

SENATE JUDICIARY COMMITTEE

ORRIN G. HATCH
CHAIRMAN

FACSIMILE TRANSMITTAL SHEET

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|-------------------------------------|--------------------------------------|------------------------|------------------------|
| TO: | Lester Crawford c/o Patrick Ronan | FROM: | Senator Orrin G. Hatch |
| FAX NUMBER: | (301) 443-5897 | DATE: | 9/29/2004 |
| PHONE NUMBER: | (301) 827-9774 (v) | SENDER'S PHONE NUMBER: | (202) 224-6306 |
| TOTAL NO. OF PAGES INCLUDING COVER: | 9 | SENDER'S FAX NUMBER: | (202) 228-0029 |
| RE: | Weider Nutrition International | | |

NOTES/COMMENTS:

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United States Senate

WASHINGTON, DC 20510-4402

September 29, 2004

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The Honorable Lester Crawford
Acting Commissioner of Food and Drugs
Food and Drug Administration
Office of Legislation
5600 Fishers Lane
Rockville, MD 20857

Dear Commissioner Crawford:

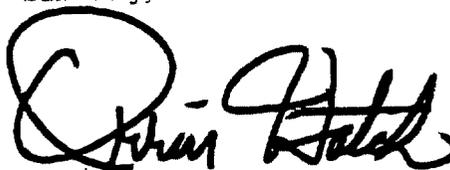
I am enclosing, for your review, a copy of a letter and enclosures that I received from Bruce Wood, one of my constituents, and President and Chief Executive Officer of Weider Nutrition International, Inc.

In summary, Mr. Wood is concerned about the FDA's resistance to their pending health claim petition concerning the relationships between glucosamine and chondroitin and reduction of the risks of osteoarthritis.

I appreciate any insights that you may have on Mr. Wood's situation regarding the pending health claim petitions. Please forward any correspondence to my Washington, D.C. office in care of Ms. Karen LaMontagne at fax number: 202.228.0029.

Thank you for your consideration of this matter.

Sincerely,



Orrin G. Hatch
United States Senator

OGH:kil

Enclosure

WEIDER-NUTRITION GROUP, INC.

2002 South 5070 West
Salt Lake City, Utah 84104-4726
Telephone: (801) 975-5000
Facsimile: (801) 975-1924

FACSIMILE TRANSMISSION

DATE: August 25, 2004

| NAME | FAX NO. | PHONE NO. |
|---------------|--|-----------|
| Senator Hatch | (202) 224-6331 228-0029 9/28/04 | |

FROM: Bruce Wood (TODD)

RE: Weider Nutrition International and the FDA

| | |
|---|-------------------------------------|
| <input type="checkbox"/> Original(s) Will Follow - No | Number of pages, including cover: 7 |
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*Todd Crowley
Crowleigh?
8/887-5293*

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IF THERE ARE ANY PROBLEMS WITH THIS TRANSMISSION, PLEASE CALL (801) 975-5389.



BRUCE WOOD
PRESIDENT
CHIEF EXECUTIVE OFFICER

August 23, 2004

Senator Orrin G. Hatch
104 Hart Senate Office Building
Washington, DC 20510-4402

Dear Senator Hatch:

I am the President and CEO of Weider Nutrition International, Inc. I and other members of our executive team have had the pleasure of making your acquaintance at various functions over the last few years.

I write on behalf of Weider to solicit your help and counsel concerning the FDA's unreasonable resistance to our pending health claim petition concerning the relationships between glucosamine and chondroitin and reduction of the risks of osteoarthritis, joint degeneration, cartilage deterioration, and osteoarthritis-related joint pain, tenderness, and swelling. As you recall, a health claim for a dietary supplement is a statement that a substance can diagnose, treat, mitigate, cure, or prevent a disease or health-related condition. Different from a general structure/function claim made under DSHEA, a health claim requires the review and approval of the FDA. However, the FDA is required to permit health claims that are supported by credible scientific evidence.

As you know, the FDA's implementation of DSHEA has sometimes limited education of consumers about the reduction of the risk of diseases such as arthritis, which has resulted in the intervention by courts at times. While the FDA blocks this important and valuable information from reaching consumers, millions more consumers will become afflicted by arthritis, further adding to the billions of dollars of health care costs and workplace disability expenses and productivity losses. (For sake of brevity, I have enclosed a brief synopsis of the monumental scope of the problem of osteoarthritis, ineffective treatment methods, and the benefits of glucosamine and chondroitin for addressing these issues.)

