Endorsed by sports superstars, Nobel Prize winners, top physicians . . . ." [Classified ad in USA Today]

- "An optometrist we sponsored in Illinois told me that the morning stiffness he has had since childhood has disappeared since he began taking the vitamins and marine lipids and that he has had a great deal more energy. My cholesterol has dropped 13% and my total lipids dropped 13.9% after four months on the Master Formula and Formula Plus. I made no other changes in my diet or lifestyle. USA, Inc. was not developed to be used for the treatment of disease, and I am not advocating it for this purpose. I am merely stating what is true for me." [Prospecting letter from Texas physician to laypersons.]

- "You can make these products available to your patients in your office and/or enroll them as distributors and they can purchase from the company with profit dollars to you. Most important, you can say with conviction, 'This reflects the current scientific opinion of world-wide medical researchers. In deed, America's finest research scientists have assembled to create a revolutionary nutrition plan.'" [Prospecting letter from a Pennsylvania dentist to other dentists.]
Sales meetings

Many USA distributors invited prospects to sales meetings at their home or at a public meeting. In July 1986, ACSH Research Associate Diane Wosnicki attended a sales demonstration in New York City. After USA's introductory videotape was shown, samples of the Fiber Energy Bar and a Calorie Control Formula shake were offered and the business opportunity was explained. The presenter said that distributors are not qualified to answer questions about the medical aspects of the program. But he did say, "Everyone knows the benefits of fish oils in preventing heart attacks . . . that's why they're in the product." For further information, prospects were referred to USA's Medical Communications Division hotline to speak to a "trained medical mid-expert," and were advised that a Medical Library videotape could be purchased for $25.

The Fast Start Success School was an intensive training program held weekly in Dallas, Texas, by several top distributors in the McIntyre downline. This seminar, which attracted people from all over the U.S., consisted of four hours of discussion followed by a trip to company headquarters. The meetings were conducted mainly by Robert Roundtree, who ranked 11th on USA's list of sales leaders in June and was elected chairman of USA's Presidential Director Advisory Council, a group formed to advise the company on business issues.

Roundtree developed two telephone introductions which he advised seminar participants to write down word-for-word. (The object of these approaches was to persuade the prospect to view USA's introductory videotape.) The 90-second pitch was:

United Sciences of America opened its doors for business on the first of January of this year. However, 18 months prior to that USA gathered and documented all known clinical information on the subject of nutrition worldwide. They then gave it to its scientific advisory board for product evaluation and development. The scientific advisory board includes, among others, Dr. Michael DeBakey, Dr. Andrew Schally, Dr. Julius Axelrod--both of whom in different years won the Nobel Prize for medicine--one in medicine and chemistry, the other one in medicine and physiology. Dr. Robert Good, who's been featured on the cover of Time Magazine as one of the world's leading immunologists, Dr. Alexander Leaf, Chairman of the Department of Preventive Medicine at Harvard Medical School. Through their research and recommendation, four products were developed which are now available for sale through USA Independent Associates: #1, a vitamin/mineral/trace element and amino acid tablet; #2, a high-fiber energy bar; #3 a cardiovascular tablet, the purpose of which is to improve the circulatory system; and #4, a delicious 100-calorie high-fiber meal replacement milkshake. Everything about the products and the company is dramatically featured on a 26-minute color video narrated by William Shatner of Star Trek. Because of the timing, because of the unprecedented medical credibility that accompanies this program, and #3, from a marketing standpoint, the relative simplicity and potential speed with which it is possible for a
person to build a network marketing company, to me it represents the most significant business opportunity with which I've ever been acquainted.

The 15-second pitch was:

United Sciences of America opened its doors for business on the first of January of this year. It has basically been put together by a world's Who's Who in medicine. And from a marketing standpoint, it's a network marketing company that is breaking all known U.S. sales records. Everything is on a 26-minute videotape which I'd like to send you.

**Criticism of USA products**

USA's most vocal critics have been Fredrick J. Stare, M.D., Ph.D., chairman of ACSH's board of directors and emeritus professor of nutrition at Harvard University School of Public Health, and John H. Renner, M.D., president of the Kansas City Committee on Health and Nutrition Fraud and Abuse. In the October 9, 1986, New England Journal of Medicine, Dr. Stare charged that "USA seems to want to outdo others in person-to-person peddling of unnecessary or unproved diet supplements" (3). In the same journal, Dr. Renner wrote:

I doubt that United Sciences' products are "a highly effective program for optimal health." As far as I know, they were not tested before marketing. Moreover, an optimal health program should involve more than high-priced food supplements, protein powder, and candy bars" (12).

Subsequently, ACSH asked 48 of its advisors to examine USA's formulas and to complete a detailed questionnaire about one of them. (Twelve advisors were assigned to each product.) A total of 28 questionnaires were completed and returned: Master Formula (10); Formula Plus (7); Calorie Control Formula (8); and Fiber Energy Bar (3). All 28 felt that USA's Medical Library Tape and product brochures contained claims for product ingredients that were false, unproven and/or premature. In most cases, the advisors felt that the product formulations were irrational and that it has not been established that long-term use is safe. Those who reviewed the Master Formula disagreed that it provides the body with the right nutrients in the right amounts or increases immunity in people whose diets contain the Recommended Dietary Allowances of essential nutrients. Those who reviewed Formula Plus felt that fish oils may turn out to have value in preventing or treating various conditions, but no data exist to recommend supplements for "everyone over 30" as USA recommends. Some who reviewed the Calorie Control Formula felt that "meal substitutes" are useful in weight control programs, while others felt they are not. Two advisors who commented on the fiber energy bar did not believe that daily long-term use would be beneficial, while the other said that insufficient data are available to evaluate the product.

**Weight control program**

USA's Calorie Control Formula and Fiber Energy Bar were said to be part of a Weight Management Plan that included guidance in choosing a balanced low-fat diet. USA said the plan was "the result of months of
research into existing diet and nutrition programs, as well as pilot studies among selected groups of people nationwide" (24).

