BASS & ULLMAN, P.C.
COUNSELORS AT LAW
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

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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

REQUEST FOR AN EXTENSION OF THE COMMENT PERIOD -- DOCKET NO. 96N-0417

CURRENT GOOD MANUFACTURING PRACTICE IN MANUFACTURING, PACKING, OR HOLDING DIETARY SUPPLEMENTS

Submitted on behalf of the NUTRITIONAL HEALTH ALLIANCE

Dear Sir/Madam:

This request for an extension of the comment period is submitted on behalf of the Nutritional Health Alliance ("NHA").[1]

In the February 6, 1997 Federal Register, FDA published an Advance Notice of Proposed Rulemaking Concerning Current Good Manufacturing Practice ("CGMPs") in Manufacturing, Packing, or Holding Dietary Supplements ("the ANPR"). The purpose of this publication was to solicit comments from interested parties regarding their views on whether FDA should actually commence promulgation of CGMPs and if so, what form they should take.

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[1] 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, market, label, and sell natural food products and dietary supplements.

This is obviously an issue of great importance to every company in the dietary supplement industry. As stated in the ANPR, the document outlining suggested CGMPs was presented to the agency by a number of industry representatives at a meeting held on November 30, 1995. Unfortunately, the NHA was not a party to that meeting, nor did it have an opportunity to participate in the drafting of the outline document contained in the ANPR.

NHA as been working with its membership across the country collecting input and comments to be presented to the agency. NHA and this firm have been and are continuing to receive questions, comments, and suggestions from the membership. Many NHA members, including a number of major dietary supplement manufacturers, did not have an opportunity to participate in the drafting of the outline document prior to its presentation to FDA and have only just had the opportunity to review it with the publication of the ANPR.

The deadline for the submission of comments to the agency is currently May 7, 1997. At this point in time, we do not believe it likely that the NHA will be able to present its response by that deadline. According to the ANPR, the agency has been in possession of the outline for almost a year-and-a-half. NHA respectfully requests that the agency extend the comment period for 90 days in order to permit the NHA to have an adequate opportunity to fully address all of the issues with its membership and to then respond fully to all of the concerns raised by the agency.

Thank you for your courtesies in this matter.

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