Attached are the following documents or web addresses for documents to support our position on collecting information under the Pharmaceutical Development Study.

(1) Janets Woodcock's (deputy commissioner of the fda) presentation at FDA Science Board

01-11-16 jw.ppt
(49 KB)

(2) Critical Path Initiative http://www.fda.gov/oc/initiatives/criticalpath/

(3)Report from Pharmaceutical CGMP for the 21st Century Initiative
http://www.fda.gov/cder/gmp/gmp2004/GMP_finalreport2004.htm

(4) Presentations on quality by design

60921-ACPS-QbD
Nasr.ppt (190 ...

uqbd.ppt (524 KB

kqbd.ppt (506 KB

5) Federal Register Notice on CMC Pilot for QbD for new drugs

Federal
egister.doc (46 KE

(6) CTD guidance http://www.fda.gov/cder/guidance/4539Q.htm

(7) Guidance on process analytical technologies http://www.fda.gov/cder/guidance/6419fnl.htm