

**Standard Costs for Components of the Process for the Review of Human Drug Applications<sup>1</sup> (\$000)**

**Revised to Incorporate FY 2011 Standard Costs**

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

Submission Type	All determined on the basis of the Arthur Anderson model developed in 1993								KPMG Model		From Time Rpt									
	FY93	FY94	FY95	FY96	FY97	FY98	FY99	FY00	FY01	FY02	FY03	FY04	FY05	FY06	FY07	FY08	FY09	FY10	FY11	
<b>Drug Applications</b>																				
IND	\$70	\$79	\$98	\$97	\$84	\$94	\$105	\$119	\$200	\$211.8	\$299	\$203.3	\$240	\$249.6	\$284.7	\$236.5	\$290.9	\$362.1	\$423.3	
NDA with Clinical Data - NME	\$887	\$1,004	\$1,243	\$1,233	\$1,065	\$1,194	\$1,328	\$1,503	\$1,920	\$2,037.0	\$2,116	\$1,987.1	\$2,456.3	\$2,986.2	\$2,250.9	\$3,736.4	\$4,021.0	\$4,316.6	\$5,091.6	
NDA with Clinical Data - Non-NME	\$298	\$337	\$417	\$414	\$358	\$401	\$446	\$505	\$929	\$985.9	\$746	\$760.1	\$684.6	\$777.1	\$804.9	\$1,320.9	\$1,313.1	\$1,863.6	\$2,368.5	
NDA without Clinical Data	\$127	\$144	\$178	\$177	\$152	\$171	\$190	\$215	\$261	\$276.6	\$561	\$411.5	\$476.5	\$481	\$239.6	\$288.7	\$398.4	\$502.1	\$917.1	
Supplement with Clinical Data	\$151	\$171	\$212	\$210	\$181	\$203	\$226	\$256	\$111	\$118.1	\$175	\$142.2	\$255.4	\$224.4	\$247.8	\$364.0	\$555.9	\$615.7	\$693.7	
Supplement without Clinical Data	\$6	\$7	\$8	\$8	\$7	\$8	\$9	\$10	\$8	\$8.1	\$18	\$16.7	\$16.5	\$22.7	\$19.4	\$13.8	\$28.7	\$31.4	\$17.8	

**Biologic Applications**

IND	\$184	\$230	\$234	\$266	\$204	\$173	\$243	\$175	\$287	\$278.9	\$361	\$400.4	\$437.1	\$393.9	\$427.5	\$802.8	\$860.4	\$791.9	\$1,000.8
BLA						\$1,118	\$1,568	\$1,128	\$2,788	\$2,708.2	\$4,394	\$4,074.7	\$4,492.2	\$2,626.2	\$3,141.6	\$2,726.7	\$3,529.6	\$6,081.5	\$11,203.5
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	\$189.6	\$228	\$367.4	\$239.4	\$265.2	\$627.1	\$511.5	\$681.8	\$655.4	\$661.3
Supplement without Clinical Data	\$34	\$42	\$43	\$49	\$38	\$32	\$45	\$32	\$31	\$29.8	\$21	\$41	\$41.9	\$40.2	\$53	\$49.4	\$68.3	\$72.8	\$83.8

<sup>1</sup> 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 costs beginning in 2004.