Proposed Revised Addendum A

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 & Med	01234567801	$10.94	2,097	$12.00	TRADE NAME	20 mg/ml	10	5	11/22/06	04/01/06	0	012345	01/20/06	NDA	Insert "Y" to indicate that a data element other than Manufacturer's ASP or Number of ASP Units has changed.
Centers for Medicare & Med	12345003510	$12.50	135	$13.50	BRAND NAME	50 mg tab	100	1			22.4	234560	prior to October 2003	BLA	
Centers for Medicare & Med	98765040101	$0.257	333,444		ACTIVE INGREDIENT	0.90%	3	5			0	654321	unknown	ANDA	
Centers for Medicare & Med	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	08/08/08	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