FDA has represented that it would announce a decision on the arthritis petition by September 2004. We believe ample science supports the proposed arthritis health claims. Nevertheless, we anticipate outright denial of the petition by FDA for reasons other than scientific efficacy, and seek your assistance in this matter at a time when there is great interest and need to address the issue of arthritis.

The history of FDA's handling of the petition suggests that denial may be a foregone conclusion. On May 29, 2003, Weider Nutrition filed the health claim petition, which requested allowance of 12 health claims (four general claims, with three subcategories for each general claim):

- Glucosamine may reduce the risk of osteoarthritis.
- Chondroitin Sulfate may reduce the risk of osteoarthritis.
- Glucosamine and Chondroitin Sulfate may reduce the risk of osteoarthritis.

- Glucosamine may reduce the risk of joint degeneration.
- Chondroitin Sulfate may reduce the risk of joint degeneration.
- Glucosamine and Chondroitin Sulfate may reduce the risk of joint degeneration.

- Glucosamine may reduce the risk of cartilage deterioration.
- Chondroitin Sulfate may reduce the risk of cartilage deterioration.
- Glucosamine and Chondroitin Sulfate may reduce the risk of cartilage deterioration.

- Glucosamine may reduce the risk of osteoarthritis-related joint pain, tenderness, and swelling.
- Chondroitin Sulfate may reduce the risk of osteoarthritis-related joint pain, tenderness, and swelling.
- Glucosamine and Chondroitin Sulfate may reduce the risk of osteoarthritis joint pain, tenderness, and swelling.

On October 3, 2003, the FDA denied the health claim petition outright on the grounds that "these claims concern treatment or mitigation of an existing disease, osteoarthritis, rather reducing the risk of contracting that disease." Please note that the claims refer to the possible reduction ("may") in the various outlined risks, and do not profess to cure arthritis.

Weider was finally able to meet with the FDA about the denial on November 24, 2003. Three months later, the FDA reversed its position and agreed to allegedly evaluate the petition on the merits. FDA's evaluation began more than six months after the procedural deadline for accepting or denying the petition had passed.

On March 1, 2004, the FDA announced that the evaluation of issues relating to scientific substantiation for the proposed health claims would be referred to a Food Advisory Committee (FAC) meeting on June 7 and 8, 2004. Prior to the meeting, before receiving any evaluation or discussion from the FAC, FDA announced its "tentative conclusion" that the proposed claims have no substantiation whatsoever. This tentative conclusion disregarded more than 5,000 published scientific papers reporting and supporting the beneficial effects of these substances against arthritis. Ironically, on the same day of the FAC meeting, Congress held hearings on the proposed Arthritis Prevention, Control and Cure Act of 2004, which is aimed at providing more information and research concerning arthritis prevention and treatment.

The FDA added several temporary voting members to the Food Advisory Committee. These temporary members came from or are affiliated with the Center for Drug Evaluation and Research (CDER), and some appear to have conflicts of interest that should have disqualified them from service on the FAC. For example, some have in the past accepted research funding and grants from pharmaceutical companies that sell non-steroidal anti-inflammatory drugs (NSAIDS) used in the treatment of joint pain and other symptoms of osteoarthritis. These companies could be adversely affected if the FAC made recommendations in favor of the proposed claims because a reduction in the risk of osteoarthritis may result in lower demand for NSAIDS for treatment of osteoarthritis.

At the FAC meeting, FDA asked the panel to report on biomarkers or risk factors FDA should consider in evaluating whether the proposed health claims enjoyed scientific evidence. Unfortunately, FDA's instructions diverted the panel into evaluating the scientific evidence in the context of a drug approval, which is not the scientific standard applicable to dietary supplements (which is to analyze if there is any credible scientific evidence that supports the proposed health claim). Weider was not permitted to address the panel on the applicable scientific standard prescribed by the courts. Thus, FDA's

pre-announcement of its conclusion, improper instructions and conflicts of interest had the effect of predisposing the FAC panel against the proposed claims.

As stated in the preamble to DSHEA, reduction of health care costs is of paramount importance to the future of the country, and "consumers should be empowered to make choices about preventative health care programs based on data from scientific studies of health benefits related to particular dietary supplements." Where the hallmarks of osteoarthritis are cartilage deterioration, impaired function, and pain, widespread use of glucosamine and chondroitin to reduce the risk of progression to full-blown arthritis will reduce the number of people disabled by arthritis and the billions of dollars of health care costs to help them cope with chronic pain. The reduction of arthritis health care costs from use of chondroitin has been demonstrated in France. In examining 11,000 patient records, the study noted that 50% of the people were able to discontinue NSAIDS completely by taking 1200 mg of chondroitin daily. The use of chondroitin reduced NSAIDS consumption, decreased physical therapy visits, and fewer complications related to NSAIDS.

