**Disclosure Statement**

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 0938-0578. The time required to complete this information collection is estimated to average 5,200 hours per response including the 0ne-time reconfiguration of labeler drug pricing systems and the one-time cost of training drug manufacturer staff. If you have comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, Maryland 21244-1850.