PERRIGO®

Dr. Robert J. Moore
Center for Food Safety and Applied Nutrition (HFS-456)
Food and Drug Administration 200 C St., SW
Washington, DC 20204

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

April 14, 1997

Dear Dr. Moore;

This is to request a 90-day extension of the comment period to the advance notice of proposed rulemaking for Current Good Manufacturing Practice in Manufacturing, Packing or Holding Dietary Supplements published in the *Federal Register* on February 6, 1997. The Perrigo Company is the largest private label manufacturer of health and beauty aid products in the country, including dietary supplements with a dedicated manufacturing plant in Greenville, South Carolina.

Along with the Nonprescription Drug Manufacturer's Association and the Council for Responsible Nutrition, we have been evaluating the proposal which includes industry proposed GMP's for dietary supplements. The FDA has requested comments on eight issues related to the proposed GMPs for dietary supplements. One issue in particular, the appropriateness of the principles of Hazard Analysis and Critical Control Points (HACCP) to dietary supplements, requires education of and careful consideration, by our company and the rest of the dietary supplement industry. Many companies in the industry, including the Perrigo Company, have a background in the drug industry. Therefore we are unfamiliar with the HACCP principles.

In order to best respond to FDA's request for information, it is apparent that more time is needed to fully understand HACCP and its implications to our dietary supplement business. We are currently learning about HACCP and we feel it is a worthwhile program to further evaluate. At this point we do not have enough information to make an informed decision by the May 7th deadline. We are hopeful that the agency will provide additional time to allow us to make a fully informed decision.

The FDA desires well thought out comments to the issues raised in this ANPR. An extension of time will allow the Perrigo Company and others in the industry the opportunity to better educate ourselves. This will provide the FDA with comments that have been researched and well formulated to provide the best possible information to the questions asked.

The Perrigo Company appreciates your consideration of this request.

Sincerely,

Timothy Hertzler
Regulatory Affairs

96N-0417

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