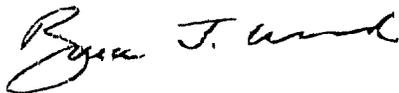
We are continuing negotiations with FDA, but fear denial of the petition absent some influence from Congress or the courts. We respectfully request a brief meeting with you to discuss ways in which you or your staff may enable us to provide the public with this important health care information they deserve under the auspices of DSHEA.

I would welcome the opportunity to speak with you concerning this matter to make arrangements to meet. Please contact me at (801) 975-5055 or through our General Counsel, Dan Thomson, at (801) 975-5173. We are also sending copies of this letter to other members of the Utah Congressional delegation.

We appreciate your support of providing valuable information and safe and effective dietary supplements for consumers. Thank you for your consideration of this very important matter.

Very truly yours,

WEIDER NUTRITION INTERNATIONAL, INC.



Bruce J. Wood
President and Chief Executive Officer

ARTHRITIS SUMMARY INFORMATION

The following is a brief synopsis of the scope of the problem of arthritis, ineffective treatment methods, and the benefits of glucosamine and chondroitin for addressing these issues.

More than 70 million Americans suffer from joint disabilities and arthritis today, and an additional 70 million will likely develop arthritis in the next three decades.

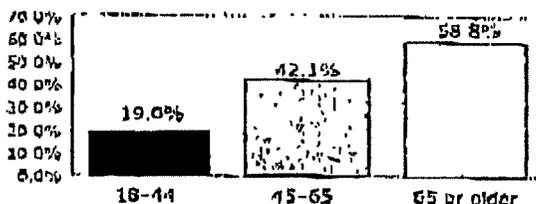
Our Schiff brand *Move Free*® product, which contains glucosamine and chondroitin, is one of the leaders in the joint care supplement business.

Glucosamine and chondroitin are the natural building blocks of joints. These two ingredients have been clinically tested repeatedly beginning more than twenty years ago. We are aware of more than 5000 studies on these ingredients. These products have been shown to reduce the risk of joint degeneration and cartilage deterioration, reduce arthritis related joint pain as well or better than pain killers – OTC and prescription—and improve the functioning of the joints.

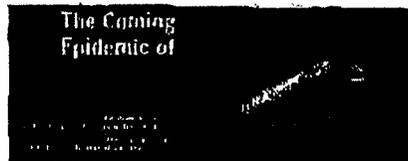
In 2002, the Centers for Disease Control and Prevention (CDC) reported that arthritis and joint issues are the number one cause of disability in America!

- 70 Million people are affected – 49 million with arthritis and another 21 with joint disability.
- The impact is expected to *double* by 2030. Age, obesity and lack of exercise are key parts of the trend.
- The costs are \$86 Billion per year and rising.

Prevalence of Arthritis or Chronic Joint Symptoms (CJS) by Age Group Among U.S. Adults, 2001



Time Magazine had a cover story on arthritis called this "The Age of Arthritis."



and

Recent bipartisan legislation was introduced into Congress to deal with the arthritis issue. The Arthritis Foundation said the following:

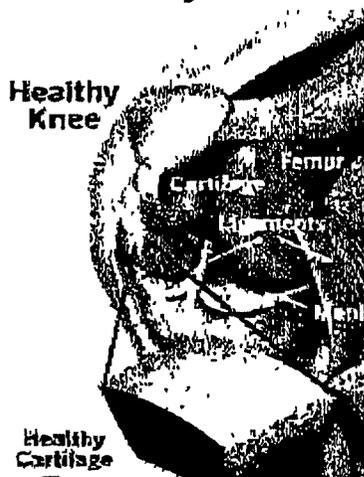
"The first piece of arthritis legislation in more than 30 years, the **Arthritis Prevention, Control and Cure Act of 2004 (S. 2338/H.R. 4610)**, has been introduced by Senators Kit Bond (R-MO) and Edward Kennedy (D-MA) and Representatives Chip Pickering (R-MS) and Anna Eshoo (D-CA). With arthritis prevalence at an all-time high, this legislation will significantly increase the government's investment in arthritis research and public health activities."

Since this is the number one health disability in the United States and its medical and Medicare costs are significant, this issue has a very broad and important constituency.

