

FDA User Fee Schedule – 2008-2012

October 1 to September 30

	2008	2009	2010	2011	2012
Full PMA/BLA	\$ 185,000	\$ 200,725	\$ 217,787	\$ 236,298	\$ 256,384
Price for Small Businesses	\$ 46,250	\$ 50,181	\$ 54,447	\$ 59,075	\$ 64,096
Panel Track Supplements	\$ 138,750	\$ 150,544	\$ 163,340	\$ 177,224	\$ 192,288
Price for Small Businesses	\$ 34,688	\$ 37,636	\$ 40,835	\$ 44,306	\$ 48,072
180-Day Supplements Full	\$ 27,750	\$ 30,109	\$ 32,668	\$ 35,445	\$ 38,458
Price for Small Businesses	\$ 6,938	\$ 7,527	\$ 8,167	\$ 8,861	\$ 9,614
Real Time Supplements Full	\$ 12,950	\$ 14,051	\$ 15,245	\$ 16,541	\$ 17,947
Price for Small Businesses	\$ 3,237	\$ 3,512	\$ 3,810	\$ 4,134	\$ 4,485
510k Submissions*	\$ 3,404	\$ 3,693	\$ 4,007	\$ 4,348	\$ 4,717
Price for Small Businesses	\$ 1,702	\$ 1,847	\$ 2,004	\$ 2,174	\$ 2,359
30-Day Notice	\$ 2,960	\$ 3,212	\$ 3,485	\$ 3,781	\$ 4,102
Price for Small Businesses	\$ 1,480	\$ 1,606	\$ 1,742	\$ 1,890	\$ 2,051
513(g)	\$ 2,498	\$ 2,710	\$ 2,940	\$ 3,190	\$ 3,461
Price for Small Businesses	\$ 1,249	\$ 1,355	\$ 1,470	\$ 1,595	\$ 1,731
Establishment Registration	\$ 1,706	\$ 1,851	\$ 2,008	\$ 2,179	\$ 2,364
Price for Small Businesses	\$ 1,706	\$ 1,851	\$ 2,008	\$ 2,179	\$ 2,364
Annual Report Filing	\$ 6,475	\$ 7,025	\$ 7,623	\$ 8,270	\$ 8,973
Price for Small Businesses	\$ 1,619	\$ 1,756	\$ 1,906	\$ 2,068	\$ 2,243

NOTE: Small Businesses are those defined as having less than US\$100,000,000 in sales worldwide.

* FDA submissions for devices intended solely for pediatric use are exempt from the FDA fee. If the product will also be used for adult use, a new 510k must be submitted.