



Council for Responsible Nutrition

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April 4, 1997

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

RE: Docket 96N - 0417
ANPR, Current Good Manufacturing Practice for Dietary Supplements

Dear Sirs:

This is to request a 90-day extension of the comment period regarding the above-mentioned ANPR on Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Supplements.

The Council for Responsible Nutrition, a trade association of dietary supplement manufacturers, was instrumental in preparing the draft GMP's that FDA published on February 6, 1997, as an ANPR. Therefore, CRN and its member companies are thoroughly familiar with the issues surrounding GMP's for dietary supplements. However, FDA raises a number of related issues which are of fundamental importance and which require more discussion not only among CRN member companies but among the members of a number of trade associations representing different segments of the dietary supplement industry. Although numerous meetings and discussions have already taken place, we do not believe it will be possible for the industry to reach agreement on the major issues raised by FDA in time to meet the current comment date of May 7, 1997. Since we believe the process is best served when the industry can work out areas of disagreement before comments are submitted, we hereby request an extension of 90 days.

Sincerely,

A Dickinson

Annette Dickinson, Ph.D.
Director of Scientific and Regulatory Affairs

cc: Dr. Robert J. Moore, Dr. Elizabeth Yetley, Dr. Fred Shank

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