

# ULLMAN, SHAPIRO & ULLMAN, LLP

COUNSELORS AT LAW

299 BROADWAY, SUITE 1700  
NEW YORK, NY 10007  
TEL. (212) 571-0068  
FAX. (212) 571-9424  
USU@USULAW.COM

ROBERT ULLMAN  
STEVEN SHAPIRO\*  
MARC S. ULLMAN

ELIZABETH S.  
GIOIOSA DILLABOUGH †

OF COUNSEL:  
MILTON A. BASS  
IRVING L. WIESEN

\* ADMITTED IN N.Y. & N.J.  
† ADMITTED IN D.C., MA., &  
ONTARIO, CANADA ONLY

TRADEMARK COUNSEL:  
DENNIS H. CAVANAUGH  
274 MADISON AVE.  
SUITE 300  
NEW YORK, NY 10016

WASHINGTON AFFILIATE  
James M. Johnstone  
1776 K STREET, N.W. - THIRD FL.  
WASHINGTON, D.C. 20006

LONDON AFFILIATES  
Wedlake Bell  
16 BEDFORD STREET  
COVENT GARDEN  
LONDON WC2E 9HF  
ENGLAND

E.U. CORRESPONDENT  
Lafli, Van Crombrughe  
& Partners  
VOSSENDREEF 6 BUS 1  
B-1180 BRUSSELS,  
BELGIUM

August 20, 1999

Certified Mail - Return Receipt Requested

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

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

**Docket No. 99N-1174**

**Submitted On Behalf of Ullman, Shapiro & Ullman, LLP  
Traco Labs, Inc.; Naturade Products, Inc.;  
and Nutramedix, Inc**

---

Dear Sir/Madame:

These comments are submitted on behalf of:

1. Ullman, Shapiro & Ullman, LLP, attorneys at law whose practice specializes in the representation of clients in the natural products industry;
2. Traco Labs, Inc., a manufacturer and supplier of dietary supplements providing numerous health benefits based in Champaign, Illinois;
3. Naturade Products, Inc., a distributor and marketer of dietary supplements based in Irvine, California; and
4. Nutramedix, Inc., a distributor and marketer of dietary supplements, based in Tequesta, Florida.

99N-1174

C56

# ULLMAN, SHAPIRO & ULLMAN, LLP

Dockets Management Branch (HFA-305)  
Food and Drug Administration  
August 20, 1999  
Page 2

On August 4, 1999, members of Ullman, Shapiro & Ullman, LLP ("USU") appeared at the Food and Drug Administration's ("FDA") public meeting on structure/function claims. Presenting comments on behalf of the firm and Traco Labs, the USU attorneys argued that FDA's proposal to change the definition of the term "disease or health related condition" from:

"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"

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 . . ."

represented a vast, unauthorized, ill-advised, expansion of the terms coverage. Moreover, these comments, in essence, argued that the proposed change was arbitrary and capricious, and contrary to law and the Congressional intent behind the enactment of the Dietary Supplement Health and Education Act, and should be abandoned.

During the course of the public meeting, a representative of the Consumer Healthcare Products Association ("CHPA") set forth an alternative to FDA's proposed redefinition:

- "a disease is any adverse deviation from, or impairment of, or interruption of the normal structure or function of any part, organ, or system (or combination thereof) of the body that is manifested by one or more signs or symptoms that are not characteristic of a natural state or process."
- "a natural state or process is a life change or physiologic manifestation expected in the normal course of life progression."

We respectfully submit, in the event that FDA determines that, despite the numerous comments urging that no such action is necessary or appropriate, it is necessary to adopt a new definition of disease, that the definition proffered by CHPA should be adopted in lieu of FDA's proposed definition.

The CHPA proposal is superior to FDA's in two important respects. First, the exclusionary phrase "that are not characteristic of a natural state or process" makes it clear that the definition of disease does not include normal, expected consequences of the human life cycle. Such consequences, such as hot flashes associated with menopause or reduced sexual function associated with aging, were clearly intended by Congress to be appropriate subjects for structure/function claims, and should not be considered disease states.

ULLMAN, SHAPIRO & ULLMAN, LLP

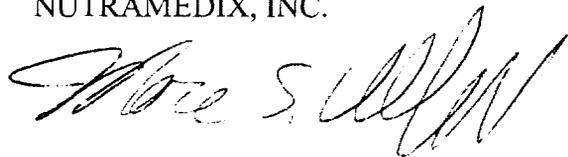
Dockets Management Branch (HFA-305)  
Food and Drug Administration  
August 20, 1999  
Page 3

Second, the qualification of the term "normal" by the phrase "adverse deviation" further establishes that expected life consequences are not considered "disease" states. Thus, conditions such as arthritis or toxemia of pregnancy would be included within the definition of disease, but pregnancy would not.

It is respectfully submitted that the new definition of disease proffered by CHPA would provide a superior regulatory framework than the revised definition proffered by FDA in its April 29, 1998 proposal. As noted in the comments submitted in connection with the August 4<sup>th</sup> public meeting by USU and Traco, FDA's proposal leaves open the possibility that a wide range of claims associated with expected events in the life process could be barred based upon the Agency's arbitrary interpretation of the term "normal". Thus, we asked "Normal for who? You, me, a twenty year old decathlete, or a sixty-five year old post-menopausal retiree?" This significant issue is not present in the CHPA proposal, which expressly accounts for the changing parameters of what is considered normal at different times throughout the life process.

While the present definition of disease, which was operative at the time Congress enacted DSHEA, provides an adequate regulatory framework, we believe that many of the concerns expressed by FDA in its April 29, 1999 proposal about the adequacy of that definition, and the dietary supplement industry's concerns with FDA's proffered new definition in that proposal, are addressed by the CHPA proposal. In the event that the Agency determines that it is necessary to promulgate a new definition of disease, we urge that it adopt the definition proffered by CHPA.

Respectfully submitted,  
ULLMAN, SHAPIRO & ULLMAN, LLP  
TRACO LABS, INC.  
NATURADE PRODUCTS, INC.  
NUTRAMEDIX, INC.



Marc S. Ullman

CERTIFIED  
Z 025 634 422

MAIL

★ ★ ★ UNITED STATES POSTAGE  
196 PB9670854  
7040 5 03.420 AUG 20 99  
4278 MAILED FROM ZIP CODE 10007

**ULLMAN, SHAPIRO & ULLMAN, LLP**

COUNSELORS AT LAW  
299 BROADWAY, SUITE 1700  
NEW YORK, NY 10007

**To:**

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