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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

**Re: FDA Request for Public Comment on
the Scope and Nature of FDAMA
Authoritative Statement Health Claims**

Docket No. 99N-0554

Submitted On Behalf of Traco Labs, Inc.

Dear Sir/Madame:

These Comments are submitted on behalf of Traco Labs, Inc., ("Traco") of Champaign, Illinois. Traco is a manufacturer and supplier of high quality dietary supplements providing numerous health benefits to consumers.

In the Federal Register of March 24, 1999, the Food and Drug Administration ("FDA") published a request for public comment on the structure of any regulations it may promulgate in order to implement Sections 303 and 304 of the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). These sections provide for the use of health claims based upon authoritative statements of scientific bodies of the United States Government with responsibility for public health, other than FDA. The short version of Traco's response is that FDA is bound to abide by the plain language of FDAMA and to facilitate, rather than obstruct, the use of health claims based upon statements of appropriate government bodies other than FDA with responsibility for public health issues. Traco, therefore, urges FDA to structure these regulations

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in manner which facilitates the transmission of important, truthful and nonmisleading, health information to the American public in accordance FDAMA and the recent decisions by the United States Court of Appeals for the District of Columbia Circuit in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999) and the United States District Court for the District of Columbia in Washington Legal Foundation v. Freidman, 13 F. Supp.2d 51 (D. D.C. 1998), (“WLF”) both of which rejected Agency regulations as violative of First Amendment Free Speech principles.

Background

In November, 1997, largely as a result of FDA’s failure to take action in response to requests that it authorize a health claim designed to alert women to the relationship between the consumption of adequate amounts of folic acid and reduced incidence of neural tube defects (such as spinal bifida), Congress enacted sections 303 and 304 of FDAMA. In this portion of the law, Congress intended to broaden the range of permissible health claims by creating a “streamlined procedure” designed to allow “scientifically sound nutrition information to be provided to consumers”. (Joint Explanatory Statement of the Committee of Conference, Congressional Record, H10477 (November 9, 1997). This goal was to be accomplished through providing for the use of health claims based upon “authoritative statements” published by “a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition.”

On February 23, 1998, the Weider Nutrition International, Inc. provided FDA with notice of 9 authoritative statement health claims it intended to utilize in accordance with FDAMA. These claims dealt with information concerning the relationship between a variety of nutrients and health related conditions or diseases including poor bone health, heart disease and certain cancers. In response, FDA promulgated 9 Interim Final Rules prohibiting the use of each of the proposed claims. In taking this action FDA transmuted the three simple requirements set forth by FDAMA which merely requires that an authoritative statement be:

1. Published by a scientific body with responsibility for public health matters (such as the Centers for Disease Control);
2. Not made by an employee of the scientific body in the individual capacity of that employee; and
3. In effect at the time the health claim is presented to FDA.

into the five significantly more burdensome requirements that the statement must:

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1. Represent the official policy of the scientific body;
2. Be the product of a deliberative review of the scientific evidence on the subject of the statement;
3. Not be based on preliminary or inconclusive evidence;
4. Document a valid nutrient-disease relationship that actually exists – not one that is hypothetical or merely under study; and
5. Satisfy FDA's "significant scientific agreement" standard.

As noted in Comments submitted by a variety of companies and Representative Dan Burton (R-Ind.), Chairman of the House Committee on Government Reform, creation of this new standard constituted a violation of FDAMA, and an impermissible effort by FDA to establish itself as the sole arbiter of what health information should be transmitted to the American public.

Refuting FDA's claimed authority for adoption of this onerous standard, Chairman Burton's October 26, 1998 letter to Commissioner Henney takes issue with FDA's insistence that it is within its powers to require that FDAMA health claims satisfy the "significant scientific agreement" standard. This position, Chairman Burton argued "guts Section 303 of meaning" and flouts Congressional intent to provide "a meaningful alternative" to the existing regulatory scheme. Moreover, he noted that the Senate Report Cited by FDA in the nine Interim Final Rules sets forth only one example where this standard would be applicable to FDAMA health claims – and that is where FDA specifically adopts, or has already adopted, a health claim concerning a disease-nutrient relationship. No other circumstances justifying the application of this onerous standard are mentioned in the Senate Report, or anywhere else in FDAMA or its legislative history.

Nevertheless, in a January 21, 1999 Federal Register Notice, FDA stated that the Agency "advises that the process and principles" announced in connection with its rejection of each of the Weider Claims continues to "reflect the agency's current thinking with respect to implementation" of the FDAMA health claim procedure. 64 Fed. Reg. at 3252. Traco responded to this by filing lengthy Comments on March 29, 1999 arguing that FDA's obdurate insistence that FDAMA authorized FDA to apply the onerous "significant scientific agreement" standard to authoritative statement health claims constituted a violation, not only of the terms of FDAMA, but of the First Amendment to the United States Constitution as elucidated in two recent federal court decisions, striking down FDA regulations which unreasonably suppressed truthful and nonmisleading speech concerning health related issues.