According to Dr. Fisher, in September 1985, USA began following over 200 people enrolled in a weight control program designed by the company. The program included USA products, group and individual counseling, behavior modification services, and before-and-after measurements of body composition, metabolic function, aerobic fitness, and blood chemistry values (25). Information distributed to interested physicians stated:

Combining two Calorie Control Formulas and one Fiber Energy Bar along with one nutritious meal will provide approximately 1,000 calories, 40-50 grams of protein, 15-17% fat, and 20-30 grams of fiber daily . . . Once desired weight is maintained, one Calorie Control Formula drink can be eliminated (26).

When marketing of USA's products began, no dietary instructions accompanied them, but in mid-1986, the company began including a one-page instruction sheet in its monthly supply kits. The sheet cautioned that the Calorie Control Formula was not intended to be a sole source of nutrition but should be substituted for one or two meals a day. The instructions included brief suggestions for reducing portion sizes, cutting fat intake, increasing fiber intake, and drinking 6-8 glasses of water daily (27).

Although USA announced that a videotape describing its weight-control program would be released in the Fall of 1986, it was not. Thus the products were sold for more than a year without complete instructions.

Recent developments

From August through December 1986, USA received a steady stream of criticism from the news media--triggered mainly by reporters' reactions to the Introductory Videotape. In mid-December, Dr. Fisher said:

USA obviously made some mistakes. We deserve to have our wrist slapped. We practically had our back broken. And I am embarrassed. We've stopped distributing all of our previous promotional material and are doing everything over. We are really changing our total approach. Our original goal was to build a company to formulate products based on the scientific literature.

I think the concept upon which our products are based is valid and that the products are interesting and exciting enough that they don't need to be hyped. I agree there has been way too much hype. Hyping it only detracts from product credibility.

Marketing people sometimes get too enthusiastic. In the future I expect to exert editorial control over the promotional materials. Even though most of the Scientific Board Members approve of our products, we will make it clear that the appearance of their name and picture in company materials does not necessarily imply endorsement of our products.
When asked whether the majority of medical and nutrition scientists agree with USA's idea that vitamin supplements above the Recommended Dietary Allowances are likely to benefit most people, he replied:

Most would disagree with us, but we believe their view is narrow-minded. I used to feel the same way until I began to investigate the literature and came up with a different conclusion.

Beliefs on nutrition form a spectrum, with conservatives feeling that nutrition has little to do with disease prevention. Granted, not all the facts are in. But since supplements like ours are safe, we believe that risk/benefit analysis favors using them with the hope that they will be helpful (13).

Not long afterward, Robert Adler notified USA distributors that he had sold the company but would continue to serve on its board of directors (28). The buyers are T.J. Talley, D.D.S., a retired dentist with special interest in nutrition, and Peter J. Speckman, Jr., an attorney with a background in marketing and sales. In a letter to distributors, they announced:

Because the success system, sales aids and videos are now over a year old, we have temporarily discontinued selling them. This does not mean you have to curtail your sponsoring [recruiting] activities. An updated success system, exciting sales aids and videos, including the innovative Weight Management Program are being prepared (29).

In response to detailed questions about USA's intended claims for its products, Dr. Fisher said:

We are not claiming that our formulas have any specific preventive or therapeutic effect (as you know, the FDA strictly prohibits this) but, rather are calling upon the scientific literature to inform people about the specific research that has been published about various nutrients. The fact that most of these nutrients are in our formulas is, of course, not coincidental but still, in my mind, does not constitute a claim (30).

He also said that "USA Inc.'s distributors were not authorized to tell prospective customers that its formulas have a protective effect.

When asked whether USA claimed or intended to suggest that people who take its formulas will improve their appearance, feel more energetic, and improve their feeling of mental well-being (as suggested near the end of USA's Introductory Videotape), Dr. Fisher replied:

Reducing caloric intake can lead to reduced weight which will have an effect in improving appearance and making one more energetic. In addition there are several nutrients . . . which tend to have a stabilizing effect on blood sugar. The mental well-being that comes from a feeling that one is taking positive steps toward being healthy is undeniable.

When asked whether USA's distributors were authorized to tell prospective customers that USA products could help them look their best,
feel maximum physical energy and mental well-being, or enjoy total health, Dr. Fisher said they were not. He also said that his comment on the Medical Library videotape about USA's products making him so healthy-looking "obviously was a joke" (30).

On ABC's Nightline (January 8, 1987), the following debate on the effectiveness of USA's products took place between Dr. Fisher and Dr. Stare:

STARE: As long as Dr. Fisher uses the word "may" be able to help us, maybe they will. My point is there isn't any evidence yet that these products . . .

FISHER: That's ridiculous . . . There's tremendous amount of evidence.

STARE: Not from your products. There isn't a single report in the medical literature where your products have been used and shown . . .

FISHER: The ingredients in the products have been tested tremendously.

STARE: Oh, yes. But you have these same ingredients in food. Why spend $135 a month per person . . .

FISHER: Not at those levels . . .

After Dr. Fisher said that fish oils may exert a protective effect on the cardiovascular system, Nightline's host Ted Koppel zeroed in:

KOPPEL: There again, is that wonderful word "may." As a former diplomatic correspondent, I, too, listen carefully to words. "May" isn't really worth 135 bucks a month, is it?

STARE: Per person.

FISHER: Well, I think it is when you apply risk versus benefit. These things will almost definitely--I will be stronger--almost definitely have a tremendous positive effect . . .

KOPPEL: Almost definitely doesn't mean a thing. It's either definitely or its not.

STARE: You're quite right, Mr. Koppel. It doesn't mean a damn thing.

FISHER: All right, definitely. I will say definitely they do.

KOPPEL: Definitely.

FISHER: Yes. As sure as we can be at the present time.

KOPPEL: What does that mean, Dr. Stare?

STARE (laughing): It doesn't mean a thing.

FISHER: Of course it means something.

