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April 7, 2000

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

**Re: Food Labeling; Dietary Supplements Health Claims;
Implementation of Pearson v. Shalala; Use of Health
Claims Concerning Effects on Existing Diseases**

Docket No. 00N-0598

Submitted On Behalf of Traco Labs, Inc.

Dear Sir/Madame:

These comments are submitted on behalf of Traco Labs, Inc., ("Traco") of Champaign, Illinois. They include and expand upon the substance of the oral comments presented by Traco at the Food and Drug Administration's ("FDA") public meeting of April 4, 2000 on these same issues.

Traco is a manufacturer and supplier of dietary supplements, based in Champaign, Illinois. It was a claimant in one of what have come to be known as "The Black Currant Oil Cases," which resulted in judicial rejection of FDA's basic approach to the regulation of dietary supplements as unsafe food additives, United States v. Two Plastic Drums . . . Black Currant Oil (Traco Labs, Inc.), 984 F.2d 815 (7th Cir. 1993). Over the past 10 years, Traco has consistently urged FDA to permit the free flow of all truthful and nonmisleading information concerning the important health benefits of dietary supplements. This position has been grounded in the notion that only with this complete information can American consumers take full control over matters related to their health, and make fully-informed, intelligent decisions on this all important issue.

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As a preliminary matter, Traco notes, with some alarm, that nearly 15 months have elapsed since the United States Court of Appeals for the D.C. Circuit handed down its decision in Pearson v. Shalala, 164 F.3d 650, (D.C. Cir. 1999), which declared FDA's use of the significant scientific agreement standard for health claims to be an unconstitutional burden on free speech as applied to dietary supplements. Since that time, FDA has flouted the Court's decision and continued to apply this standard to all health claims submitted to it for review. Traco respectfully submits that the time for consideration of issues relating to the "implementation" of the Court's mandate in Pearson is long over. It is beyond dispute that any FDA regulated company that disregarded any Court Order in an action commenced by FDA in a similar manner would have been subjected to efforts to have it held in contempt, or even more serious enforcement actions. Moreover, Traco notes that testimony presented on April 4 by the plaintiffs in Pearson indicated that they had been threatened with criminal sanctions by FDA if they attempted to utilize the claims at issue in that case. Such an approach by the Agency suggests an inexcusable disregard for any notion of fair play and due process. It is incumbent upon FDA to take immediate interim action to comply with the Court's ruling in Pearson, and to specifically disavow any threats of criminal enforcement actions against the Pearson plaintiffs for the use of the claims at issue in that matter.

In the *Federal Register* Notice of March 16, 2000, FDA requested the submission of comments addressing a series of questions the Agency posed pertaining to implementation of Pearson, and the viability of health claims relating to the treatment or mitigation of diseases or health related conditions. These comments will attempt to address the most pertinent of these in the order in which they were presented in the *Federal Register*.

Implementation of the Pearson Decision

1. What is the best regulatory approach for public health?

Traco firmly believes that the answer to this question is one which allows for the free flow of truthful and nonmisleading information. The public health is best served when consumers are provided with truthful information relating to the broad range of health benefits that can be provided by dietary supplements. Moreover, our First Amendment jurisprudence repeatedly has expressed a preference for disclosure rather than suppression of information. Thus, in its 1977 ruling in Bates v. State Bar of Arizona, the Supreme Court noted that, "We view as dubious any justification that is based on the benefits of public ignorance." Similarly, in his 1996 opinion for the plurality in 44 Liquormart v. Rhode Island, Justice Stevens recognized that, "The First Amendment directs us to be especially skeptical of regulations that seek to keep people in the dark for their own good."

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Of equal import, however, Traco believes that there is no place in the market for misleading, false information. Such information is entitled to no First Amendment protection, and the full array of FDA's enforcement powers are properly utilized against those individuals and companies marketing products on the basis of such misinformation. Such products are misbranded and adulterated under the most fundamental provisions of the Federal Food, Drug and Cosmetic Act ("FDCA"), and have no place in the market.

2. Can qualifying language (including disclaimers) be effective in preventing consumers from being misled by health claims based on preliminary or conflicting evidence?

The answer to this question is an unqualified yes. Such qualifications can be clearly presented in a manner that alerts the consumer to the actual state of current scientific belief, without causing undue confusion. Several examples of such disclaimers were cited by the D.C. Circuit in the Pearson decision. To the extent that FDA has expressed concern that certain disclaimers and qualifying language may be so broad as to justify even the most outrageous claims, Traco respectfully submits that the Pearson decision does not require the Agency to validate any and all claims, so long as they are accompanied by a disclaimer. It is well established in our case law that false promotional claims may not be protected by over-arching disclaimers. What Pearson does require, however, is that FDA explain the basis for its decision in rejecting a claim, rather than simply announcing that it has failed to pass some unarticulated standard.

