

Alcon Inc.
Comments Submitted on Docket No. 2004D-0443
Draft Guidance on Quality System Approach to Pharmaceutical
Current Good Manufacturing Practice Regulations

Page 13 (line 474) - Further definition of "continued training" would be helpful. Interpretation of the term "continued training" could lead one to understand that training on every procedure every month / year (?) would be a requirement. In conjunction with this statement, Line 489 - 490 notes "It is important that supervisory managers ensure that skills gained from training be incorporated into day-to-day performance." This might lead one to understand that daily audits on training effectiveness / job performance would be required.

Page 15 (line 577) "Distinct labels with discriminating features for different products,marketed with different strengths, should be included to prevent mislabeling and" The Falcon products within a product line or type (i.e. Levobunolol, Timolol Maleate, Betaxolol HCL) are not distinctively different. See below.

On page 18 (line 677) the statement "Process steps should be verified using a validated computer system or a second person." piqued our interest. For example, It would appear that for some processing steps (compounding validated recipes, etc.) we could eliminate the second signature.

END