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December 23, 2002

Dockets Management Branch Food and Drug Administration Fishers Lane Rockville, Maryland 20857

FDA's proposed Amendments to 21 C.F.R. Part 314 Re:

Dear Madam/Sir,

Kos Pharmaceuticals, Inc. submitted the enclosed comments to the FDA's proposed amendments to 21 C.F.R. Part 314 electronically and is following up with the enclosed hardcopy. Should you have any questions, please contact me at (305) 523-3643.

Sincerely,

Kos Pharmaceuticals, Inc.

She h Karen Messick



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