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EXPRESS MAIL
RETURN RECEIPT REQUESTED

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Drive, Room 1-23
Rockville, MD 20857

COMMENTS AND OBJECTIONS TO THE ADVANCE NOTICE OF PROPOSED RULEMAKING CONCERNING CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY SUPPLEMENTS

Re: Docket No. 96N-0417

SUBMITTED ON BEHALF OF TRACO LABS, INC.

Dear Sir or Madam:

This initial comment is submitted on behalf of Traco Labs, Inc., a marketer of dietary supplements and a supplier of dietary supplement ingredients.[1]

Traco Labs is compelled to express its immediate concern that FDA appears to be attempting to use the authority granted by the Dietary Supplement Health and Education Act of 1994 ("DSHEA") to promulgate good manufacturing practice ("GMP") regulations for dietary supplements as a means to circumvent case law and statutory authority by raising unfounded strawman safety concern as an impediment to the sale of dietary supplements.

In the Advance Notice, FDA states that, "many dietary ingredients have little history of use in food in the United

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[1] Traco Labs reserves the right and expects to submit additional comments and objections at a later date.

States or of use in amounts that would be used in a dietary supplement." 62 Fed. Reg. 5708. Therefore, according to FDA, because dietary ingredients are excepted from the food additive definition, "it may be appropriate to provide that CGMP requires that a manufacturer critically evaluate the available scientific information on the safety of the dietary ingredients that it intends to use in its products to assure itself that those products will be safe." Id.

Traco does not disagree that all companies have an obligation, in the first instance, to ensure that all products which they sell are safe for their intended use and contain safe ingredients. Certainly, in terms of new and unfamiliar ingredients a full scientific review may be appropriate. It was, no doubt, for this reason that Congress included Section 8 in DSHEA, which addresses "new dietary ingredients" requiring FDA pre-approval for dietary ingredients that were not marketed in the United States before October 15, 1994. 21 U.S.C. §350b (§413 of the Act). However, FDA's statements are not limited to such "new dietary ingredients."

Moreover, FDA is requesting comments on whether good manufacturing practices for dietary supplements should require that manufacturers "critically evaluate" all "available scientific safety information" and whether to require that such an evaluation be adequately documented in a firm's records. 62 Fed. Reg. 5708. Requiring such files would allow FDA to fully circumvent the agency's burden of proof as discussed by the United States Court of Appeals for the Seventh Circuit and codified in DSHEA. During an inspection, FDA could merely review the files and pronounce them inadequate. Rather, then FDA bearing the burden in Court a company could find itself in the unenviable position of defending its files that its pre-market evaluation was sufficient.

In United States v. Two Plastic Drums (Traco Labs), 984 F.2d 814 (7th Cir. 1993), a Federal Court of Appeals rejected FDA's argument that black currant oil, an ingredient in dietary supplements, was a "food additive". Rather, the Court found that black currant oil in a dietary supplement was a "food". FDA's purpose was to shift its burden of proof on to the manufacturer. As stated by Circuit Judge Cudahy:

> The determination of whether a substance is a food additive is critical in establishing the safety of the substance because, if the substance is deemed a food additive, it is presumed to be unsafe, and the processor has

> the burden of showing that the substance is GRAS. On the other hand, if a substance is not a food additive, but food in the generic sense, then the substance is presumed safe and the FDA has the burden of showing that the substance is injurious to health.

Id. at 816 (citation and footnote omitted) (emphasis added).

Thus, the Seventh Circuit held:

> Because the FDA has not shown that BCO is adulterated or unsafe in any way, there is no basis to condemn the two drums at issue. If BCO is injurious to health, the statute requires the FDA to prove as much.

Id. at 820.

Congress followed the reasoning of the Seventh Circuit opinion when it enacted DSHEA. Under DSHEA, dietary supplement ingredients were explicitly excluded from the food additive definition. 21 U.S.C. §321(s)(6) (§201(s)(6) of the Act). DSHEA further provides that in any determination of the safety of a dietary supplement, "the United States shall bear the burden of proof on each element to show that a dietary supplement is adulterated, 21 U.S.C. §342(f)(2) (§402(f)(s) of the Act), and that if good manufacturing practice regulations for dietary supplements are promulgated, they should be modelled after current GMPs applicable for food products. 21 U.S.C. §342(g) (§402(g) of the Act). The authority to promulgate good manufacturing practice regulations applicable to dietary supplements should not be used as a ruse by the agency to shift its own obligation to meet legal and statutory burdens of proof, particularly when there is no evidence that a particular dietary substance or ingredient is not safe.

Very truly yours,

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