

Manufacturer's Name,11-Digit National Drug Code,"Manufacturer's  
 Average Sales Price",Number of ASP Units,"Wholesale  
 Acquisition Cost ",Name of Drug or Biological,Strength of the Product,"Volume  
 Per Item",Number of Items Per NDC,"Expiration Date  
 of Last Lot Sold",Date of First Sale,Number of CAP Units Excluded,FDA  
 Application Number,FDA Final Pre-Marketing Approval Date,FDA Approval  
 Type,Descriptive Data Corrected  
 Currently collected data elements,,,,,,,,,,,,,Proposed New Data Elements,,,  
 EXAMPLE DATA,,,,,,,,,,,,,  
 Centers for Medicare & Medicaid Services,1234567801,\$10.94 ,"2,097",  
 \$12.00 ,TRADE NAME,20  
 mg/ml,10,5,11/22/2006,4/1/2006,0,12345,1/20/2006,NDA,"Insert ""Y"" to indicate  
 that a data element other than Manufacturer's ASP or Number of ASP Units has  
 changed."  
 Centers for Medicare & Medicaid Services,12345003510,\$12.50 ,135,\$13.50 ,BRAND  
 NAME,50 mg tab,100,1,,,22.4,234560,prior to October 2003,BLA,  
 Centers for Medicare & Medicaid Services,98765040101,\$0.26 ,"333,444",,ACTIVE  
 INGREDIENT,0.90%,3,5,,,0,654321,unknown,ANDA,  
 Centers for Medicare & Medicaid Services,98765123402,\$123.45 ,"99,000",,TRADE  
 NAME,100 mg\*,1\*\*,12,,,0.33,K056789 ,not currently available,510K,  
 ,,,,,,\*powdered form,"\*\*use ""1"" if powder form (or other specialized form such  
 as a sheet) and Column G identifies amount of drug in one  
 item",,,,,,P123045,8/8/2008,PMA,

"According to the Paperwork Reduction Act of 1995, no persons are required to  
 respond to a collection of information unless it displays a valid OMB control  
 number. The valid OMB control number for this information collection is 0938-  
 0921."

"The time required to complete this information collection is estimated to  
 average (40 hours) per response, including the time to review instructions,  
 search existing data resources, gather the data needed, and complete and review  
 the information collection. If you have comments concerning the accuracy of the  
 time estimate(s) or suggestions for improving this form, please write to: CMS,  
 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Mail Stop C4-26-  
 05, Baltimore, Maryland 21244-1850. "  
 CMS 10110 approval pending