STARE: No it doesn't.

FISHER: It means that with existing scientific evidence, these products have a beneficial effect on your health.
Toward the program's end, Dr. Stare asked Dr. Fisher if there were any truth to rumors that USA was about to file for bankruptcy. Dr. Fisher replied: "I am the head of the medical/scientific aspect of the company. I don't know anything about the marketing aspect."

Two weeks later, USA petitioned in federal court for Chapter 11 bankruptcy, listing total assets of $7,300,000 and liabilities of $8,600,000. (The purpose of this type of bankruptcy is to stave off creditors to give the company time to restructure its indebtedness with the hope of remaining in business.) The petition named Robert Adler as sole shareholder and director of USA, Inc., and Jerris Leonard's law firm as its eighth largest unsecured creditor, with $121,379.69 owed. No official sales figures have been released, but press reports suggest that USA's 1986 gross income totaled $60 million.

**Government prosecution**

On December 12, 1986, the FDA sent USA a regulatory letter ordering it to stop suggesting that any of its products are effective in the cure, mitigation, treatment or prevention of disease. The agency said that claims of this type in its videotapes make the products "new drugs" that are illegal to sell in interstate commerce because they lack FDA approval. In addition, the product labels were defective in other ways (31). [See Appendix 3 for the full text of the regulatory letter.]

On January 28, 1987, the Attorneys General of Texas, New York and California filed suit in their respective states, charging that USA, Inc., had made improper claims for their products and that their sales plan constituted an illegal pyramid scheme. The Texas suit charged that USA had not properly registered as a manufacturer, and the New York suit demanded that Chris Evert-Lloyd, Joe Montana, Steve Carvey, Gary Carter and Bill Rodgers appear in court to explain their financial relationship with the company. The New York Attorney General's office indicated that many USA distributors were not paid commissions owed them by the company (32). The California suit asked for civil penalties of at least $1,000,000 plus the cost of prosecution.

On February 5, the District Court of Dallas County, Texas, issued a temporary injunction based on an agreement between USA and the Texas Attorney General. Its terms barred the company from:

- Marketing any current products without sending a "correction letter" acceptable to the Attorney General to all distributors.
- Shipping any products unless accompanied by an acceptable disclosure statement that they are not for the prevention or treatment of disease.
- Representing that USA's products have any effect in: infectious and parasitic disease; tumors; endocrine, nutritional and metabolic diseases and immunity disorders (including AIDS); diseases of the blood; mental disorders; diseases of the nervous, circulatory, respiratory, digestive, genitourinary or musculoskeletal systems; complications of pregnancy or childbirth; birth defects; injury or poisoning; or ill-defined conditions.
- Manufacturing any food products without being registered as a manufacturer by the Texas Commissioner of Health.
• Selling products through a multi-level distributorship (33).

During the next few weeks, no products were sold and phone calls to company headquarters were answered with a recorded message: "At this time we are unable to take your call. This is a temporary situation. You will be informed as more information becomes available."

On March 5, Peter Speckman, Jr., notified the FDA that he was sending letters informing USA's active distributors that: 1) he and Dr. Talley had completed purchase of the company; 2) the FDA had issued a regulatory letter; 3) three state attorneys general had filed suit against USA; 4) the company had agreed to an injunction; 5) products would be available for sale on March 16th; 6) the company plans to develop new sales materials and a new marketing plan that do not violate state laws; and 7) all existing videotapes should either be destroyed or returned to the company for partial credit. Speckman told the FDA he would enclose a copy of the injunction and would warn distributors not to make any claim that USA's products are effective against any disease. He also said that henceforth, all USA products would bear the following disclosure:

IMPORTANT NOTICE

The products you have purchased are a nutritional supplement. They are not intended for the prevention, treatment or cure of any disease, illness or other condition. Please disregard any claims you have been told to the contrary. Thank you for using USA products (34).

USA is now under completely new management. David Lough, its current vice president for marketing, said that Jerris Leonard resigned in November (a fact not revealed to most USA employees) and Dr. Fisher and the rest of USA's original management team left when the company went bankrupt. It seems likely that adverse publicity and/or lack of payment have driven away the rest of USA's scientific advisors and endorsing athletes. But Mr. Lough said he had no information on this because the company has not had recent contact with them. He estimated that Mr. Speckman's letter of March 5th went to about 5,000 of USA's most active distributors (35). But in February, USA's top distributor, Robert McIntyre, invited his downline to join Ameriplus, another multilevel company with products similar to those of USA.

Overview

Though some of its stated goals were laudable, United Sciences of America promoted its products with enormous exaggeration. Its Scientific Advisory Board, though prestigious, had no monopoly on the ability to analyze scientific data. USA's products were formulated by pooling the opinions of Dr. Fisher and the members of his advisory board who believe that virtually everyone should take dietary supplements. Skeptics were involved minimally if at all.

Within the past two years, the National Academy of Sciences has endured raging controversy over whether it is actually possible to determine "optimal" levels of nutrients at this time. Even if USA's formulations turn out to be optimal—which is very doubtful—it was extremely presumptuous to represent them as "state-of-the-art
nutrition." They were merely a guess by a small group of scientists who espouse minority viewpoints on supplementation.

USA's imagery and puffery certainly didn't reveal this. USA boasted of "analyzing 1,300 new research papers a month" to be sure its product formulations were up-to-date. That statistic might persuade laypersons that emergent scientific data are too voluminous for ordinary mortals (like their personal physician) to keep up with. However, it is doubtful that so many papers are relevant to USA's products. Even if they are, the number of papers entered in one's computer bank is not as important as the data they contain and the logic used to analyze them.

Nor was USA's method of gathering information anything special. Many medical facilities, researchers and practicing physicians have ready access to computerized data bases. And many scientists not only follow the scientific literature but know about important studies before they are published. Significant information is spread rapidly throughout the medical community through journals, lectures, informal discussions among doctors, cable television programs, and other channels of communication.

