

FDA User Fee Schedule – 2010-2012

October 1 to September 30

	2010	2011	2012
Full PMA/BLA	\$ 217,787	\$ 236,298	\$ 256,384
Price for Small Businesses	\$ 54,447	\$ 59,075	\$ 64,096
Panel Track Supplements	\$ 163,340	\$ 177,224	\$ 192,288
Price for Small Businesses	\$ 40,835	\$ 44,306	\$ 48,072
180-Day Supplements Full	\$ 32,668	\$ 35,445	\$ 38,458
Price for Small Businesses	\$ 8,167	\$ 8,861	\$ 9,614
Real Time Supplements Full	\$ 15,245	\$ 16,541	\$ 17,947
Price for Small Businesses	\$ 3,810	\$ 4,134	\$ 4,485
510k Submissions*	\$ 4,007	\$ 4,348	\$ 4,717
Price for Small Businesses	\$ 2,004	\$ 2,174	\$ 2,359
30-Day Notice	\$ 3,485	\$ 3,781	\$ 4,102
Price for Small Businesses	\$ 1,742	\$ 1,890	\$ 2,051
513(g)	\$ 2,940	\$ 3,190	\$ 3,461
Price for Small Businesses	\$ 1,470	\$ 1,595	\$ 1,731
Establishment Registration	\$ 2,008	\$ 2,179	\$ 2,364
Price for Small Businesses	\$ 2,008	\$ 2,179	\$ 2,364
Annual Report Filing	\$ 7,623	\$ 8,270	\$ 8,973
Price for Small Businesses	\$ 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.*