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June 4, 2004

VIA UPS NEXT DAY AIR
AND FACSIMILE 301-443-3100

Lester M. Crawford
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
HF-1
Rockville, MD 20857

Dear Acting Commissioner Crawford:

We are writing on behalf of our client Weider Nutrition International, Inc. ("Weider") to explain Weider's dissatisfaction with FDA's recent issuance of "Tentative Conclusions" on Weider's health claims in advance of what was to be an "independent" evaluation on those claims. Since May 29, 2003, Weider has diligently pursued a health claim petition the grant of which would permit the dissemination of valuable information to Americans who may be at risk of developing osteoarthritis. Since that submission, FDA has repeatedly delayed making a decision.¹ Weider was led to believe that no

¹ On May 29, 2003, Weider filed a health claim petition requesting that the agency authorize a claim characterizing a relationship between glucosamine and chondroitin sulfate and (1) osteoarthritis; (2) osteoarthritis-related joint pain, tenderness and swelling; (3) joint degeneration; and (4) cartilage deterioration. Weider submitted a total of twelve claims. On October 3, 2003 the Food and Drug Administration ("FDA") forwarded a letter denying the petition. After much negotiation, the agency finally agreed to meet with Weider to discuss the denial. On November 8, 2003, FDA met with Weider and its scientists to re-evaluate the claims and the science in support. On February 13, 2004, FDA forwarded a letter stating that it reconsidered its October 3, 2003 letter denying the petition. Instead, FDA explained that it decided to file the petition for comprehensive review to further consider nine of the twelve claims. After receipt of that letter, through negotiations with the Chief Counsel's office, Weider agreed that the agency would submit the petition for review to the independent Food Advisory Committee (instead of the normal internal FDA review). FDA explained that the FAC was an independent scientific body that would deliberate and formulate an independent assessment of the scientific evidence in support of the petition and offer its recommendation to FDA. FDA assured Weider that it would not make a decision until it heard from the FAC and other scientists presenting at the meeting. FDA made it clear to Weider that it expected that FAC to be free of outside influence and to reach an independent decision. In fact, although FDA has had the petition since October 2003 and filed the petition for comprehensive review on February 13, 2004, FDA stated that it would require another 60 days after the meeting to review the first three claims and 30 days after the meeting to review the last six claim and to issue its decision. The FAC meeting is scheduled for this Monday and Tuesday, June 7-8 2004.

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action would be taken on its petition until after the agency evaluated the recommendations and scientific evidence from the Food Advisory Committee ("FAC"). The Tentative Conclusions reveal that FDA has an unscientific bias against those claims.

On June 3, 2004, two business days before the FAC meeting that will consider Weider's petition, FDA published its "Tentative Conclusions" about the glucosamine and chondroitin sulfate petitions.² FDA gave no advance notice to Weider of its intent to publish that document. Moreover, Weider was not given the opportunity to publish and post on the web its position on the state of the scientific evidence in support of its proposed claims. Had FDA intended the meeting on Monday and Tuesday to remain an unbiased and untainted process, it would have posted all relevant positions on the matter.

We consider the publication of the Tentative Conclusions an act of bad faith, a violation of the Administrative Procedure Act, Weider's due process rights, and Weider's agreement with the agency on how its petition would be reviewed. We understood and were repeatedly told that no conclusions about the health claim petition would be reached until after the agency received input and recommendations from the FAC. Although the document uses the term "tentative," it is a clear message to the FAC and to the public that the agency does not intend to authorize the claims. The publication of its conclusions prejudices the FAC decision-making process and breaches the independence of that Committee. The publication is an unacceptable exercise of FDA influence over the FAC panel and a conflict of interest for the agency. That is especially so because FDA selects the members of the FAC.

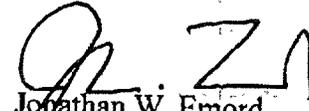
We understand that the agency needs to provide talking points and questions to direct and focus the FAC deliberations. However, that information was provided to the FAC through the *Federal Register* Notice of the FAC meeting and again in the briefing materials. The publication of the document on the Internet makes the meeting scheduled for Monday and Tuesday appear to be a mere formality. When our client agreed to have the FAC evaluate the petition, it was viewed as an opportunity to have an independent scientific body evaluate the scientific evidence and make a recommendation to the agency **before any** decision would be reached. Our client has spent considerable time and money in preparing for this meeting. The role of the advisory committee is to offer FDA independent scientific advice and to lend credibility to FDA's decision-making process. Due to the pre-meeting publication of the agency's Tentative Conclusions, FAC's role has been compromised.

While it is impossible to restore independence to the proceedings, at a minimum, we respectfully request that FDA immediately remove the Tentative Conclusions document from the website. We also request that FDA announce at the meeting that it

² That document provides a detailed explanation of the agency's conclusion and states that "a relationship between glucosamine and chondroitin sulfate and a reduced risk of osteoarthritis is not established." Based on that language it appears that the only thing tentative about that document is its title.

seeks a truly independent decision from the FAC and nothing FDA has done heretofore should influence the panel's deliberations.

Sincerely,



Jonathan W. Emord
Claudia A. Lewis-Eng
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Kathryn E. Balmford

cc: Michael Landa, Office of Chief Counsel
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FACSIMILE COVER SHEET

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Client Code: 20080-004

FROM: Jonathan W. Emord and Claudia A. Lewis-Eng

Date: Friday, June 04, 2004

No. of Pages: 4 (including this cover sheet)

MESSAGE:

Please deliver the attached to Commissioner Crawford. Thank you.

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