Exaggeration was also involved in recruiting distributors. Although those who sign up during the first few months of a successful multilevel company can make a great deal of money, the later the entry, the less the chance of success.

Although USA stopped distributing all of its questionable promotional materials, the claims they generated may circulate indefinitely by word of mouth.

The fact that USA pledged to support research was laudable, but its approach was backwards. Before asking the American public to spend millions (or billions) of dollars on USA products, they should have been tested for both effectiveness and long-range safety.

It seems unlikely that USA, Inc., can recover from its legal and financial difficulties and remain in business.

**ACSH's recommendations**

- Be aware that the majority of medical and nutrition scientists do not recommend supplements to people eating a reasonable diet, and that balancing one's diet is usually not difficult.

- If you aren't sure whether your diet is adequate, record what you eat for several days and ask your doctor or a registered dietitian to evaluate it.

- If you still wish to supplement for "nutrition insurance," avoid products that contain more than 100% of the U.S. RDA for any ingredient.

- Be aware that although fish oils are the object of considerable research interest, the scientific majority still believes that eating fish is more prudent than taking fish oils supplements.

- Be aware that the concept of "building immunity" with vitamin/mineral/antioxidant supplements is not scientifically accepted.

- Multilevel companies should be required by law to give realistic income projections to prospective distributors.
References


14. Statement from the Scientific Advisory Board (undated), furnished by Dr. Fisher to Dr. Barrett in December 1986.

15. c 1986, Daniel W. Stephenson. A manual "developed for the exclusive use of the Robert W. McIntyre and Daniel W. Stephenson organizations." (Not an official USA publication.)


27. Recommendations for use of the USA, Inc. nutritional plan (1986).
APPENDIX 1

USA, INC. PRODUCT INGREDIENTS

Master Formula, Formula Plus, Fiber Energy Bars and Calorie Control Formula contain the highest quality ingredients available today. These ingredients meet the exacting standards established by USA, Inc. in conjunction with the USA, Inc. Scientific Advisory Board.

MASTER FORMULA

Recommended adult use: Take three tablets, three times daily prior to or with meals.

<table>
<thead>
<tr>
<th>Nutrient</th>
<th>9 Tablets</th>
<th>% U.S. RDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vitamin A (Acetate)</td>
<td>5,000 IU</td>
<td>100</td>
</tr>
<tr>
<td>Beta Carotene</td>
<td>25,000 IU</td>
<td>500*</td>
</tr>
<tr>
<td>Thiamine (Thiamine-HCl)</td>
<td>50 mg</td>
<td>3333</td>
</tr>
<tr>
<td>Riboflavin</td>
<td>20 mg</td>
<td>1176</td>
</tr>
<tr>
<td>Niacin</td>
<td>25 mg</td>
<td>125</td>
</tr>
<tr>
<td>Niacinamide</td>
<td>100 mg</td>
<td>500</td>
</tr>
<tr>
<td>Pantothenic Acid (d-Calcium)</td>
<td>50 mg</td>
<td>500</td>
</tr>
<tr>
<td>Vitamin B-6 (Pyridoxine-HCl) Concentrate</td>
<td>30 mcg</td>
<td>500</td>
</tr>
<tr>
<td>Vitamin B-12 (Cobalamin Concentrate)</td>
<td>1500 mcg</td>
<td>2500</td>
</tr>
<tr>
<td>Ascorbyl Palmitate (Lipid Soluble Vitamin C—42 mg as Vit. C)</td>
<td>100 mg</td>
<td>70</td>
</tr>
<tr>
<td>Vitamin D-3</td>
<td>200 IU</td>
<td>50</td>
</tr>
<tr>
<td>Folic Acid</td>
<td>400 mcg</td>
<td>100</td>
</tr>
<tr>
<td>Biotin</td>
<td>150 mcg</td>
<td>50</td>
</tr>
</tbody>
</table>

Vitamin E Complex

Vitamin E (d-Alpha-Tocopherol Acetate) | 400 IU | 1333 |
Mixed Tocopherols (Beta, Gamma, Delta Tocopherols) | 100 mg | 333* |

Amino Acid Anti-Oxidant Complex

L-Cysteine (L-Cystine-HCl) | 200 mg | * |
L-Methionine | 50 mg | * |
L-Glutathione | 15 mg | * |
Selenium | 100 mcg | * |
Seleno-Methionine | 100 mcg | * |

Lipoenic Complex

Choline (Choline Bitartrate) | 250 mg | * |
Inositol | 250 mg | * |
L-Taurine | 150 mg | * |

Minerals and Chelates

Calcium (Calcium Carbonate) | 1000 mg | 100 |
Magnesium (Magnesium Oxide) | 500 mg | 125 |
Potassium (Potassium Chloride) | 99 mg | 5 |
Zinc (Zinc Gluconate) | 30 mg | 200 |
Copper (Copper Gluconate) | 2 mg | 100 |
Manganese (Manganese Gluconate) | 2.5 mg | * |
Iodine (Potassium iodide) | 50 mcg | 33 |
Molybdenum (Sodium Molybdate) | 125 mcg | * |
Chromium (Natural Trivalent Chromium) | 250 mcg | * |

Additional Nutrients

Bioflavonoids (Hesperidin Complex) | 250 mg | * |
PABA (Para Amino Benzoic Acid) | 25 mg | * |
Allium sativum (Pure Gar Co.) | 250 mg | * |

* 15 mg of beta carotene supplies 25,000 IU of precursor vitamin A activity.
* Activities of mixed tocopherols vary—level of activity based on 100 mg of dl-alpha-tocopherol equivalents.
* Determined to be an essential nutrient but actual requirements have not been established.
* No nutritional requirement established.

FORMULA PLUS

Recommended use: Take 3 to 6 capsules once per day with a meal.