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In the first of those decisions, Washington Legal Foundation v. Friedman, 13 F. Sup. 2d 51 (D. D.C. 1998), Judge Royce Lamberth of United States District Court for the District of Columbia held that FDA regulations severely restricting the manner in which drug manufacturers could disseminate information concerning off-label use of drug products to physicians violated First Amendment free speech principles. Rejecting FDA's argument that its regulations were necessary to ensure that physicians were not confused by information disseminated by drug companies, Judge Lamberth stated:

If there is one fixed principle in the commercial speech arena, it is that a "State's paternalistic assumption that the public will use truthful, nonmisleading commercial information unwisely cannot justify a decision to suppress it." To endeavor to support a restriction upon speech by alleging that the recipient needs to be shielded from that speech for his or her own protection, which is the gravamen of FDA's claim here, is practically an invitation to have that restriction struck. (Citations omitted)

13 F. Supp at 69-70.

In the other decision, Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), the United States Court of Appeals for the District of Columbia ruled that FDA's failure to provide any definition of "significant scientific agreement" and blanket refusal to consider "qualified" health claims in rejecting four proposed health claims submitted to it by dietary supplement marketers in 1993, failed to pass muster under both the First Amendment to the United States Constitution and the Administrative Procedure Act. In reviewing FDA's contention that any qualified health claim is inherently misleading and it is therefore essential to apply the "significant scientific agreement" to all proposed health claims, the Circuit Court stated:

As best we understand the government, its first argument runs along the lines: that health claims lacking "significant scientific agreement" are inherently misleading because they have such an awesome impact on consumers as to make it virtually impossible for them to exercise any independent judgment *at the point of sale*. It would as if the consumers were asked to buy something while hypnotized, and therefore they are bound to be misled. We think this contention is almost frivolous. (Emphasis in original.)

164 F.3d at 655. The Court further explained that:

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The government disputes that consumers would be able to comprehend appellants' proposed health claims in conjunction with the disclaimers we have suggested – the mix of information would, in the government's view, create confusion among consumers. But all the government offers in support is the FDA's pronouncement that "consumers would be considerably confused by a multitude of claims with differing degrees of reliability". 59 Fed. Reg. 405. ***Although the government may have more leeway in choosing suppression over disclosure in response to the problem of consumer confusion where the product affects health, it still must meet its burden of justifying a restriction on speech***— here the FDA's conclusory assertion falls far short. See Ibanez, 512 U.S. at 146 ("If the protections afforded commercial speech are to retain their force, we cannot allow rote invocation of the words 'potentially misleading' to supplant the [government's] burden to demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.") (emphasis added).

164 F. 3d at 659.

On the heels of these two important decisions upholding First Amendment free speech principles in the face of FDA efforts to suppress the communication of truthful and nonmisleading health information, and Chairman Burton's cogent analysis of the misguided nature of FDA's response to the Weider submissions, the Agency nevertheless issued a January 21, 1999 Federal Register Notice wherein it stated that the Agency "advises that the process and principles" announced in connection with its rejection of each of the Weider Claims "reflect the agency's current thinking with respect to implementation" of the FDAMA health claim procedure. 64 Fed. Reg. at 3252. In Comments submitted on March 29, 1999 Traco responded by this pronouncement, arguing that "the Agency's obdurate instance in the January 21, 1999 Federal Register that its interpretation of its authority under the United States Constitution and FDAMA is correct despite the clear expressions to the contrary of Chairman Burton and the Pearson Court, is yet another unfortunate indication of the Agency's efforts to usurp for itself the role of sole arbiter of what health information may be conveyed to the American public."

Traco continues to stand by this position. It is incumbent upon FDA to accept the holdings of the WLF and Pearson Courts, and the express purposes of Congress in the creation of FDAMA authoritative statement claims: ***to permit the free flow of important truthful and***

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nonmisleading health information to the American Public. As is reflected below in Traco's responses to each of the questions posed by FDA concerning its approach to formulation of substantive regulations concerning authoritative statement health claims, Traco submits that this is the only approach that will lead to the promulgation of regulations which comport with the requirements of the law.

Issue 1. The Scientific Basis For Claims

Question a. What is an authoritative statement?

Response: FDAMA provides clear, concise guidance in response to this question. The law provides that in order to form the basis of a health claim, the statement in question must be:

1. Published by a scientific body with responsibility for public health matters (such as the Centers for Disease Control);
2. Not made by an employee of the scientific body in the individual capacity of that employee; and
3. In effect at the time the health claim is presented to FDA.

