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April 25, 2003

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

RE: DOCKET NO. 96N-0417
*Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Dietary Ingredients and Dietary Supplements*

Dear Administrator:

Kos Pharmaceuticals, Inc. is submitting written comments in response to the request published in the March 13, 2003, edition of the Federal Register that proposes current good manufacturing practice (CGMP) regulations for dietary ingredients and dietary supplements. Kos wishes to provide its conditional support to these regulations as discussed herein. Kos commends the Food and Drug Administration for proposing a rule that will provide greater protection of public health.

Should you have any questions concerning the enclosed comments, please do not hesitate to contact me directly at (305) 512-7007. Thank you for the opportunity to respond to this Proposed Rule.

Yours very truly,

Marvin F. Blanford, PharmD
Vice President, Compliance

Cc: Dr. Mark B. McClellan, Commissioner
Dr. Robert Temple, Director, Office of Medical Policy
Mr. Daniel Troy, Chief Counsel
Mr. John Taylor, Associate Commissioner of Regulatory Affairs

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