Three 1 gram capsules daily supply:

- EPA (icosapentaenoic acid) | 540 mg |
- DHA (docosahexaenoic acid) | 360 mg |
- Allium sativum extract | 150 mg* |
- d-alpha-tocopherol | 21 mg** |
- Ascorbyl palmitate | 6 mg |

** Contains a certified allin content of 1 mg determined by measuring levels of enzymatically liberated pyruvic acid.
** Vitamin E activity of 27 IU—equivalent to 88% US RDA. Gelatin capsules colored naturally with carob, and contain no artificial flavors or preservatives.

FIBER ENERGY BAR

Nutrition Information Per Serving

- Serving Size: (2.0 oz) 56.7 g
- Calories: 200
- Dietary Fiber: 9 g
- Protein: 8 g
- Carbohydrates: 25 g
- Fat: 6 g
- Sodium: 18 mg
- Potassium: 100 mg

Ingredients: USA, Inc. coating, lycasin (polysorbate), Fiber blend (oat flakes, high fiber crisp brown rice, guar gum, barley flakes, cellulose, oat bran, apple bran, barley bran, rice bran, pectin, yucca fiber, carrot fiber, beet root powder), fructose syrup, cottonseed nuts, UltraProtein blend (cottonseed protein, calcium-sodium caseinate, Lactose Free whey protein concentrate, surimi, garlic, flax seed, natural flavors, maltodextrin, potassium chloride, lactic acid, mixed tocopherols, ascorbic acid.

USA, Inc. Coating ingredients: Fractionated palm kernel oil, crystalline fructose, maltodextrin, roasted dahlia root powder, cellulose, cottonseed protein, lecithin.

CALORIE CONTROL FORMULA

Nutrition Information Per Serving

- Serving Size: (1.08 oz) 30.4 g
- Servings per container: 14
- Calories: 100
- Protein: 9 g
- Carbohydrates: 16 g
- Fat: less than 1 g
- Fiber: 4 g
- Sodium: 45 mg
- Potassium: 200 mg

Percentage of U.S. Recommended Daily Allowances (% of U.S. RDA)

- Protein: 15 Calcium: 15
- Vitamin A: 25
- Vitamin C: 15 Phosphorus: 15
- Thiamin: Magnesium: 20
- Riboflavin: Zinc: 45
- Niacin: *Less than 2% U.S. RDA

Ingredients: UltraProtein Blend (high protein cottonseed flour, calcium/sodium caseinate, Lactose Free whey protein concentrate, surimi, garbanzo bean flour), fructose, Fiber Blend (oat bran, gar gum, celulose, barley bran, rice bran, pectin, apple fiber, yucca fiber, carrot powder, beet root powder), maltodextrin, lecithin, natural and artificial flavors, carrageenan, tricalcium phosphate, magnesium oxide, potassium chloride, calcium ascorbate, ferrous fumarate, zinc oxide. This product has no derivatives of soy, yeast or wheat. Sweetened only with fructose. Contains no sucrose, artificial sweeteners, artificial colors or preservatives.
APPENDIX 2
UNITED SCIENCES OF AMERICA
"COMPANY INTRODUCTION" VIDEOTAPE

This is William Shatner. And I'd like to invite you to take a journey with me to a brave, new world of optimum health and vitality. What you are about to see could change your life. So take this opportunity to be a part of a revolutionary development in nutritional science. It's been years in the making.

The vision of John F. Kennedy inspired our nation's foremost scientists to work together and lead our country to a new frontier in space. Man landed on the moon, and all Americans were one as we celebrated our finest hour.

The earth does look like a magnificent blue jewel from space. But the gem is rapidly losing its splendor. While advanced technology has given us valuable gifts, it has done so with a deadly pricetag. Our air, water and food are becoming contaminated. Since 1950, 63,000 new chemicals have been developed for industrial, agricultural and household use. Hundreds of these toxic killers have invaded our lives through the air we breathe and the food we eat. Just living the average American lifestyle of the 80s poses unseen threats to our health and well-being. One out of every three families will be stricken with some form of cancer whether it be lung cancer, breast cancer, or 120 other varieties—and it's on the rise. Two out of five people will die of heart disease or stroke. The total cost of health care in the United States today exceeds that of the national defense. That shouldn't surprise you. Just consider the food we eat. Is it natural? Not by a long shot.

Our farm animals are now victims of our new society. Laboratory-developed steroids, hormones, antibiotics, artificial additives, food dyes and chemicals are pumped into our prime sources of protein. Government nutritional experts admit that soil in huge tracts of our best farmland has been depleted of vital, life-giving nutrients and important earth minerals such as selenium and zinc. Man has created artificial fertilizers, pesticides, insecticides, fungicides and other powerful substances that attack the nutritional validity of [unclear]. The constant barrage of hostile pollutants not only effects the foods we eat but is washed through the damaged soil by acid rain into our water supplies.

Presently, the Environmental Protection Agency has identified over 130 dangerous chemical pollutants which have been found in our drinking water. These toxins insidiously invade our bodies through the water we drink, wash in, and use for laundry. If you live in the city, you constantly breathe oxides, carbon monoxide, and other deadly gases from cars, trucks, busses and planes.

Recent studies show that even breathing secondhand smoke can be as dangerous as smoking itself, but no matter where you live or what you do, you can't avoid it. The potentially catastrophic problem of proper waste disposal has become a national crisis. There are literally hundreds of millions of tons of chemical waste, nuclear waste and sewage
that isn't properly disposed of and is poisoning our environment. The EPA admits there is no solution in sight.

One man in Dallas, Texas, believed that something could be done. In the 1970s, Robert Adler and his brother, Michael, with no more than a vision, formed a computer company that revolutionized communications for several Fortune 500 companies. Today, Adler has devoted his insights, energies and resources into developing a brain trust of medical and scientific experts who have pioneered one of the most dramatic programs in the history of nutritional science. United Sciences of America was born as a counter-revolution working toward better health for all Americans. Their mission is clear: to develop a complete nutritional program to protect us from the growing dangers that are threatening the health of our nation.

