

PDUFA Standard Cost Estimates for the Process of Human Drug Review (Dollars in Thousands)

UNIT COSTS (\$000/application receipt)

	FY93	FY94	FY95	FY96	FY97	FY98	FY99	FY00	FY01	FY02	FY03	FY04	FY05	FY06	FY07	FY08	FY09	FY 2010	FY 2011	FY 2012	FY 2013
<u>Drug Applications</u>																					
IND	\$70.0	\$79.0	\$98.0	\$97.0	\$84.0	\$94.0	\$105.0	\$119.0	\$200.0	\$211.8	\$299.0	\$203.3	\$240.0	\$249.6	\$284.7	\$236.5	\$290.9	\$362.1	\$423.3	\$498.5	\$449.5
NDA NME with Clinical	\$887.0	\$1,004.0	\$1,243.0	\$1,233.0	\$1,065.0	\$1,194.0	\$1,328.0	\$1,503.0	\$1,920.0	\$2,037.0	\$2,116.0	\$1,987.1	\$2,456.3	\$2,986.2	\$2,250.9	\$3,736.4	\$4,021.0	\$4,316.6	\$5,091.6	\$3,279.0	\$5,122.0
NDA xNME with Clinical	\$298.0	\$337.0	\$417.0	\$414.0	\$358.0	\$401.0	\$446.0	\$505.0	\$929.0	\$985.9	\$746.0	\$760.1	\$684.6	\$777.1	\$804.9	\$1,320.9	\$1,313.1	\$1,863.6	\$2,368.5	\$1,936.1	\$1,474.7
NDA xNME w/o Clinical	\$127.0	\$144.0	\$178.0	\$177.0	\$152.0	\$171.0	\$190.0	\$215.0	\$261.0	\$276.6	\$561.0	\$411.5	\$476.5	\$481.0	\$239.6	\$288.7	\$398.4	\$502.1	\$917.1	\$982.7	\$1,020.7
Supplement with Clinical	\$151.0	\$171.0	\$212.0	\$210.0	\$181.0	\$203.0	\$226.0	\$256.0	\$111.0	\$118.1	\$175.0	\$142.2	\$255.4	\$224.4	\$247.8	\$364.0	\$555.9	\$615.7	\$693.7	\$525.9	\$372.3
Supplement w/o Clinical	\$6.0	\$7.0	\$8.0	\$8.0	\$7.0	\$8.0	\$9.0	\$10.0	\$8.0	\$8.1	\$18.0	\$16.7	\$16.5	\$22.7	\$19.4	\$13.8	\$28.7	\$31.4	\$17.8	\$27.0	\$49.8
<u>Biologic Applications</u>																					
Bio IND	\$184.0	\$230.0	\$234.0	\$266.0	\$204.0	\$173.0	\$243.0	\$175.0	\$287.0	\$278.9	\$361.0	\$400.4	\$437.1	\$393.9	\$427.5	\$802.8	\$860.4	\$791.9	\$1,000.8	\$771.7	\$550.7
BLA						\$1,118.0	\$1,568.0	\$1,128.0	\$2,788.0	\$2,708.2	\$4,394.0	\$4,074.7	\$4,492.2	\$2,626.2	\$3,141.6	\$2,726.7	\$3,529.6	\$6,081.5	\$11,203.5	\$5,905.8	\$4,089.8
PLA	\$1,078.0	\$1,345.0	\$1,369.0	\$1,560.0	\$1,194.0	\$1,016.0	\$1,426.0	\$1,026.0													
ELA	\$177.0	\$221.0	\$225.0	\$256.0	\$196.0	\$167.0	\$234.0	\$168.0													
BLA Supplement with Clinical	\$561.0	\$700.0	\$713.0	\$812.0	\$622.0	\$529.0	\$742.0	\$534.0	\$195.0	\$189.6	\$228.0	\$367.4	\$239.4	\$265.2	\$627.1	\$511.5	\$681.8	\$655.4	\$661.3	\$1,166.8	\$459.0
BLA Supplement w/o Clinical	\$34.0	\$42.0	\$43.0	\$49.0	\$38.0	\$32.0	\$45.0	\$32.0	\$31.0	\$29.8	\$21.0	\$41.0	\$41.9	\$40.2	\$53.0	\$49.4	\$68.3	\$72.8	\$83.8	\$80.4	\$78.1