

notification should occur immediately and without delay. Where circumstances of the theft or significant loss are immediately known, a DEA Form 106, Report of Theft or Loss of Controlled Substances, should be used to detail the circumstances of that theft or significant loss. When details concerning the specific circumstances surrounding the theft or loss are unknown at the time of discovery, DEA recommends initial notice be provided by faxing a short statement to DEA advising of the theft or significant loss. While such initial notice may alternatively be mailed, delays occurring due to the mailing process may hinder investigative efforts by DEA. A DEA Form 106, Report of Theft or Loss of Controlled Substances, is not immediately necessary. The registrant may then make efforts to determine the facts involved by conducting inventories, internal audits, and/or investigations using internal or law enforcement resources, as appropriate. The DEA Form 106 should be submitted once the circumstances surrounding the theft or significant loss are clear. The DEA Form 106 must document the circumstances of the theft or significant loss and the quantities of controlled substances involved. DEA recognizes that some time may elapse between the time initial notice of a theft or loss is provided and the conclusion of the investigation. DEA suggests that if an investigation takes more than two months to complete, registrants provide updates regarding the investigation to DEA. The conduct of an investigation does not obviate the need for immediate notification of the theft or significant loss by the registrant to the local DEA field office. If, after an investigation of the circumstances surrounding the disappearance of the material, it is determined that no theft or significant loss occurred, no DEA Form 106 need be filed. However, DEA recommends the registrant advise DEA that a DEA Form 106 is not needed or will not be filed regarding the incident.

What Other Actions Should a Registrant Take When a Theft or Significant Loss Occurs?

The theft of controlled substances from a registrant is a criminal act, and a source of controlled substances diversion requiring notification of DEA. Although not specifically required by DEA law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification of law enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion.

Complete accountability by a registrant for all controlled substances handled is a fundamental requirement of the closed distribution system mandated by the Controlled Substances Act (CSA). The CSA requires: “* * * every registrant under this title manufacturing, distributing, or dispensing a controlled substance or substances shall maintain, on a current basis, a complete and accurate record of each such substance manufactured, received, sold, delivered, or otherwise disposed of by him,* * *.” (21 U.S.C. 827(a)(3)). No registrant should disregard any unexplained shortage of controlled substances. Registrants should treat an individual theft or significant loss seriously and should monitor occurrences so that patterns do not remain undetected. Record keeping must be accurate and complete so as to serve as a reliable reporting and recording device.

DEA has become aware of instances in which registrants have used a DEA Form 106 to document or explain minor inventory discrepancies, thereby “balancing the books.” DEA wishes to stress that the DEA Form 106 should be used only to document thefts or significant losses of controlled substances. Minor inventory discrepancies, not attributable to theft, should not be reported to DEA or recorded on a DEA Form 106. Rather, registrants should make appropriate notations of minor inventory discrepancies in their records, indicating the amount of variance between the physical count and the amount accounted for through records. Such discrepancies need not be reported to DEA if they are not significant or actual losses. If a registrant is unsure of the significance of a loss after considering the factors described below, the registrant should file the report. Any continuing pattern of loss of seemingly insignificant quantities should always be considered significant.

What Specific Regulations Does This Rulemaking Propose To Amend?

Specifically, this rulemaking proposes the amendment of 21 CFR 1301.74(c) and 1301.76(b) to insert the word “immediately” before the phrase “upon discovery” to clarify the points raised in the previous discussion. Although not specifically mentioned in the previous discussion, such reports include the report by a supplier of in-transit thefts or losses of controlled substances by the common or contract carrier selected by the supplier pursuant to 21 CFR 1301.74(e). Further, this rulemaking proposes a minor technical correction to § 1301.76(b) to remove the reference to

BND Form 106, as this form is no longer used.

Significant Loss of Controlled Substances

What Constitutes a Significant Loss?

Questions have arisen as to exactly what constitutes a “significant loss.” There is no single objective standard which can be established and applied to all registrants to determine whether a loss is significant. Any unexplained loss or discrepancy should be reviewed within the context of a registrant’s business activity and environment. What constitutes a significant loss for one registrant may be construed as comparatively insignificant for another. For example, the loss by a pharmacy of a 100-count bottle of controlled substance tablets would be viewed as significant, whereas the same loss by a full line distributor may be viewed differently, particularly if the loss is an unexplained inventory discrepancy that may have resulted from a picking error. A manufacturer may experience continuous losses in the manufacturing process due to atmospheric changes, mixing procedures, etc. Such losses may not be deemed by the registrant to be significant, and may be recorded in batch records. Conversely, for registrants other than manufacturers, the repeated loss of small quantities of controlled substances over a period of time may indicate a significant aggregate problem which must be reported to DEA, even though the individual quantity of each occurrence is not significant.

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

- (1) The actual quantity of controlled substances lost in relation to the type of business;
- (2) A pattern of such losses, and the results of efforts taken to resolve them; and, if known,
- (3) Local trends and other indicators of the diversion potential of the missing material.

Specific questions which a registrant should ask to identify whether a loss is significant include, but are not limited to:

- (1) Has a pattern of loss been identified? Would this pattern result in a substantial loss of controlled substances over that period of time?
- (2) Are specific controlled substances being lost, and do the losses appear to be random?
- (3) Are the specific controlled substances likely candidates for diversion?
- (4) Can losses of controlled substances be associated with access to those