

all registrants at the distributor level. They include, but are not necessarily limited to:

- **Security:** All applicants must install, at the registered premises, physical security controls that meet the existing standards of 21 CFR 1301.71 and 1301.72.

- **Recordkeeping:** In accordance with 21 CFR part 1304, periodic inventories and records of all controlled substances received, destroyed, or returned to the original, registered manufacturers must be maintained for two years. The registrant must adequately describe the receipt and accountability methods and records to be employed to ensure the establishment of effective controls against diversion.

- **Order Forms** must be completed for all Schedule I and II items received and transferred.

- **Reports** are required under the Automation of Reports and Consolidated Orders System (ARCOS), as specified in 21 CFR 1304.33.

In addition to DEA requirements, reverse distribution applicants must obtain the appropriate State and Federal approvals for controlled substances and disposal activities.

After publication of the August 1995 NPRM, DEA completed a rulemaking project in 1997 (62 FR 13938, March 24, 1997) that reorganized and clarified the regulations that would have been affected by that NPRM. The 1997 rulemaking also addressed the gender-specific and other editorial changes that were contained in the 1995 NPRM.

Therefore, proposed changes to 21 CFR 1301.26 (now 21 CFR 1301.24), Exemption of law enforcement officers; 21 CFR 1301.32 (now 21 CFR 1301.13), Application forms; contents; signature; and 21 CFR 1304.34 (now 21 CFR 1304.33(a)), Reports generally, are not included in this interim final rule. For the proposed changes that relate to reverse distributors, this interim final rule amends the appropriate CFR sections as changed in 1997. Throughout the preamble, citations to both previous section number and current section number are provided, where relevant.

Public Comments on the NPRM

Eight comments were received regarding the proposed rule. Commenters included reverse distributors and disposers currently operating under Memoranda of Understanding (*i.e.*, facilities such as incinerators that destroy controlled substances) and some of their representative organizations. While some commenters supported the intent of the rule, all commenters were against

some or all aspects of the rule. The following discussion summarizes the issues raised by commenters and DEA's response to these issues.

Proposed Definition and Registration Requirements

Most commenters opposed the proposal to classify the activities they engage in as either disposal or manufacturing and stated that doing so would subject them to unnecessary and burdensome regulations.

One commenter stated that since reverse distributors neither process nor package/repackage controlled substances within the meaning of the statutory definition of "manufacturer," it is beyond DEA's statutory authority to regulate these companies as manufacturers. Another commenter stated that the primary goal of disposers is not to render a controlled substance unusable, but, rather, it is to sort, inventory and perform other activities necessary to distribute products back to the original manufacturer and only secondarily, arrange for the actual destruction of controlled substances.

Four commenters stated that the proposed definition of disposer implies that a disposer is manipulating the product and, therefore, that waste is being accepted. This would, in turn, require disposers to comply with the more burdensome guidelines of the Food and Drug Administration (FDA) and EPA.

DEA Response

In response to these comments, DEA has decided to establish a definition for reverse distributor and is establishing a new category of registration as reverse distributors. In this interim final rule, DEA is adding the definition for "reverse distributors" to 21 CFR 1300.01(b). Reverse distributors are defined as "a person who receives controlled substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal." When reverse distributors return unwanted, unusable, or outdated controlled substances acquired from legitimate medical, scientific, research or other industrial channels to a manufacturer or a manufacturer's agent, they must follow the same DEA requirements as distributors follow. When reverse distributors process controlled substances or arrange for processing controlled substances for disposal, they must follow the same

procedures that distributors would follow in complying with 21 CFR 1307.21, "Procedure for disposing of controlled substances."

Applicability to Practitioners and Others

One commenter stated that classifying dentists and other small disposers as manufacturers would be burdensome because they would now have to register and pay burdensome registration fees. This could result in dentists removing themselves from regulatory control by refusing to handle controlled substances, which could adversely affect their patients. This commenter recommended that the proposed rule either exempt dentists and other small disposers by quantity, or state that they are not members of the "disposer" subcategory.

Another commenter stated that previous contacts with DEA indicated that the rulemaking is intended to regulate disposers that dispose of or offer controlled substances for disposal over which they have legal control. This commenter requested that DEA clarify that it should not be subject to the proposed rule provided that it is acting as an agent of DEA through a contract; or that it disposes of controlled substances for manufacturers provided that the manufacturer's representatives bring the controlled substances to a disposal facility and witness the destruction, thus maintaining legal responsibility for the controlled substances.

DEA Response

In this interim final rule, DEA is not changing the procedures for disposing of controlled substances under 21 CFR 1307.21. Those procedures are designed to ensure that controlled substances are under the control of a DEA registrant until they are destroyed or rendered unusable. If a disposal company never takes legal control of a controlled substance and the actual destruction is witnessed by two representatives of a DEA registrant, the disposal company itself is not required to obtain a DEA registration. On the other hand, if a disposal company receives controlled substances from a DEA registrant and then disposes of them later, the disposal company becomes part of the chain of responsible parties and must therefore be registered by DEA as a reverse distributor.

Under the interim final rule, DEA registrants who need to periodically dispose of controlled substances, such as practitioners, would continue to follow their current procedures for disposal of controlled substances.