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Marjorie L. Fine
Vice President
and General Counsel
Shaklee U.S. and
Shaklee Technica

June 3, 1997

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Via Federal Express

Dockets Management Branch (HFA-305)
U.S. Food & Drug Administration
12420 Parklawn Drive - Room 1-23
Rockville, Maryland 20857

Re: Docket No. 96N-0417
Current Good Manufacturing Practice in Manufacturing, Packing,
or Holding Dietary Supplements

Gentlemen:

These comments on the FDA's Advance Notice of Proposed Rulemaking (ANPR) regarding good manufacturing practices for dietary supplements (GMPs) are submitted by Shaklee Corporation, which manufactures and distributes vitamin and mineral, herbal, soy protein and fiber dietary supplements. Shaklee is a member of the Council for Responsible Nutrition (CRN) and participated in the Industry Quality Standards Working Group that developed the GMPs submitted to FDA which were published as the ANPR earlier this year. Shaklee also participated in developing the comments submitted by CRN on behalf of the industry. Shaklee agrees with and endorses CRN's comments.

In particular, Shaklee wishes to express, along with CRN, concern that a number of the questions posed by FDA address issues which go beyond the scope of GMPs. Shaklee is strongly opposed to any effort to circumvent the intent of the Dietary Supplement Health & Education Act (DSHEA) by imposing a requirement for mandatory proof of safety or a system of post-market surveillance for dietary supplement ingredients. Any such requirement would go well beyond GMPs "modeled after" food GMPs as required by DSHEA.

Shaklee is committed to assuring the safety of all dietary supplements it markets and would welcome industry-wide discussion on the various alternatives for accomplishing this objective. However, such discussion does not belong in the context of establishing GMPs for dietary supplements.

96N-0417

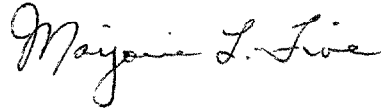
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Shaklee looks forward to working with FDA as it continues to dialog with the industry on the issues raised in the ANPR.

Sincerely,

A handwritten signature in cursive script that reads "Marjorie L. Fine".

Marjorie L. Fine

MLF/dkp

cc: Council for Responsible Nutrition