FDAMA, Pub. L. No. 105-115, Title 3, §§ 303, 403(r)(3) (codified at 21 U.S.C. § 403(r)(3)). Any qualifying requirement beyond these three simple guidelines that might be adopted by FDA will constitute a violation of the plain language of FDAMA and would be an impermissible effort by the Agency to expand its powers beyond the purview of the FDCA.

In establishing whether a specific statement falls within these requirements, Traco submits that the legislative history of FDAMA (in particular as it relates to FDA's mishandling of the Folic Acid health claim) makes it clear that the term "authoritative statement" is intended to encompass all communications of scientific bodies of the United States Government with responsibility for the maintenance of public health in furtherance of that objective. FDA should take no regulatory action that would in any way restrict the scope of this definition and interfere with the communication of truthful and nonmisleading health information to the American public.

Question b. Who defines "authoritative statement?"

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Response: Congress. As discussed in the previous response, the edicts of FDAMA are clear. The authoritative statement health claim process was designed to facilitate the free flow of truthful and nonmisleading health information. The legislative history of FDAMA, and Chairman Burton's analysis of the Congressional intent behind the creation of this class of health claims makes it clear that all statements of official public health agencies of the United States which are issued in order to convey information relating to public health should be considered to be "authoritative". (See, S. Rep. 105-43 at 49).

Question c. Who decides if a particular statement is an "authoritative statement?"

Response: FDAMA expressly places the burden upon FDA to review any claim that is presented to it for use as an authoritative statement for compliance with the requirements of the law. This review should be limited to consideration of whether the statement satisfies the three requirements set forth above in response to Question a. The implementation of regulations containing any other requirements would be arbitrary and capricious, and without authority in the law.

Traco notes, however, that there may be instances where a scientific body of the United States Government issues an *independent* opinion that information it is conveying may be based upon data that is so preliminary or inconclusive as to cause the statement not to be authoritative. In such instances, this opinion is entitled to considerable weight in any review by the FDA.

Question d. Is the "context" of a statement in the publication in which it appears relevant to that determination? If so how?

Response: The answer to this question is contained within the plain language of FDAMA. Section 303(iv) of FDAMA provides that the claim must be stated in such a manner that is "is an accurate representation of the authoritative statement". Submission of a notification to FDA of intent to use a claim that is based upon a statement that is taken out of context from a larger body of information will not satisfy this requirement. Traco submits that application of such a standard would be consistent with the transmission of only truthful and nonmisleading information.

Question e. How does the significant scientific agreement standard apply to health claims based on authoritative statements?

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Response: It does not. FDAMA was enacted for the very purpose of circumventing application of this onerous standard by FDA. Any action to the contrary by FDA would interfere with the goal of facilitating the transmission of truthful and nonmisleading health information to the American public, and would be arbitrary, capricious and contrary to law.

This point is clearly enunciated in Comments submitted by Chairman Burton in his letter of August 13, 1998 to Dr. Michael Friedman, Lead Deputy Commissioner which states:

“Congress enacted Section 303 in reaction to FDA’s poor track record on the folic acid health claim. FDA’s interpretation of the [significant] scientific agreement standard could have contributed to thousands of needless preventable deaths when, in the years following the public recommendations of the Public Health Service and the Centers For Disease Control (associating consumption of folic acid with a reduction in neural tube defect births), FDA continued to prohibit the claim. We sought to prevent that kind of unnecessary event from recurring by enacting Section 303. *Your interim final rules, however, only reinforce the existing censorship effected by the [significant] scientific agreement standard.* Consequently, I fully expect that FDA’s denial of vital health information to the public will pose a continued threat to the health of the American public.” (Emphasis added.)

Issue 2. Existing Regulatory Requirements

Question a. What requirements of 21 CFR 101.13 and part 101, subpart D should we apply to nutrient content claims based on authoritative statements?

Response: Only those portions of the regulations which restrict certain nutrient content claims due to the presence of other nutrients that may be deleterious to the public health. Such restrictions seem necessary to render any nutrient content claim truthful and nonmisleading.

Question b. What requirements of 21 CFR 101.14 should we apply to health claims based on authoritative statements?

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Response: Only 21 CFR 101.14(a)(5) can validly be applied to FDAMA authoritative statement health claims. This portion of the existing regulations deals with disqualifying levels of potentially deleterious nutrients such as fat, cholesterol and sodium. Application of this regulation to restrict the use of an otherwise valid authoritative statement health claim would seem to be necessary in order to ensure that only truthful and nonmisleading health information was transmitted to the American public. Imposition of any other restrictions would be contrary to the Congressional intent behind the creation of authoritative statement health claim in FDAMA.

Issue 3. Procedural and Definitional Issues

Question a. Which agencies should we identify as scientific bodies of the U.S. Government with responsibility for public health protection or research directly relating to human nutrition under section 403(r)(2)(G)(i) and (r)(3)(C)(i) of the act?

