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August 5, 1999

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

**Re: Regulations on Statements Made for Dietary
Supplements Concerning the Effect of the Product
on the Structure or Function of the Body**

Docket No. 98N-0826

**Dietary Supplements; Center for Food Safety and
Applied Nutrition Strategy**

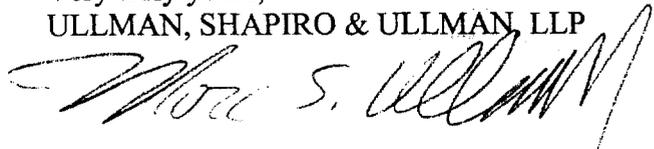
Docket No. ~~99N-1174~~

Submitted On Behalf of Traco Labs, Inc.

Dear Sir/Madame:

Enclosed please find 4 (four) copies of comments made on behalf of Traco Labs, Inc. at the FDA's public meeting on structure/function claims on August 4, 1999. In light of the abbreviated nature of the time for oral presentations, we would appreciate it if you would enter the written text of Traco's comments on both of the public dockets noted above.

Very truly yours,
ULLMAN, SHAPIRO & ULLMAN, LLP



Marc S. Ullman
Attorney for Traco Labs, Inc.

99N-1174

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COMMENTS OF MARC S. ULLMAN, ESQ ULLMAN, SHAPIRO & ULLMAN, LLP ON BEHALF OF TRACO LABORATORIES, INC. FDA PUBLIC MEETING ON STRUCTURE/FUNCTION CLAIMS AUGUST 4, 1999

Good afternoon, my name is Marc Ullman. I am a partner in the New York City law firm Ullman, Shapiro & Ullman, LLP. I appear here today on behalf of Traco Labs, Inc., a manufacturer and supplier of dietary supplements based in Champaign, Illinois. On June 10, 1998, Traco submitted comments to FDA's publication of its proposed rules governing the regulation of statements made for dietary supplements concerning the effect of such products on the structure or function of the body. Among other things, Traco's comments argued that the proposal failed to provide any meaningful guidance as to the agency's views of acceptable structure/function claims, confused the nature of what FDA views as an acceptable claim by inconsistent references to Over-The-Counter drug monographs, and was an ill-considered effort to ban what the Agency considers implied drug claims based upon its naked assertions of consumer perceptions. We respectfully refer to and incorporate those comments within Traco's comments here today, as we continue to believe that FDA's proposed regulations are designed to thwart the Congressional intent behind DSHEA to guarantee the dietary supplement industry's ability to convey truthful and nonmisleading health information to the American public. Traco's comments to FDA have consistently urged the Agency to adopt a regulatory structure that

permits the transmittal of such information, because it is mandated not only by DSHEA, but by the First Amendment to the Constitution. Only when FDA recognizes this, will the American public be armed with all of the important, truthful and nonmisleading information it needs to make intelligent decisions concerning its health care.

The Federal Register Notice calling this meeting specifically requested comments on two subjects that Traco believes are of the utmost importance. The first is the Agency's attempt to change the definition of disease following DSHEA's express authorization of structure/function claims on behalf of dietary supplements. If the proposal^{adopted} would operate to vastly expand the scope of product claims that fall within the Food, Drug and Cosmetic Act's definition of a drug as "articles intended for use in the diagnosis, cure mitigation, treatment or prevention of disease in man or other animals".

Following the passage of the NLEA in 1990, FDA defined the term "disease or health related condition" as meaning, in relevant part, "damage to an organ, part, structure or system of the body such that it does not function properly (e.g. cardiovascular disease) or a state of health leading to such dysfunctioning." The proposal, however, would vastly expand this definition to include "any deviation from, impairment of, or interruption of the *normal* structure or function of any part, organ, or system (or combination thereof) of the body . . . or a state of health leading to such deviation . . ." FDA has acknowledged that this change represents a vast expansion of the definition of disease. To take such action after Congress enacted DSHEA based upon the then operative definition is tantamount to a spoiled child changing the rules of the game after it realizes that things are not going exactly as planned. Traco also believes that use of the term "deviation from normal" in FDA's proposal is so vague that it provides no meaningful guidance to the industry, and could be interpreted in a manner that would bar almost any claim beyond

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“helps maintain normal [you fill in the blank]”. Thus, we ask normal for who? You, me a twenty-one year old decathlete in peak physical condition, or a sixty-five year old female retiree? If normal is the decathlete, we respectfully submit that we are all in trouble.

