

FDA
Center for Drug Evaluation and Research
(CDER)

Recalls – Top Ten Reasons in Fiscal Year 2005
(Oct 04 – Sept 05)

No. of Recalls	Reason
144	cGMP deviations
55	Failed USP dissolution test requirements
30	Microbial contamination of non-sterile products
25	Lack of efficacy
24	Labeling error
18	Impurities/degradation
17	Lack of assurance of sterility
16	Product lacks stability
13	Misbranded – promotion literature with unapproved claims
12	Subpotent

Presented by Kristen Evans
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CDER Guidance and Policy Team
Division of Manufacturing and Product Quality

October 24, 2005 at IVT Validation Week Annual Conference