Adler knew instinctively that the counterattack had to come from documented scientific studies by experts whose credibility was impeccable. There was no other option in tackling a problem of this magnitude. And so a new era was born. United Sciences of America computerized all pertinent medical and nutritional research from 150 countries. Science and data information vice president Dr. John Wise condensed a quarter of a million pages of documented studies into 10,000 pages of categories and subtitles. Dr. Wise's research division had access to all known research data using the world's largest information sources. His computer banks now hold all state-of-the-art research findings on every vitamin, amino acid, mineral, element, electrolyte, and nutrient known to modern science. But all of this data was just the beginning. For the first time ever, the 250,000 pages of research were assimilated and analyzed to determine precisely which micronutrients and in what amounts--according to documented studies--have been shown to promote optimum health.

Then United Sciences of America took a bold step. The company assembled the best and the brightest in the world of science to develop a revolutionary health program predicated on this massive data base. The executive scientific board is comprised of world renowned authorities in pathology, cardiology, immunology, gynecology, microbiology, epidemiology, biochemistry, anatomy, nutrition and cancer research. This distinguished group of experts have published a staggering 6,500 research papers and are responsible for some of the significant medical breakthroughs of the last 20 years. Two of the 16-member executive advisory board are Nobel Prizewinners in medicine.

Dr. Julius Axelrod, Nobel Laureate, an USA scientific advisory board member states, "Our board possesses a broad range of expertise in so many of the key areas of health and nutrition. These men and women are truly leaders in their fields."

Dr. Robert Good, former president and director of Memorial Sloan-Kettering Institute in New York is advisory board chairman of USA and speaks for the board when he says: "An explosion of new information shows the proper combination of nutrients with a reduction in caloric intake will help fortify the body's immune system and aid in fighting against disease. I'm convinced that United Sciences of America with its primary emphasis on only scientific documented information is going to
have a significant impact on the health of America. I'm proud to be a member, and highly endorse our program and this entire organization."

According to Dr. Christiaan Barnard,* the famed pioneer of heart transplant surgery, who now heads the cardiovascular division of USA's scientific advisory board: "It has now become obvious to me that one of the keys to a healthy heart and cardiovascular system is proper nutrition. United Sciences of America has developed a program, in my opinion, that can enormously help anyone who follows it as prescribed. I strongly recommend it for everyone interested in maximum health."

The program Dr. Barnard refers to is USA's four steps to optimum health. The first of the four formulas is the Master Formula, a state-of-the-art integrated blend of 38 high-potency antioxidants with a rich blend of amino acids, vitamins, minerals, nutrients, and trace elements. The Master Formula is for everyone. This scientifically based program eliminates the guesswork and serious risk you take when buying vitamins and minerals at random off the shelf at a supermarket or health food store.

USA's executive scientific board has developed two unique high-fiber, nutritionally enriched formulas to help increase nutritional and help reduce caloric intake. Along with the Master Formula comes a Calorie Control Formula, a scientific breakthrough incorporating all of the elements needed for a medically approved meal replacement. The concept is simple: a delicious liquid meal that emphasizes a calorie-controlled, low-fat, high-fiber diet now recommended by the American Heart Association, the National Science Foundation and the American Cancer Society.** The Calorie Control Formula contains exciting new sources of protein from sirumi and cottonseed which have the highest known protein efficiency of any plant or seafood source. Equally important, this Calorie Control Formula has a scientific blend of ten different fibers from natural sources of fruit, vegetable and grain which offer maximum benefits of dietary fiber without the commonly known allergic reactions. It's delicious, hypoallergenic and protein-rich.

The third part of USA's optimum health program is a Fiber Energy Bar—another nutritional first. Also low in calories, it consists of cottonseed and sirumi protein that's loaded with extra dietary fibers and complex carbohydrates. Major medical studies have shown the value of bran, apple pectin, guar gum, and cellulose fibers, all of which are dangerously low in the average American diet. Our Fiber Energy Bar contains 12 different fibers and is a powerful scientific tool for losing weight and then maintaining your desired weight. Best of all, it

*Author's note: Dr. Barnard was removed from USA's Scientific Advisory Board because other board members disapproved of his promotion of Glycel "anti-aging" skin products.

**Author's note: In March 1986, the American Heart Association threatened to take legal action if USA did not stop using the Association's name and logo in this videotape. A few months later the company edited out this sentence and advised distributors to return their original tapes. But many continued to use them.
tastes great! The Calorie Control Formula and the high-fiber energy bar are so uniquely formulated, United Sciences of America has applied for both U.S. and international patents.

Scientific board member Dr. Robert Morin, of UCLA Medical School states: "USA's program, as opposed to fad diets, has been thoroughly researched and is truly nutritionally sound. You lose weight safely. It is the finest weight-loss program ever developed and offers a sensible solution for millions of overweight Americans."

USA's fourth formula is Formula Plus for people 30 and over—a unique blend of marine lipids which are concentrated to provide a rich source of the biologically active omega-3 fatty acids EPA and DHA. The formula is derived from natural fish oil now known to be of remarkable nutritional value.

In regard to the USA program, Dr. Alexander Leaf, Chairman of the Department of Preventive Medicine at Harvard Medical School, says: "The four formulas of the USA Corporation together constitute a nutritional plan that is the finest and most complete I have ever seen."

Each month scientists worldwide are publishing more than 1,300 studies vital to your health. That's 15,000 critical articles a year affecting the lives of you and your family. No one man, least of all your busy family doctor, has the time needed to read and analyze this ever-increasing avalanche of new information from laboratories, major universities and research institutions. But United Sciences of America's extraordinary computer technology and its staff of experts are dedicated to doing just that. Our scientists will continually incorporate all new documented data and advancements into the USA program, automatically updating the formulas to keep it the most powerful health tool in the world. In addition, United Sciences of America has a clinical advisory board of more than 100 of America's top practicing physicians. These working professionals will be constantly monitoring USA product efficiency in one of the largest human studies ever conducted.