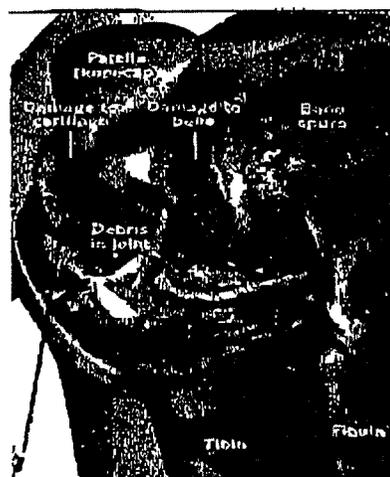
The Prevention, Treatment and Cures for Arthritis

Nobody knows exactly what causes arthritis. What is well accepted is that there is a process that can lead to arthritis. Most people begin life with normal joints and then wear, tear, age, injury, etc. leads down the slope to loss of cartilage, pain, and disability. The first few steps are asymptomatic. Arthritis is not diagnosed until there are symptoms. It is fairly clear, that except for injuries, when there is little degradation and deterioration of cartilage, it is unlikely someone will develop arthritis.

Healthy Knee



Arthritic Knee



Normal Degradation Deterioration Degeneration Dysfunction Destruction

Is there a cure for arthritis? No.

Are there treatments for arthritis? There are many, but most fall into two groups.

The first are pain killers – prescription and OTC products like aspirin.

- These provide some pain relief.
- Recent studies have shown that inadequate pain relief is a huge issue in the US.
- Even when pain killers relieve some pain, they do nothing to deal with the underlying condition and do not help to rebuild the joint. They have none of the building blocks of joints.
- In some cases, use of pain killers actually accelerates joint destruction.
- The side effects of pain killers are staggering, with over 100,000 people hospitalized and estimates of 10,000-20,000 deaths yearly, and billions of dollars of health care costs.

The second category includes glucosamine and chondroitin.

- Glucosamine and chondroitin are the building blocks of joints – cartilage, joint fluid, etc.
- As we age, the cycle of repair becomes less efficient and effective. The body does not manufacture glucosamine and chondroitin as well. Therefore, supplements provide the building blocks for joints.
- Long term studies have found evidence that glucosamine and chondroitin halt the progressive loss of cartilage – a first for any agent, and something no drug can do.

- Glucosamine and chondroitin have been shown to reduce arthritis related joint pain as well as or better than pain killers. Since they are not pain killers themselves, they work by addressing the cause of the pain – joint deterioration and dysfunction.
- Even the FDA's experts concede that glucosamine and chondroitin are effective treatments for joint related and arthritis issues. The irony is that the FDA has prohibited claims that report the benefits of glucosamine and chondroitin with respect to joint problems.

Just as calcium is the building block of bones, glucosamine and chondroitin are the building blocks of joints. Calcium products are allowed to say that they reduce the risk of osteoporosis. We believe that an analogous claim concerning osteoarthritis should be permitted for qualifying glucosamine and chondroitin products.

Imagine what women would suffer and say if the FDA did not allow calcium supplements to report that calcium supplementation reduces the risk of osteoporosis? How many children would suffer birth defects if the FDA continued to prevent folic acid supplements to report the reduced risk of neural tube defects? This is the position the FDA has forced upon arthritis sufferers. The choice forced by the FDA is to continue the treatment with pain killers even though they only partially work, do not address the fundamental issues, and may have serious side effects. What choice is that?

Is there any prevention for arthritis? Yes. Exercise. Good diet. Weight control.

What will help prevent arthritis beyond these? Glucosamine and chondroitin. By reducing the risks of joint deterioration and degeneration, they reduced the risk of developing arthritis and arthritis-related pain. This reduced risk can be a delay or a reduction in severity. Either would be greatly appreciated by people who are suffering from joint pain and arthritis.

Approximately 20% of the people with arthritis are between 18-44 years old. What should they be told? Take pain killers for the next fifty years? What do we tell the children who have arthritis? Take pain killers for the next 70 years?

For the moment, we, the 70 million people who suffer from joint problems and arthritis, and the probable 70 million future sufferers of arthritis, face a dilemma: Although the FDA agrees that glucosamine and chondroitin halt progression of osteoarthritis and its pain, the FDA denies the evidence and inference that these substances may reduce the risk that cartilage will deteriorate into osteoarthritis. In the absence of this information, as many as 70 million people may be doomed to develop osteoarthritis and a pain killer treadmill, serious side effects, work place disability, and enormous health care costs.

We think this is wrong. Most importantly, the 70 million people suffering from arthritis and joint problems in this country today and the 70 million more coming in the next thirty years deserve much better information about their health than the FDA allows.

We fully support continued research and hope that science finds the cause and cure of arthritis. Until then, we believe that supplying the body with the raw materials it needs to rebuild joints is a win-win for everyone. We believe the public should be appropriately informed and then allowed to make its own choice.