

Special Flight Permits

(e) Special flight permits may be issued in accordance with §§ 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be done.

Issued in Burlington, Massachusetts, on June 30, 2003.

Francis A. Favara,

Acting Manager, Engine and Propeller Directorate, Aircraft Certification Service.

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DEPARTMENT OF JUSTICE**Drug Enforcement Administration****21 CFR Part 1301**

[Docket No. DEA-196P]

RIN 1117-AA73

Reports by Registrants of Theft or Significant Loss of Controlled Substances

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Notice of proposed rulemaking; guidance.

SUMMARY: DEA is proposing the amendment of its regulations to clarify its policy regarding reports by registrants of theft or significant loss of controlled substances. There has been some confusion as to what constitutes a significant loss, and when and how initial notice of a theft or loss should be provided to DEA. This Notice of Proposed Rulemaking proposes the clarification of DEA regulations and provides guidance to registrants regarding the theft, significant loss and explained loss of controlled substances.

DATES: Written comments must be postmarked on or before September 8, 2003.

ADDRESSES: Comments should be sent to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/CCR.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, Telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:**Background**

DEA is publishing this Notice of Proposed Rulemaking (NPRM) to

propose the clarification of its policies and procedures regarding the reporting by registrants of the theft or significant loss of controlled substances.

Title 21, Code of Federal Regulations, § 1301.74(c) "Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs." requires that: "The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances upon discovery of such theft or loss. The supplier shall be responsible for reporting in-transit losses of controlled substances by the common or contract carrier selected pursuant to § 1301.74(e), upon discovery of such theft or loss. The registrant shall also complete DEA Form 106 regarding such theft or loss. Thefts must be reported whether or not the controlled substances are subsequently recovered and/or the responsible parties are identified and action taken against them."

Title 21, Code of Federal Regulations, § 1301.76(b) "Other security controls for practitioners." further requires that: "The registrant shall notify the Field Division Office of the Administration in his area of the theft or significant loss of any controlled substances upon discovery of such loss or theft. The registrant shall also complete DEA (or BND) Form 106 regarding such loss or theft."

A number of questions have arisen regarding the meaning of certain terms in these paragraphs. Specifically, there seems to be confusion within the regulated industry as to the exact meaning of the phrase "upon discovery". Therefore, as further discussed below, DEA is proposing the amendment of the regulations to insert the word "immediately" before the phrase "upon discovery" to clarify this point. Further, DEA is proposing the amendment of its regulations to list certain factors which registrants should consider when determining whether a loss of controlled substances is significant. Finally, this document provides guidance to registrants on the reporting of breakage, spillage or other explained losses of controlled substances. No regulatory amendments are being proposed regarding this guidance.

Theft or Other Unexplained Significant Loss of Controlled Substances

What Is a DEA Registrant Required To Do When a Theft or Significant Loss Is Discovered?

Every DEA registrant is required to notify the DEA field office in their area

of any theft or significant loss of controlled substances upon its discovery. DEA has always viewed "upon discovery" to mean that notification should occur immediately and without delay. Every DEA registrant (practitioner, pharmacy, hospital/clinic, manufacturer, distributor, etc.) must comply with this requirement, and such compliance cannot be overridden by an internal corporate policy that is contrary to the notification requirement. For example, a DEA-registered pharmacy must provide notice to the local DEA field office when a theft or significant loss is discovered. This requirement is not satisfied by the reporting of the theft or significant loss internally to individuals in corporate management. DEA must be notified directly and immediately of the theft or significant loss of the controlled substances. A corporation that owns/operates multiple registered sites and wishes to channel all notifications through a central point such as corporate loss prevention, corporate security, or other corporate entity may do so but must still fulfill the requirement to provide notice to DEA immediately upon discovery by the actual registrant. However, this immediate notification does not always occur. Therefore, DEA is proposing the amendment of its regulations to insert the word "immediately" before the phrase "upon discovery" to clarify this point.

The purpose of immediate notification is to provide an opportunity for DEA, state, or local participation in the investigative process when warranted, and to create a record that the theft or significant loss was properly reported. It also alerts law enforcement to more broadly based circumstances and patterns of which the individual registrant may be unaware. This notification is considered part of a good-faith effort on the part of the regulated industries to maintain effective controls against the diversion of controlled substances, as required by 21 CFR 1301.71(a). Lack of prompt notification could prevent effective investigation and prosecution of individuals involved in the diversion of controlled substances. Withholding or failing to provide information is a violation of the law and regulations (21 U.S.C. 821, 21 U.S.C. 842(a)(5), 21 CFR 1301.74(c), 1301.76(b)).

How Should Notice of a Theft or Significant Loss Be Provided?

The regulations require that notice of a theft or significant loss must be reported to DEA upon its discovery. As noted above, DEA has always viewed "upon discovery" to mean that