No investment pays greater dividends than an investment in your health. Looking your best, feeling maximum physical energy and mental well-being, enjoying total health is everything. The decision is yours because this program is now available to every family in America. It's here at last.

United Sciences of America wants to become a working member of your family. So please join us in this great new enterprise. This is William Shatner. Thank you.
December 12, 1986

REF: 87-DAL-06

REGULATORY LETTER

HAND DELIVERED

Mr. Robert M. Adler, II, Chairman
United Sciences of America, Inc.
2724 Realty Road
Carrollton, Texas 75006

Dear Mr. Adler:

An inspection conducted in May 1986 of your facility at the above address and subsequent investigation by the Food and Drug Administration (FDA) has disclosed that your firm is marketing the products Master Formula, Formula Plus, Calorie Control Formula and Fiber Energy Bar. The promotional materials such as printed brochures and a video tape which we have reviewed represent and suggest that these products are useful in preventing and treating serious disease conditions.

Although you refused to provide specific product formulations at the time of our inspection, we conclude, based on our review of other materials, that your products contain in part: Master Formula - vitamins A, C, E, beta carotene, selenium and cysteine, calcium, magnesium, mixed tocopherols, L-glutathione, selenomethionine, L-taurine, PABA (Para Aminobenzoic Acid), Allium Sativum (garlic extract), and bioflavonoids; Calorie Control Formula - protein from various sources, "Ultraprotein" blend; fiber from various sources and fructose; Fiber Energy Bar - fiber from various sources, and Formula Plus - eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA), Allium sativum (garlic extract), d-alpha-tocopherol and ascorbyl palmitate.

A brief review of the labeling available to us indicates that these products are offered as safe and effective for the prevention and/or treatment of conditions such as (examples only):

Master Formula - protects against cellular toxins and pollutants through use of anti-oxidants, antithrombotic effect, eliminates chronic degenerative diseases, reduces blood pressure, protects from cancer, protects from free radicals, reduces risk of rheumatoid arthritis, lowers uric acid levels, utilizes blood sugar better, converts insulin to its active form, stimulates collagen production, has toxic effect against rhinovirus, shortens duration and severity of colds, prevents AIDS, stimulates and strengthens immune system, reduces frequency and severity of asthmatic attacks, helps colitis, reduces the negative effects of estrogen, improves acne, prevents cancer, reduces dangerous free radical diseases such as alcoholism,
protects lungs from smoke and reduces risk of emphysema, reduces risk of kidney stone formation.

Formula Plus - helps lower blood pressure, provides antithrombotic activity, inhibits breast tumors (in mice), protects tissues from inflammation, won't increase your risk of cancer, has beneficial effects on vision, raises immunity, has beneficial effect on PMS symptoms, prevents cancer.

Calorie Control Formula - reduces insulin response.

Fiber Energy Bar - lowers cholesterol, reduces risk of diabetes, treats diabetes, helps blood sugar, controls hyperglycemia, delays the deterioration of the immune system, prevents AIDS, lowers incidence of heart disease, and stabilizes blood sugar.

Because such labeling includes statements which represent and suggest that the articles are intended to be used in the cure, mitigation, treatment or prevention of disease, or are intended to affect the structure or any function of the body of man, these products are drugs as defined in section (§) 201(g) of the Federal Food, Drug, and Cosmetic Act (the Act). Further, we are unaware of any substantial evidence which demonstrates that these drugs are generally recognized as safe and effective for their intended uses. Accordingly, continued marketing of these drugs constitutes serious violations of the Act as follows:

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<td>502(a)</td>
<td>The articles are misbranded in that their labeling is false and misleading by representations and suggestions that there is substantial scientific evidence to establish that the articles are safe and effective for the prevention or treatment of those conditions specified above, or for any other drug uses.</td>
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<td>502(f)(1)</td>
<td>The articles are misbranded in that their labeling fails to bear adequate directions for the uses for which they are represented or suggested, as described above, and they are not exempt from this requirement under regulation 21 CFR 201.115 since the articles are new drugs within the meaning of § 201(p) and no approvals of applications filed pursuant to § 505(b) are effective for the drugs. The articles are further misbranded in that their labeling does not contain adequate directions for use as this term is defined in 21 CFR 201.5 since most of the conditions for which they are offered are not amenable to self-diagnosis and treatment by the laity; therefore, adequate directions for use cannot be written under which the layman can use these drugs safely and for the purposes for which they are intended.</td>
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The articles are drugs within the meaning of § 201(g) of the Act which may not be introduced or delivered for introduction into interstate commerce under § 505(a) of the Act, since they are new drugs within the meaning of § 201(p) of the Act and no approvals for applications filed pursuant to § 505(b) are effective for such drugs.

Removal of all statements which represent and suggest that the articles are intended to be used in the cure, mitigation, treatment or prevention of disease, or are intended to affect the structure or any function of the body of man or other animals would transfer your products into the category of foods as defined by § 201(f) of the Act, and the products would then be in violation of Chapter Four of the Act as follows:

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<td>402(b)(1)</td>
<td>&quot;Fiber Energy Bar&quot; coded 81396 is adulterated in that our analysis revealed that the product contained less protein per serving (55.2% on original and 63.9% on check analysis) than declared.</td>
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<td>403(a)(1)</td>
<td>The products are misbranded in that their labeling bears numerous false and misleading claims regarding alleged properties and functions of vitamins, minerals, other nutrients, and substances (e.g., &quot;vitamin E and selenium have an enhancing or synergistic effect on each other when precisely balanced&quot;, &quot;ultra protein blend... provides the highest protein efficiency (P.E.R.) of any plant or seafood source&quot;, &quot;calcium may be assimilated almost twice as efficiently in the body if taken in a combined multivitamin form than if taken alone&quot;). There is no scientific evidence to support such claims and no such dietary efficacy has been demonstrated for these nutrients and substances.</td>
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<td>403(a) and (j)</td>
<td>The product &quot;Calorie Control Formula&quot; is falsely represented as a &quot;low calorie&quot; drink in that it fails to comply with the requirements of Title 21 CFR 105.66(c) which defines a low calorie food as one which provides no more than 40 calories per serving and no more than 0.4 calories per gram.</td>
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<td>403(j)</td>
<td>The products &quot;Calorie Control Formula&quot; and &quot;Master Formula&quot; are represented as hypoallergenic foods, however, their labels fail to bear the information required by Title 21 CFR 105.62.</td>
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In addition to these more serious violations our review also shows the following label violations which should receive prompt attention.
Fiber Energy Bar, carton label

1. The term "Fiber Energy Bar" is not an appropriate identity statement for the product. We would not object to the name "A Sweetened Oat, Rice, Barley and Cottonseed Bar" or another sufficiently descriptive name which explains the basic nature of the food, its characterizing properties or ingredients.