To the extent that the Agency has sought information from the supplement industry demonstrating that disclaimers and qualifying language can be used in conjunction with certain health claims without causing consumer confusion, Traco respectfully notes that the Pearson Court expressly recognized that *the burden is on FDA* to justify any restriction it may seek to place on speech and that it is not the industry's burden to justify the speech. Specifically, the Court stated that "Although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech." 164 F.3d at 656.

Comments presented to FDA at the April 4 meeting by The Center For Science In The Public Interest ("CSPI") arguing that the Court's statement concerning products affecting health opened the door for the Agency to continue to apply the significant scientific agreement standard to all proposed health claims are incorrect. These comments fail to consider the entirety of the Court's statement, which placed the burden squarely on FDA's shoulders to "meet its burden of justifying a restriction on speech." Traco submits that reliance on generalized statements and

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newspaper reports such as those found in the CSPI's comments fall far short of satisfying this burden.

3. Is there a way to preserve the existing regulatory framework for health claims consistent with the First Amendment?

Traco respectfully submits that the Pearson Court has already answered this question in the negative. The Circuit Court specifically held that FDA's interpretation of this standard as applied to all proposed claims, as necessarily prohibiting the use of disclaimers/qualifying language relating to what has become known as "emerging science," was violative of the First Amendment. While the Circuit Court did not reject the preapproval process as it related to health claims, its decision clearly mandates a revision of FDA's basic regulatory approach to health claims such as those presented by the Pearson plaintiffs.

In revising its approach to the health claims approval process for dietary supplements, Traco believes that the Agency should consider adoption of a sliding scale of scientific support, which is required depending upon the nature of the claim presented. Where the claim relates to disease prevention, and there are no significant public safety issues connected with the proposed claim, such as in the case of the four claims considered by the Pearson Court, the standard applied should simply be truthful and nonmisleading. Where the claims presented relate to disease treatment or mitigation, some higher standard, perhaps even significant scientific agreement, may be justified, if FDA provides a clear and cogent explanation of the standards it chooses to apply. If the claim relates to treatment of a serious condition that presents a significant health safety issue, FDA may be justified in requiring scientific evidence that is the substantial equivalent of that which is required for substances undergoing the drug approval process.

For example, the Agency probably would have little difficulty in presenting a justifiable rationale for requiring specific clinical studies in support of a claim that an herbal extract was useful in the treatment of tumors. The key to such a ruling, however, would be that the Agency satisfy its burden under Pearson and the First Amendment and present its rationale for its decision, rather than simply announcing that the claim was rejected because it had failed to pass some unarticulated standard of review. Traco further notes, in response to questions posed by Agency representatives at the April 4 meeting, that there may even be justification for the rejection of such a claim on the grounds that it relates to a condition under which there are no circumstances that consumers can safely diagnose and treat themselves.

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4. If health claims are permitted based upon a standard less rigorous than significant scientific agreement, what is the best way to distinguish among different levels of evidence so that consumers are not misled?

Traco believes that the Agency was presented with substantial testimony at its April 4 public hearing, indicating that consumers are capable of reading and understanding clear, concise disclaimers on product label, labeling and advertising. Use of statements such as “preliminary studies indicate,” “additional research is needed to confirm this data” and “a number of studies with conflicting results exist” should be sufficient to enable the consumer to gauge the weight and value that should be attached to the claim. See, The Federal Trade Commission Guidance, Dietary Supplements: An Advertising Guide for Industry, pp. 6-17.

5. If health claims are permitted based on a less rigorous standard, what actions can be taken to provide incentives to manufacturers to conduct further research on emerging substance-disease relationships?

The mere fact that the Agency has chosen to pose this question suggests: (a) that it continues to hold to its paternalistic view that the American consumer will be mesmerized by the appearance of any health claim on a dietary supplement label and will be unable to distinguish the quantum of support present for the claim, and (b) that the dietary supplement industry is interested only in utilizing health claims based upon the scantiest level of science justifiable and will discontinue all research as soon as any claim, even if it is qualified, is permitted.

Over the past decade, to help identify and determine the value of new products, Traco has sponsored and published more than two dozen clinical studies at leading universities and research institutions. These include projects at the University of California, Davis, Texas A&M University and The University of Georgia. By funding its own product research, Traco understands that it can validate benefit claims, ensure quality levels, and gain insight and perspective into specific product benefits. Continuation of this research would not be affected in any way by a regulatory scheme permitting the use of health claims based upon emerging science.

HEALTH CLAIMS AND EXISTING DISEASE CONDITIONS

The second major area on which the Agency has sought input concerns whether claims of effects on existing diseases or conditions are permissible as health claims. Traco believes that the answer is an unqualified yes.

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In the March 16 *Federal Register*, FDA suggests that various nuances contained in the interrelationship between the statutory definitions of food, drug and medical food indicate that Congress intended that authorized health claims be limited to claims relating to reduction of the risk of disease. Thus, the Agency postulates that “if Congress had intended to permit any kind of disease claim for foods, it could have exempted all foods bearing authorized health claims from the drug definition in section 210(g) of the Act which provides that ‘an article intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease’ is a drug.”

