



FDA User Fee Schedule - 2010 - 2012

Fiscal Year: October 1 to September 30

	2010	2011	2012
Full PMA/BLA	\$217,787	\$236,298	\$220,050
Price for Small Businesses	\$54,447	\$59,075	\$55,013
Panel Track Supplements	\$163,340	\$177,224	\$165,038
Price for Small Businesses	\$40,835	\$44,306	\$41,259
180-Day Supplements Full	\$32,668	\$35,445	\$33,008
Price for Small Businesses	\$8,167	\$8,861	\$8,252
Real Time Supplements Full	\$15,245	\$16,541	\$15,404
Price for Small Businesses	\$3,810	\$4,134	\$3,851
510k Submissions*	\$4,007	\$4,348	\$4,049
Price for Small Businesses	\$2,004	\$2,174	\$2,024
30-Day Notice	\$3,485	\$3,781	\$3,521
Price for Small Businesses	\$1,742	\$1,890	\$1,760
513(g)	\$2,940	\$3,190	\$2,971
Price for Small Businesses	\$1,470	\$1,595	\$1,485
Establishment Registration	\$2,008	\$2,179	\$2,029
Price for Small Businesses	\$2,008	\$2,179	\$2,029
Annual Report Filing	\$7,623	\$8,270	\$7,702
Price for Small Businesses	\$1,906	\$2,068	\$1,925

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.*

(Data Compiled 16 August 2011 by Emergo Group)