

Standard Costs for Components of the Process for the Review of Human Drug Applications ¹ (\$000)

Revised to Incorporate FY 2007 Standard Costs

Estimates Made Pursuant to Section 736(d)(2) of the Federal Food, Drug, and Cosmetic Act

Submission Type	<i>All determined on the basis of the Arthur Andersen model developed in 1993</i>								<i>KPMG Model</i>		<i>From Time Rpt.</i>				
	FY93	FY94	FY95	FY96	FY97	FY 98	FY99	FY 00	FY 01	FY 02	FY 03	FY 04	FY 05	FY 06	FY 07
Drug Applications															
IND	\$70	\$79	\$98	\$97	\$84	\$94	\$105	\$119	\$200	\$212	\$299	\$203	\$240	\$250	\$285
NDA with Clinical Data - NME	\$887	\$1,004	\$1,243	\$1,233	\$1,065	\$1,194	\$1,328	\$1,503	\$1,920	\$2,037	\$2,116	\$1,987	\$2,456	\$2,986	\$2,251
NDA with Clinical Data - Non-NME	\$298	\$337	\$417	\$414	\$358	\$401	\$446	\$505	\$929	\$986	\$746	\$760	\$685	\$777	\$805
NDA without Clinical Data	\$127	\$144	\$178	\$177	\$152	\$171	\$190	\$215	\$261	\$277	\$561	\$411	\$476	\$481	\$240
Supplement with Clinical Data	\$151	\$171	\$212	\$210	\$181	\$203	\$226	\$256	\$111	\$118	\$175	\$142	\$255	\$224	\$248
Supplement without Clinical Data	\$6	\$7	\$8	\$8	\$7	\$8	\$9	\$10	\$8	\$8	\$18	\$17	\$17	\$23	\$19
Biologic Applications															
IND	\$184	\$230	\$234	\$266	\$204	\$173	\$243	\$175	\$287	\$279	\$361	\$400	\$437	\$394	\$427
BLA						\$1,118	\$1,568	\$1,128	\$2,788	\$2,708	\$4,394	\$4,075	\$4,492	\$2,626	\$3,142
PLA	\$1,078	\$1,345	\$1,369	\$1,560	\$1,194	\$1,016	\$1,426	\$1,026							
ELA	\$177	\$221	\$225	\$256	\$196	\$167	\$234	\$168							
Supplement with Clinical Data	\$561	\$700	\$713	\$812	\$622	\$529	\$742	\$534	\$195	\$190	\$228	\$367	\$239	\$265	\$627
Supplement without Clinical Data	\$34	\$42	\$43	\$49	\$38	\$32	\$45	\$32	\$31	\$30	\$21	\$41	\$42	\$40	\$53

¹ Standard costs include all costs associated with application review, including rent, overhead, and centrally funded costs. Method revised in FY 2001-2002 based on KPMG study, and in 2003 on time reporting data. Time reporting method revised with better allocation of indirect cost beginning in 2004.