

November 30, 2004

Division of Dockets Management
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

Re: Docket No. 2004D-0443

Dear Sir or Madam:

Provided herewith are two (2) copies of Alcon's comments regarding FDA's Draft Guidance on "Quality Systems Approach to Pharmaceutical Current Good Manufacturing Practice Regulations".

If you have any questions regarding these comments, please contact me via e-mail at garry.heidel@alconlabs.com or via telephone at (817) 551-6813.

Sincerely,

Garry G. Heidel
Associate Director
Regulatory Compliance
Alcon Research, Ltd.

Attachment