



Council for Responsible Nutrition

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July 8, 2003

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

**RE: DOCKET NO. 96N-0417, GOOD MANUFACTURING PRACTICES
FOR DIETARY SUPPLEMENTS**

The Council for Responsible Nutrition (CRN) is one of the leading trade associations representing the dietary supplement industry. CRN has been a strong supporter of Good Manufacturing Practices (GMPs) over the years, and we have an active Regulatory Affairs Committee composed of industry experts in dietary supplement regulation and in the technical aspects of production processes, including GMPs. CRN's member company experts in this arena drafted the guidelines for nutritional supplement manufacturing practices adopted by USP over a decade ago and also prepared the industry draft GMPs submitted to FDA in November 1995 by CRN, joined by other industry trade associations. FDA published the industry draft verbatim as the ANPR on dietary supplement GMPs in 1997.

**SUBMISSION OF FOUR-WAY COMPARISON
OF THE CURRENT PROPOSAL, THE ANPR,
THE FOOD GMP, AND THE DRUG GMP**

During the next month, CRN will be submitting a wave of comments on the FDA proposed CGMPs for dietary supplements, addressing several major topics in a series of separate documents. At this time, we are submitting a comprehensive 4-way comparison of the existing food and drug GMPs, the industry draft published in 1997 as the ANPR, and the current FDA proposed rule. This submission is relevant to the question of whether the proposal is sufficiently "modeled after" food GMP regulations. (NOTICE: For those wishing to print this comment, please note that it is 103 pages in length.)

CRN fully accepts the fact that, when Congress enacted the provision of the Dietary Supplement Health and Education Act authorizing FDA to adopt dietary supplement GMPs "modeled after" food GMP regulations, Congress did not mean to require that the new GMPs be identical to the food GMPs. If this were the case, there would have been no need for a separate regulation. Indeed, the industry draft that was published as the ANPR also departed from the food GMPs and incorporated additional procedures and

practices that CRN members and other industry representatives believed to represent CGMPs.

It is nevertheless relevant during this comment period to consider the origins of each component of the FDA proposal and to consider whether the total document is sufficiently modeled after food GMPs.

The 4-way comparison attached was prepared by the Chairman of CRN's Regulatory Affairs Committee, Paul Bolar, Vice President for Regulatory and Legal Affairs of the Pharmavite Corporation. It has proved invaluable in our consideration of the current proposal, and we are submitting it for the record to assist FDA and other parties in their analysis.

The comparison clearly identifies those portions of the rule that are virtually identical to the food GMPs and thus might actually be omitted from the document, with a cross-reference indicating that the food GMPs in 21 CFR Part 110 also apply. It also identifies some areas in which the drug GMPs or other provisions appear to have served as the model. We are currently analyzing GMPs for other food categories to identify potential models that may be useful. The comparison also illustrates the fact that some provisions included in the industry draft published as the ANPR were omitted from the current FDA proposal, including a number of provisions that would have required written procedures for key operations and that would have provided for expiration dating or other features considered essential to the marketing of today's dietary supplements. We will be giving these topics further careful consideration and will be recommending that some of them be restored to the proposal on the grounds that they are essential to a company's ability to develop and maintain a well-controlled production process or to manufacture and market products acceptable in today's business environment.

Sincerely,

A handwritten signature in black ink that reads "Annette Dickinson". The signature is written in a cursive, flowing style.

Annette Dickinson, Ph.D.
President