



PHARMA CHEMIE

Specialists For The Pharmaceutical Industry

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July 8, 1999

To: Center for Food Safety and Applied Nutrition (CFSAN)
From: Mark Pieloch; President of Pharma Chemie Inc. *MP*

Subject: Proposed CGMP Regulations for Dietary Supplements

I am writing to FDA in response to a letter that I received this past week regarding FDA's Center for Food Safety and Applied Nutrition's (CFSAN) interest in establishing current good manufacturing practice (CGMPs) regulations for the dietary supplement industry.

From this letter Pharma Chemie Inc. would like to make the following points known:

1. The establishment of drug CGMPs on the dietary supplement industry would have a very negative impact on the dietary supplement industry. The cost of administering drug CGMPs would be cost prohibitive, since dietary supplements sell for a fraction of the price of drug products. By implementing drug CGMPs on the dietary supplement industry, the cost of nutritional/dietary supplements would increase significantly to the consumer within the United States of America. The higher cost of implementing industry compliance with drug CGMP regulations would cause higher consumer product prices, which would result in less of these products being available to the bulk of consumers within this country.
2. Dietary supplements are in fact sold more often as nutritional or food supplements, rather than as drug products. Thus, dietary supplements would be best regulated under food CGMPs. The use of food CGMPs would be best for the industry and the consumer. The cost of all dietary supplement manufacturers to implement food CGMPs would be minimal, thus dietary supplement product prices should not rise significantly to the consumer. The use of food CGMPs would provide the dietary supplement industry with regulations that would address consumer product safety issues, while maintaining an industry environment beneficial to the consumer from a product pricing perspective.
3. The implementation of food CGMPs would have a minimal impact on small business entities, such as Pharma Chemie Inc. We currently already produce all of our dietary supplements following at a minimum food CGMPs and would have no compliance issues with all dietary supplement manufacturers following food CGMPs.

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Please consider this letter as a response to CFSAN's request for comments on the issue of CGMPs for the dietary supplement industry. I will be unable to attend FDA's July 12, 1999 public meeting in Las Vegas due to previous commitments and the short leadtime of notification of this meeting.

Mark Pielak