In its Federal Register Notice, FDA also asked whether retention of term “damage” in the present definition would exclude any conditions that are medically considered diseases. Traco believes that the agency’s narrow focus of this question is disingenuous at best. The current definition not only encompasses actual damage, but also “a state of health leading to such dysfunctioning”. This is sufficiently broad to cover any state of health that could rationally be considered a disease. To the extent that FDA has called upon the supplement industry to justify maintenance of this definition, Traco submits that if it is going to attempt to change the rules of the game, concepts of fundamental fairness, and the provisions of the Administrative Procedure Act squarely place the burden upon the Agency to justify that change.

The second issue we wish to address is FDA’s misguided effort to ban what it considers “implied disease claims.” Any analysis of this portion of the Agency’s proposal must start with an understanding of the basic proposition that the First Amendment to the United States Constitution protects all truthful and nonmisleading speech. Even where the speech in question would be considered “commercial speech,” the Supreme Court has clearly stated that so long as it is truthful and nonmisleading, the government must demonstrate a substantial interest that is directly advanced by its regulation without burdening substantially more speech than necessary. This principle was re-affirmed last week in the ██████ United States District Court for the District of Columbia in Washington Legal Foundation v. Henny and Shalala. There, FDA took the position that the “Court should not apply First Amendment commercial speech scrutiny [to the law and FDA regulations restricting the dissemination of information concerning the off-label

use of prescription drugs] because [it] permits speech so long as it complies with the requirements of the statute.” Judge Royce Lamberth rejected this notion as “preposterous”. The clear state of the law requires that whenever FDA seeks to restrict truthful and nonmisleading speech, it must set forth a compelling reason for doing so. The proposed regulations restricting the use of what FDA has characterized as implied drug claims fails to satisfy this requirement.

Perhaps the most glaring defect in the proposal on implied claims is FDA’s effort to define an implied “drug” or “disease” claim by fiat. Throughout this portion of its proposal, the Agency makes a series of pronouncements that consumers will consider certain claims to necessarily implicate disease states. For example FDA states that all claims mentioning the concept of “lower cholesterol” are impermissible disease claims as they necessarily imply claims for hypercholesterolemia. This ignores the reality that a significant number of Americans have cholesterol levels in the range of 200-239, which would be considered “high normal”. These individuals, while being well advised to attempt to lower their cholesterol levels, would not be considered to be suffering from any disease.

All that FDA has offered in support of its determination that this claim must be suppressed is its judgement of what consumers will understand. Earlier this year in Pearson v. Shalala, when confronted with a similar theory in connection with FDA’s efforts to suppress truthful and nonmisleading speech concerning the use of disclaimers in association with health claims, the United States Court of Appeals for the D.C. Circuit noted that:

The government disputes that consumers would be able to comprehend appellant’s 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”.

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.

Similarly, FDA’s conclusory assertion that it knows what consumers will understand to be an implied drug claim falls far short of satisfying the agency’s First Amendment obligations. To the extent that FDA claims these restrictions on truthful and nonmisleading speech are justified by the need to protect the consumer from potentially being misled, in the most recent WLF decision, Judge Lamberth aptly noted that:

The government, however benign its motivations, simply cannot justify a restriction on truthful nonmisleading speech on the paternalistic assumption that such restriction is necessary to protect the listener from ignorantly or inadvertently misusing the information.

Traco respectfully submits that if FDA wishes to suppress truthful and nonmisleading statements concerning the health benefits of dietary supplements, it must put forth a compelling reason far more substantial than its pronouncement of what consumers will understand those claims to mean.

In closing, Traco calls upon FDA to explain what it meant in the July 8 Federal Register Notice calling this meeting when it posed the question “Is a claim that a product ‘maintains healthy function’ an implied disease claim in all cases?” If the claim that a product “maintains healthy function” is an implied disease claim in any rational circumstances, does FDA propose to limit the realm of acceptable claims under DSHEA to “helps maintain general well-being”. Indeed, taking FDA’s “implied” logic set forth in its Federal Register Notices, even this claim could be considered an “implied disease claim”, because if you are maintaining well being, you must be considered disease free.

CROSS FILE SHEET

FILE NO: 99N-1174/C40

SEE FILE NO: 98N-0826/e19

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