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

Revised to Incorporate FY 2006 Standard Costs

Estimates Made Pursuant to Section 736(d)(2) of the 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**
Drug Applications														
IND	$70	$79	$98	$97	$84	$94	$105	$119	$200	$212	$299	$203	$240	$250
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
NDA with Clinical Data - Non-NME	$298	$337	$417	$414	$358	$401	$446	$505	$929	$986	$746	$760	$685	$777
NDA without Clinical Data	$127	$144	$178	$177	$152	$171	$190	$215	$261	$277	$561	$411	$476	$481
Supplement with Clinical Data	$151	$171	$212	$210	$181	$203	$226	$256	$111	$118	$175	$142	$255	$224
Supplement without Clinical Data	$6	$7	$8	$8	$7	$8	$9	$10	$8	$8	$18	$17	$17	$23
Biologic Applications														
IND	$184	$230	$234	$266	$204	$173	$243	$175	$287	$279	$361	$400	$437	$394
BLA						$1,118	$1,568	$1,128	$2,788	$2,708	$4,394	$4,075	$4,492	$2,626
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
Supplement without Clinical Data	$34	$42	$43	$49	$38	$32	$45	$32	$31	$30	$21	$41	$42	$40

[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