

Justification  
Report of Theft or Loss of Controlled Substances -- DEA form 106  
1117-0001

The Drug Enforcement Administration (DEA) regulations (21 CFR 1301.74 (c) and 1301.76 (b)), require registrants to notify their nearest DEA field office within one business day of the discovery of a theft or loss of controlled substances; DEA Form 106 is used for this purpose. The existing form requires that all products be listed individually to include the dosage form, strength, and quantity per container on page 2. The information provided by registrants on the DEA Form 106 is included in DEA's Drug Theft Data base. This database provides DEA with access to current and historical data on drug theft and loss. The accuracy of analyzable data derived from the database is in direct relation to the data in the database. DEA has become concerned that the information being entered into the database has the potential for error as a result of inaccurate data entry, or incorrect interpretation of data, which in turn generates problematic analyses and erroneous information.

Therefore, DEA is submitting a change request to the Office of Management and Budget (OMB) to amend DEA information collection "Report of Theft or Loss of Controlled Substances" DEA Form 106 (OMB information collection number 1117-0001). Specifically, DEA is adding one field to page 2 of this form (attached), requiring registrants to provide the National Drug Code (NDC) number of the controlled substances which were stolen or lost. The NDC number is an identification number used by manufacturers and others to identify specific drug products based on labeler code, product code and package code.

DEA believes that inclusion of the NDC number of the drug products that are lost or stolen will improve the accuracy and quality of the data contained in the Drug Theft Database, and will permit better accounting for lost or stolen controlled substances.

For registrants who submit DEA Form 106 to DEA electronically, the entry of the NDC number will prompt the system to auto-populate additional fields to include the dosage form, dosage strength, and quantity per container, potentially reducing the registrant's burden for completion of the form and reduce the potential for error. For registrants completing the form in paper, the addition of the field will not pose an increased burden as information regarding NDC numbers would be collected with other information regarding the stolen or lost controlled substances.

DEA must maintain accurate information regarding the theft or loss of controlled substances to assess trends or patterns regarding those thefts or losses. DEA is obligated to provide the public with reliable information regarding trends of those thefts and losses, and believes the inclusion of the NDC number on the DEA Form 106 would significantly reduce the potential for error, thereby enabling the DEA to collect data and respond to public queries more expeditiously; provide more responsive drug theft data; reduce resources associated with data management; and produce more effective, refined analyses. Overall, the proposed new provision would significantly reduce error by the

registrant and establish a more accurate database for internal use and support.