

2. Professional Labeling Design Costs

For a major revision in the content of professional labeling, FDA had estimated in its preliminary analysis that, on average, prescription drug manufacturers would incur costs of about \$2,600 per product, including inventory loss, because the 12-month implementation period is shorter than the average useful life of pharmaceutical labeling. To derive this estimate, labeling costs for four categories of pharmaceutical manufacturers were weighted by their market share of all

pharmaceutical products. Comments from a large pharmaceutical manufacturer, however, stated that labeling redesign costs to industry are more than three times FDA's estimate. In response, the agency has recalculated the market shares of the affected antibacterial products based on its current drug approval data (table 2). Adjusting for both inflation and market shares, FDA now estimates that manufacturers of antibacterial drugs will incur, on average, per product costs of approximately \$4,380, including \$1,040 in inventory loss. The weighted

average cost to revise drug labeling is based on input from industry consultants on the time and materials required to modify the package insert accompanying pharmaceutical products. (Table 2a shows a breakdown, by firm size, of the labor and material costs used to derive the weighted average cost of \$4,380.) While some firms may incur per product costs higher than the average estimate, the agency believes that the revised per product cost represents a reasonable estimate of industrywide costs.

TABLE 2.—MARKET SHARE OF AFFECTED ANTIBACTERIAL DRUG PRODUCTS BY CATEGORY OF FIRM

Category of Firm	Number of Firms	Number of Products	Market Share ¹
Innovator ²			
Small ³	10	18	2.69%
Medium	3	27	4.04%
Large	45	501	74.89%
Generic ⁴	43	123	18.39%
Totals	101	669	100.00%

¹ May not sum to total because of rounding.

² Includes firms manufacturing both innovator and generic products.

³ Includes 7 private firms without size data.

⁴ Includes firms manufacturing only generic products and 26 private firms without size data.

TABLE 2A.—LABELING REVISION COSTS BY FIRM SIZE

Item	Generic Drug Manufacturers	Innovator Drug Manufacturers		
		Small	Medium	Large
Labor Cost	\$830	\$830	\$1,242	\$1,812
Material Cost	\$740	\$740	\$2,230	\$3,400
Total Cost to Revise Labeling	\$1,570	\$1,570	\$3,472	\$5,212

3. Incremental Printing Costs for Professional Labeling

No comments were received on FDA's estimate of incremental printing costs for longer labeling. Therefore, FDA maintains its estimate that an average of 100,000 package inserts are printed annually for each antibacterial drug product marketed in the United States.³ Compared to the proposed rule, the final rule requires fewer statements in the labeling, thus reducing the costs to print longer labeling. Adding new information on prudent use of antibacterial drug products to professional labeling will increase the

size of current package inserts by an estimated 3.3 percent or 3.3 square inches (in²) for the average insert. Although few package inserts will change size, if all manufacturers had to increase the length of the package insert to accommodate the new statements, they would incur additional printing costs of about \$37 per affected product.⁴ If all affected products had longer labeling, printing costs for the industry would increase by less than \$25,000 annually.

4. PDR Costs

No comments were received on the impact of the rule on PDR costs for

manufacturers. According to its publisher, a page in the print version of the PDR costs an average of \$9,500 in 2001.⁵ Furthermore, according to the publisher of the electronic versions of the PDR, each full package insert published in the print version is also included in the Internet and CD-ROM versions of the PDR at no additional cost to the drug manufacturer. A search of the Internet version of the PDR showed that as many as 160 antibacterial drug products will have slightly longer descriptions in the PDR.⁶ The additional

therapeutic equivalence codes for the same manufacturer were counted separately.

³ In 1996, there were approximately 133 million prescriptions for antibacterial drugs written by physicians in office and hospital settings (Government Accounting Office, 1999). An estimated 45.3 million inserts were printed to accompany these drugs. (45.3 million = (106 retail prescriptions/3 prescriptions per container) + (19 million hospital emergency prescriptions/2 prescriptions per container) + (8 million hospital outpatient prescriptions/500 units per container/ (28 units per prescription))). An average of 56,767

inserts therefore accompanied each product (45.3 million ÷ 798 products). Also, we assume that 40,000 additional inserts per product are distributed annually by sales representatives as promotional material.

⁴ Although the length of an average package insert will only increase by 3.3 in², we rounded to 4 in² to calculate costs. The 1997 estimated incremental printing cost of \$ 0.0086 per 100 in² was adjusted for inflation by the producer price index for commercial printing (i.e., a 6 percent increase in costs between 1997 and April 2001). \$36.53 =

100,000 inserts per product x 1.06 x \$0.000086 per in² x 4 in².

⁵ \$9,500 is the estimated average industry cost. Per page charges to an individual firm will decrease as more PDR pages are purchased. The maximum per page charge listed on Medical Economics' 2001 rate card is \$19,035 (i.e., less than eight pages purchased for the year).

⁶ A search of the Internet version of the PDR by affected drug category and by indication found only 156 affected products. According to Micromedex (<http://www.micromedex.com>), all fully described