

Comments from Eli Lilly and Company
Docket: 2004N-0133 - Part 11 Public Meeting

Docket Reference: IV. B Part 11 Subpart B – Electronic Records 1.

Eli Lilly and Company recommends that all areas of part 11 should incorporate the concept of a risk-based approach, rather than limiting the scope to the areas specifically mentioned in the Part 11 Final Guidance document.

Docket Reference: IV. D. Additional Questions for Comment 2.

Eli Lilly and Company requests that FDA clarify which records are required by predicate rules where those records are not specifically identified in predicate rules but are nevertheless required by FDA.

Eli Lilly and Company further recommends that FDA allow companies to identify and evaluate any additional records that may or may not be required depending upon the context, using a risk assessment.

Docket Reference: IV. D. Additional Questions for Comment 5.

Eli Lilly and Company recommends that FDA not prescribe a specific risk management approach and tool kit, but allow organizations the flexibility to determine the appropriate risk management approach and tool kit for their organization.