This reasoning is flawed in several important respects. First, it fails to recognize that a product may be deemed a drug by virtue of things other than claims made on its behalf. For example, it may contain an ingredient that was the subject of an IND or approved NDA prior to its introduction into the marketplace as a food. This tension between drug and food is currently the subject of litigation relating to red rice yeast extracts.

Second, the FDCA states that a product will not be considered a drug by virtue of the use of an approved health claim. The presence of other, unauthorized claims may still render the product a drug. If Congress had utilized language such as suggested by the Agency in the *Federal Register* Notice, this might not be the case.

Finally, and perhaps most importantly, FDA’s approach ignores the plain language of the statute. Congress has authorized the use of health claims characterizing the relationship between a nutrient and a disease or health-related condition. Nothing in the statute indicates any Congressional intent to limit health claims solely to disease prevention. If this is what Congress had intended, it simply could have allowed health claims characterizing the relationship between a nutrient and the reduction of the risk of disease or health-related conditions. It did not do this. Indeed, the Pearson Court specifically recognized that the FDCA “creates a safe harbor from designation as a ‘drug’ for certain dietary supplements whose labels or labeling advertise a beneficial relationship to a disease or health related condition.” 164 F.3d at 650.

The plain language of the FDCA currently contains no such limitation on the scope of health claims such as is suggested by the Agency, and Traco respectfully submits that an interpretation by the Agency to the contrary would be without justification or legal basis.

At the April 4 public meeting, representatives of FDA raised several other concerns that the Agency apparently believes would justify a refusal to permit health claims concerning disease treatment or mitigation.

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1. Must health claims relating to the treatment or mitigation of a disease or health related conditions be approved under some lesser standard than significant scientific agreement in accordance with Pearson?

The answer to this question is no. As noted above, the Pearson Court did not mandate that FDA accept all health claims so long as they are accompanied by reasonable disclaimers. Indeed, the Court recognized that “although the government may have more leeway in choosing suppression over disclosure as a response to the problem of consumer confusion where the product affects health, it must still meet its burden of justifying a restriction on speech.” 164 F.3d at 656. The Court then held that in instances where the FDA was unable to articulate anything beyond the most general concerns of consumer confusion, it could not satisfy this burden.

Accepting the notion that “where the product affects health” the government can satisfy its burden of justifying a restriction on speech where it properly articulates valid concerns, Traco submits that the FDA can legally develop a regulatory scheme for health claims that requires different levels of scientific evidence depending upon the nature of the claim proposed. It is not difficult to conceive of circumstances where the Agency requires “significant scientific agreement” for treatment claims based upon specific public health concerns. The validity of the FDCA’s regulatory scheme for drug products which is based upon clearly articulated concerns such as these has been repeatedly upheld, even in criminal prosecutions. See, United States v. Park 421 U.S. 658 (1975). In Pearson, the fatal flaw in FDA’s position was that it could not articulate any such concerns in connection with the proposed claims.

Moreover, Traco believes that the Agency may be able to articulate a rationale for prohibiting certain types of health claims altogether. With proper deliberation, and explanation of its actions allowing for public comment and participation in the rule making process, FDA may be able to delineate a dividing line similar to that applicable to drugs that are available over-the-counter and those that are available by prescription only. Traco notes that in such a process the Agency should once again consider the viability of the use of disclaimers and/or consumer notices suggesting that a consultation with a physician may be appropriate, such as those used in conjunction with the OTC marketing of products indicated for use in the treatment of yeast infections.

2. Will permitting such health claims damage the market for OTC drugs?

Traco submits that the answer to this question is utterly irrelevant and has no place in FDA’s determination of whether to allow health claims concerning the treatment or mitigation of

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a disease or health related conditions. Were the Agency to rely on such a concern in rejecting any proposed claim, Traco believes that the action would be without legal justification.

3. Can a disclaimer be crafted that will allow consumers to distinguish between drug products that have satisfied FDA's review and approval process and dietary supplements bearing health claims, and address any health concerns that may arise from such confusion?

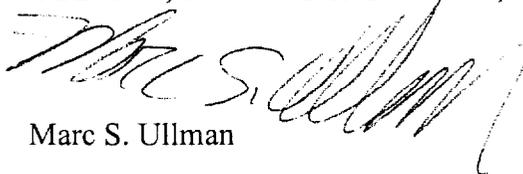
The answer to this question is absolutely yes. Such a disclaimer could read:

“THIS PRODUCT HAS NOT UNDERGONE THE FDA DRUG APPROVAL PROCESS. YOU MAY WISH TO CONSULT WITH YOUR PHYSICIAN.”

Conclusion

Traco believes that the time for FDA to “consider” issues relating to the implementation of the Pearson decision has long since past. Rather, it is time for the Agency to obey the mandate of the Court, and implement a health claims process which allows for the free flow of truthful and nonmisleading information concerning the important health benefits of dietary supplements to consumers. Only when the Agency has taken such action will it finally be acting in accordance with the will of Congress and the requirements of the First Amendment.

Respectfully submitted,
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