

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

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

controlled substances by specific individuals? Can losses be attributed to unique activities which may take place involving the controlled substances?

Individual registrants should examine both their business activities and the external environment in which those business activities are conducted to determine whether unexplained losses of controlled substances are significant. When in doubt, registrants should err on the side of caution in alerting the appropriate law enforcement authorities, including DEA, of thefts and losses of controlled substances.

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 include the factors listed above as factors which a registrant should consider when determining whether a loss is significant and, thus, must be reported to DEA. DEA encourages registrants to use other criteria, as well as those factors listed above, which they have found to be useful in the evaluation of losses of controlled substances when determining whether such losses are significant, but is proposing the provision of these factors as the minimum which registrants should consider.

Guidance Regarding Breakage, Spillage and Other Explained Loss of Controlled Substances

What Is Required of a DEA Registrant When Breakage or Spillage Occurs?

DEA has encountered instances in which registrants have attempted to report spillages or explained losses of controlled substances on a DEA Form 106. The breakage, spillage or other witnessed controlled substance losses do not require the immediate notification of DEA. If controlled substance containers are broken or damaged, or controlled substances spilled, the substances are not considered "lost" because they can be accounted for. When breakage, spillage or damage of controlled substances occurs, the affected controlled substances must be disposed of according to DEA requirements.

If there is breakage, spillage or other damage to controlled substances, but the controlled substances are still recoverable, then the registrant has two options for disposing of the controlled substances. The registrant may dispose of the controlled substances by either (1) Contacting their local DEA field office and receiving permission from that office to dispose of the controlled substances pursuant to 21 CFR 1307.21,

or (2) the registrant may send those controlled substances to a firm registered with DEA to handle returns/disposals.

If the registrant receives permission from DEA to dispose of the controlled substances pursuant to 21 CFR 1307.21, then that registrant must complete a DEA Form 41, Registrants Inventory of Drugs Surrendered, explaining the circumstances of the breakage. Two individuals who witnessed the breakage, spillage or damage must sign the DEA Form 41, indicating what they witnessed. Registrants must submit three copies of the DEA Form 41 to their local DEA field office (21 CFR 1307.21(a)(1)). Registrants are also required to maintain a copy of the DEA Form 41 in their records.

If the registrant sends the controlled substances to a DEA registered disposer, then the registrant must complete the necessary paperwork showing the distribution of the damaged controlled substances to the registered disposer.

If the breakage or spillage is clearly observed but the controlled substances are not recoverable, then the registrant must document the circumstances of the breakage in their inventory records. Two individuals who witnessed the breakage must sign the inventory records, indicating what they witnessed. These records must be maintained in the registrant's files.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. This regulation seeks to clarify existing DEA regulations regarding the reporting of thefts and losses of controlled substances. No new recordkeeping or reporting requirements are proposed in this rulemaking.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant rulemaking action. Therefore, this action has not been reviewed by the Office of Management and Budget. This rulemaking merely seeks to clarify existing DEA regulations, policies and procedures.

Executive Order 12988

This regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of state law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This rule will not result in an annual effect on the economy of \$100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1301

Administrative practice and procedure, Drug traffic control, Security measures.

For the reasons set out above, 21 CFR part 1301 is proposed to be amended as follows:

PART 1301—REGISTRATION OF MANUFACTURERS, DISTRIBUTORS, AND DISPENSERS OF CONTROLLED SUBSTANCES

1. The authority citation for part 1301 continues to read as follows:

Authority: 21 U.S.C. 821, 822, 823, 824, 871(b), 875, 877.

2. Section 1301.74 is amended by revising paragraph (c) to read as follows:

§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounds for narcotic treatment programs.

* * * * *

(c) The registrant shall notify the Field Division Office of the Administration in his area of any theft or significant loss of any controlled substances immediately 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), immediately 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. 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) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities which may take place involving the controlled substances;

(4) A pattern of such losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing material.

* * * * *

3. Section 1301.76 is amended by revising paragraph (b) to read as follows:

§ 1301.76 Other security controls for practitioners.

* * * * *

(b) The registrant shall notify the Field Division Office of the Administration in his area of the theft or significant loss of any controlled substances immediately upon discovery of such loss or theft. The registrant shall also complete DEA Form 106 regarding such loss or theft. 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) The specific controlled substances lost;

(3) Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities which may take place involving the controlled substances;

(4) A pattern of such losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known,

(5) Whether the specific controlled substances are likely candidates for diversion;

(6) Local trends and other indicators of the diversion potential of the missing material.

* * * * *

Dated: June 25, 2003.

Laura M. Nagel,

Deputy Assistant Administrator, Office of Diversion Control.

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG-130262-03]

RIN 1545-BC28

Guidance Under Section 1502; Stock Basis After a Group Structure Change

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations under section 1502 that relate to stock basis after a group structure change. These proposed regulations affect corporations filing consolidated returns.

DATES: Written or electronic comments and requests for a public hearing must be received by October 6, 2003.

ADDRESSES: Send submissions to: CC:PA:RU (REG-130262-03), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:RU (REG-130262-03), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20044.

Alternatively, taxpayers may submit comments electronically directly to the IRS Internet site at www.irs.gov/reg.

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, Marlene Oppenheim or Ross Poulsen, (202) 622-7770; concerning submission of comments and/or requests for a public hearing, Sonya Cruse, (202) 622-7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Background and Explanation of Provisions

Section 1.1502-31 applies if one corporation (P) succeeds another corporation (T) under the principles of § 1.1502-75(d)(2) or (3) as the common parent of a consolidated group in a group structure change. If a corporation acquires stock of the former common parent in a group structure change, the basis of the members in the former common parent's stock immediately after the group structure change is generally redetermined to reflect the former common parent's net asset basis. In general, the group structure change regulations were designed to prevent disparate basis consequences resulting from different forms of transactions that effect a restructuring of a consolidated group that continues to exist following the restructuring.

The IRS and Treasury are concerned that the application of the net asset basis rule may produce inappropriate results on the disposition of stock acquired in a transaction in which, under generally applicable rules, the basis of the acquired stock would otherwise be determined by reference to the acquiror's cost for the stock. Accordingly, this document proposes to modify the application of the provisions of § 1.1502-31 to permit the basis of stock acquired in a recognition transaction to reflect the cost of the acquired stock.

In particular, this document excepts from the application of the net asset basis rule stock acquired in a transaction in which gain or loss was recognized in whole. These regulations are proposed to apply to group structure changes that occur after the date these regulations are published as temporary or final regulations in the **Federal Register**. With respect to group structure changes that occur on or before the date these regulations are published as temporary or final regulations in the **Federal Register** and during consolidated return years beginning on or after January 1, 1995, these regulations are proposed to apply at the election of the group.