BASS & ULLMAN, P.C.
COUNSELORS AT LAW
747 THIRD AVENUE
NEW YORK, N.Y. 10017
(212) 751-9494
TELECOPIER (212) 758-5686

MILTON A. BASS
ROBERT ULLMAN
JACOB LAUFER
JOHN M. DESIDERIO

STEVEN SHAPIRO*
GAIL R. FRIEDBERG*

MARC S. ULLMAN
OF COUNSEL

* ADMITTED IN N.Y. & N.J.

LONDON ASSOCIATES
WEDLAKE BELL
16 BEDFORD STREET
COVENT GARDEN
LONDON WC2E 9HF
ENGLAND

WASHINGTON ASSOCIATES
FENSTERWALD & ALCORN
TYSONS CORNER
1952 GALLOWS ROAD
VIENNA, VIRGINIA 22182

June 5, 1997

EXPRESS MAIL
RETURN RECEIPT REQUESTED

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

97 JUN -9 AM 11:21 96N-0417

CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY SUPPLEMENTS; ADVANCE NOTICE OF PROPOSED RULEMAKING

Docket No. 96N-0417

Comments submitted on behalf of the NUTRITIONAL HEALTH ALLIANCE

Dear Sir/Madam:

This letter concerns the Advance Notice of Proposed Rulemaking for Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements ("the ANPR") and is submitted on behalf of the Nutritional Health Alliance ("NHA"). The NHA is a not-for-profit educational and advocacy association of consumers, health professionals, natural product retailers, and natural product manufacturers. NHA members include companies which manufacture, package, label, and market dietary supplements.

NHA appreciates the FDA having provided a 30 day extension of the comment period on the ANPR. Unfortunately, due to various time constraints, the members of the Association have not been able to complete their deliberations at this time. Thus, the NHA members are still reviewing and discussing the various provisions of the proposal and concerns raised about the questions posed by the agency. It is our hope that NHA will be able to submit comments to the agency addressing the ANPR within the next 60 days.

96N-0417 C65

Among the concerns to be addressed, in addition to the specific manufacturing procedures being proposed, are: the extent to which additional burdens are cast upon foods which are classified as dietary supplements in contrast to the requirements imposed on the manufacturing and processing of foods generally; a disdain for any attempt to undermine both judicial determinations and the determination of Congress in DSHEA that dietary supplements shall not be treated as food additives; the shifting to the dietary supplement industry of burdens of proof which Congress has placed upon the Agency; the application of FDA's HACCP approach to dietary supplements; and the imposition of mandatory reporting and third party evaluation requirements for all consumer complaints -- a requirement that exceeds GMP requirements for other products, particularly foods.

GMPs can serve a very useful purpose for the dietary supplement industry, but they can also be used to create undue hardship and problems. NHA believes that a correct balance must be created for the good of the public and the industry and looks forward to providing FDA with comments on this issue.

Respectfully submitted,

BASS & ULLMAN, P.C.

By: _____

Milton A. Bass
Robert Ullman
Steven Shapiro
747 Third Avenue
New York, NY 10017
(212) 751-9494

Counsel for the
NUTRITIONAL HEALTH ALLIANCE