Response: FDAMA expressly provides that the National Institutes of Health (“NIH”) or the Centers for Disease Control (“CDC”) or the National Academy of Sciences or any of its subdivisions are to be considered a qualifying “scientific body of the U.S. Government,” *per se*. Traco submits that the purposes of FDAMA would also be served that by the recognition that statement by the individual subdivisions of NIH and the CDC are entitled recognition as authoritative. These entities are recognized as repositories of significant scientific expertise, and are frequently charged with responsibility for conveying important health related information to the American public. Similar weight should be given to any other scientific body of the United States Government with responsibility for public health issues including the Department of Agriculture (Food, Nutrition and Consumer Services and the Center for Nutrition Policy and Information) and the Department of Health and Human Services (Office of the Surgeon General).

Question b. Should we provide by regulation that health claims based on authoritative statements may be used in the labeling of dietary supplements?

Response: Absolutely. There is no rational basis for not expressly recognizing that authoritative statement health claims may be utilized on behalf of dietary supplements. Chairman Burton’s correspondence to Deputy Commissioner Friedman and Commissioner Henney leaves little room for doubt on this issue. Traco queries why FDA has even submitted this question for public comment.

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Question c. What should we require that you submit with a notification of a health claim or nutrient content claim based on an authoritative statement?

Response: FDAMA specifically states that the information presented to FDA must consist of:

1. A notice of the claim, which shall include the exact word used in the claim and shall include a concise description of the basis on which the person believes the claim to be based upon an authoritative statement;
2. A copy of the authoritative statement; and
3. A balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers.

No grounds exist upon which FDA may require the submission of any other information.

Question d. Should we require you to submit in a notification an analytical methodology for measuring the substance that is the subject of your claims?

Response: Absolutely not. As noted above, FDAMA sets forth only three requirements for the contents of any submission to FDA of an authoritative statement health claim.

Question e. What is a balanced presentation of the scientific literature relating to the subject to which a claim refers that is required under section 403(r)(2)(G)(ii)(III) and (r)(3)(C)(ii)(III) of the act?

Response: A balanced presentation of the literature should provide sufficient information to enable FDA or any member of the public to reach a valid conclusion as to the state of the science as it relates to the proposed claim. While FDA should not require that this presentation be exhaustive, it should be complete enough to enable an expert in the field of nutrition to render an opinion as to the state of the science at the time notice of the claim is submitted to FDA. Applied in an even-handed, equitable manner, this requirement should not interfere with the transmission of truthful and nonmisleading health information.

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Question f. Should FDA keep notifications confidential for 120 days after the date of their submission or should we place them in a public docket upon receipt?

Response. There is no basis within FDAMA for applying confidentiality to notices of authoritative statement health claims to FDA. Traco believes that FDA should place such notifications on the public docket as soon as they are received by the Agency, so as to permit as the greatest possible degree of public participation in review of the claim as possible.

Question g. If a notification is incomplete or does not support a claim, should we respond to it by letter or by issuing a regulation, and what should be the legal effect of letters were we to use them?

Response. FDAMA provides that use of an authoritative statement health claim may commence 120 following days of notification to FDA unless the Agency issues a regulation prohibiting or modifying the claim. Among the grounds enunciated for such action are the finding that the notification to FDA does not support the claim or is incomplete. Thus, in order for FDA to satisfy only its minimal statutory obligations, issuance of a regulation prohibiting the use of the claim would suffice.

Traco submits, however, that utilization correspondence similar to the "courtesy letters" would be of particular benefit in as a vehicle through which the Agency could request additional information concerning an authoritative statement health claim. Such letters, can be issued by FDA with a clear statement that they are without prejudice to any final Agency action, and that they are not intended to be an all inclusive review of deficiencies in the submission in question. This procedure would facilitate rapid approval of valid authoritative statement health claims where deficiencies in the initial notification to FDA can be cured by the submission of additional data. If the agency were to respond to such situations through the formal procedure of issuing regulations, unnecessary, and potentially harmful delays in the dissemination of the information contained in the claim would likely occur.

Conclusion

Traco respectfully submits that any final regulations issued by FDA in connection with the use of authoritative statement health claims must be consistent with the goal in facilitating the transmission of important, truthful and nonmisleading health information to the American public.

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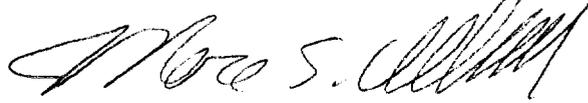
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As an agency of the Federal Government charged with responsibility for maintenance of the public health, FDA should take all reasonable to foster the increased availability of such information to all Americans. Only the promulgation of regulations with this objective in mind will satisfy the mandates of FDAMA, and of the First Amendment elucidated by the WLF and Pearson decisions.

Respectfully Submitted,

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