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

	All determined on the basis of the Arthur Andersen model developed in 1993								KPMG	Model	From Time Rpt.				
Submission Type	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

\$184	\$230	\$234	\$266	\$204	\$173	\$243	\$175	\$287	\$279	\$361	\$400	\$437	\$394	\$427
					\$1,118	\$1,568	\$1,128	\$2,788	\$2,708	\$4,394	\$4,075	\$4,492	\$2,626	\$3,142
\$1,078	\$1,345	\$1,369	\$1,560	\$1,194	\$1,016	\$1,426	\$1,026							
\$177	\$221	\$225	\$256	\$196	\$167	\$234	\$168							
\$561	\$700	\$713	\$812	\$622	\$529	\$742	\$534	\$195	\$190	\$228	\$367	\$239	\$265	\$627
\$34	\$42	\$43	\$49	\$38	\$32	\$45	\$32	\$31	\$30	\$21	\$41	\$42	\$40	\$53
	\$1,078 \$177 \$561	\$1,078 \$1,345 \$177 \$221 \$561 \$700	\$1,078 \$1,345 \$1,369 \$177 \$221 \$225 \$561 \$700 \$713	\$1,078 \$1,345 \$1,369 \$1,560 \$177 \$221 \$225 \$256 \$561 \$700 \$713 \$812	\$1,078 \$1,345 \$1,369 \$1,560 \$1,194 \$177 \$221 \$225 \$256 \$196 \$561 \$700 \$713 \$812 \$622	\$1,345 \$1,369 \$1,560 \$1,194 \$1,016 \$177 \$221 \$225 \$256 \$196 \$167 \$561 \$700 \$713 \$812 \$622 \$529	\$1,345 \$1,369 \$1,560 \$1,118 \$1,568 \$177 \$221 \$225 \$256 \$196 \$167 \$234 \$561 \$700 \$713 \$812 \$622 \$529 \$742	\$1,345 \$1,369 \$1,194 \$1,016 \$1,426 \$1,026 \$177 \$221 \$225 \$256 \$196 \$167 \$234 \$168 \$561 \$700 \$713 \$812 \$622 \$529 \$742 \$534	\$1,078 \$1,345 \$1,560 \$1,194 \$1,016 \$1,426 \$1,026 \$177 \$221 \$225 \$256 \$196 \$167 \$234 \$168 \$561 \$700 \$713 \$812 \$622 \$529 \$742 \$534 \$195	\$1,345 \$1,369 \$1,560 \$1,118 \$1,568 \$1,128 \$2,788 \$2,708 \$1,078 \$1,345 \$1,369 \$1,560 \$1,194 \$1,016 \$1,426 \$1,026 \$177 \$221 \$225 \$256 \$196 \$167 \$234 \$168 \$561 \$700 \$713 \$812 \$622 \$529 \$742 \$534 \$195 \$190	\$1,345 \$1,369 \$1,560 \$1,118 \$1,568 \$1,128 \$2,788 \$2,708 \$4,394 \$1,078 \$1,345 \$1,369 \$1,560 \$1,194 \$1,016 \$1,426 \$1,026 \$1 \$177 \$221 \$225 \$256 \$196 \$167 \$234 \$168 \$195 \$190 \$228 \$561 \$700 \$713 \$812 \$622 \$529 \$742 \$534 \$195 \$190 \$228	\$1,078 \$1,345 \$1,560 \$1,118 \$1,568 \$1,128 \$2,788 \$2,708 \$4,394 \$4,075 \$1,078 \$1,345 \$1,369 \$1,560 \$1,194 \$1,016 \$1,426 \$1,026 \$1	1.078 \$1,345 \$1,369 \$1,560 \$1,118 \$1,568 \$1,128 \$2,788 \$2,708 \$4,394 \$4,075 \$4,492 \$1,078 \$1,345 \$1,369 \$1,560 \$1,194 \$1,016 \$1,426 \$1,026 Image: Constraint of the state	1.078 \$1,345 \$1,369 \$1,560 \$1,118 \$1,426 \$1,026 \$177 \$221 \$225 \$256 \$196 \$167 \$234 \$168 \$195 \$190 \$228 \$367 \$239 \$265

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.