2. The nutrition labeling must be declared in the complete format prescribed by Title 21 CFR 101.9.

The declarations of percentage of U.S. RDA's required by § 101.9(c)(7) and the number of servings per container required by § 101.9(c)(2) are not declared on the label.

3. The specific form of the "cottonseed protein" and "chickpea protein" should be declared in the ingredient statement (e.g., "cottonseed protein isolate", "chickpea protein concentrate", or "cottonseed flour").

4. The declaration of dietary fiber content per serving should not be a part of the nutrition labeling but may be declared as a separate statement elsewhere on the label.

5. "Carrot fiber" and "yucca fiber" and "apple bran" are not common or usual names of any food ingredient.

6. Guar gum is permitted to be added to foods under the provisions of Title 21 CFR 184.1339. Guar gum may be used as an emulsifier, a stabilizer, thickener and formulation aid at the specific levels stated in the regulation. There is no provision for its use as a source of fiber.

The specific form of the cellulose used is not declared in the ingredient statement however, sodium carboxymethylcellulose is regulated by Title 21 CFR 182.1745 and methycellulose is regulated by Title 21 CFR 182.1480. Although there are no explicit restrictions on their uses in foods, the data which formed the basis for these regulations did not include its use as a source of fiber.

We therefore, conclude that the addition of guar gum, and methycellulose or sodium carboxymethylcellulose (if they are being used in the product) for the purpose of adding fiber is not in compliance with the applicable regulations. If you wish to pursue this matter, you may wish to submit a petition under Title 21 CFR 170.35 or 171.1 for the use of these substances as sources of fiber.

7. The specific source of the lecithin should be declared in the ingredient statement as required by Title 21 CFR 101.4(b) (e.g. "soy lecithin").
8. The type size of the ingredient statement, manufacturer's name, and nutrition information fail to meet the minimum 1/16 inch height requirements of Title 21 CFR 101.2(c).

9. The type size of the quantity of contents statement fails to meet the minimum 1/8 inch height requirement of Title 21 CFR 101.105(i)(2).

**Formula Plus**

1. Eicosapentanoic acid (EPA) and docosahexaenoic acid (DHA) are not deemed to be generally recognized as safe nor are there present food additive regulations which prescribe conditions for their safe use in foods.

2. You should be aware that we expect to soon publish a proposal regarding the use of health claims on food labels in the Federal Register. The present claims on the label regarding the usefulness of EPA and DHA in the diet may need to be revised in accord with the provisions of the proposed policy statement.

3. The EPA, DHA, and allium sativum (garlic) should not be declared in terms of potency (milligrams) because they are not essential and therefore, are not dietary supplements. They should be declared only in the ingredient statement in descending order of predominance by weight.

4. Carob is not presently permitted for use in foods as a color. In addition, the statement "colored naturally with carob" is incorrect. Since all added colors result in an artificially colored food, we object to the declaration of any added color as natural.

**Calorie Control Formula**

1. The percentage of U.S. RDA of phosphorus in the nutrition labeling is not declared to the nearest 5 percent increment as required by Title 21 CFR 101.9(c)(7)(i).

2. The individual ingredients of the "surimi" must be declared in the ingredient statement; either parenthetically or separately in descending order of predominance by weight as required by Title 21 CFR 101.4(b)(2).

3. The terms "Apple Fiber" and "Yucca Fiber" are not appropriate common or usual names for food ingredients. The common or usual name of the specific ingredients used must be declared in the ingredient statement.
4. The specific source of the lecithin should be declared in the ingredient statement (e.g. "soy lecithin").

5. The term "French Vanilla" is an inappropriate flavor designation for the product.

6. The declaration of fiber per serving should not be a part of the nutrition labeling format, but may be declared as a separate statement on the label.

**Master Formula**

1. The principal display panel fails to bear an identity statement (e.g. "Dietary Supplement of ____" or "Multivitamin - Multimineral Supplement").

2. Bioflavonoids, PABA (para aminobenzoic acid), and allium sativum (garlic) are not essential nutrients and therefore should not be declared in terms of potency (milligrams) but should be declared in the ingredient statement in descending order of predominance.

3. Taurine is not deemed to be generally recognized as safe, nor is there a present food additive regulation which prescribes conditions for its safe use in foods. If you have information which demonstrates its safety, this information should be submitted in the format of a food additive petition, Title 21 CFR 171.1, or a petition for generally recognized as safe status, Title 21 CFR 170.30.

The violations listed above are not intended to be all-inclusive. It is your responsibility to market products which are in full compliance with the Act.

We request that you schedule a meeting with Daniel L. Michels, Director, Office of Compliance, Center for Drugs and Biologics, Rockville, MD 20855, telephone number 301-295-8054, within ten (10) days of your receipt of this letter to inform us of what action you intend taking to bring your products into compliance with the law. If corrective action is not undertaken promptly, FDA is prepared to initiate legal action to enforce the law. The Act provides for seizure of violative products or injunction against the manufacturer or distributor of these products (21 USC 332 and 334).

Sincerely yours,

DONALD C. HEALTON
Regional Director
Food and Drug Administration

cc: Jerris Leonard, President