Final Report

Pharmaceutical Reverse Distributor Survey

Alice I. Chapman, P.E.
Local Hazardous Waste Management Program in King County
Technical Assistance and Pollution Prevention Team
This report was prepared by the Local Hazardous Waste Management Program in King County, Washington. The program seeks to reduce hazardous waste from households and small quantity generator businesses in King County by providing information and technical assistance to protect human health and the environment.

For more information or to order additional copies of this report contact:

130 Nickerson Street, Suite 100
Seattle, WA 98109
206-263-3050   TTY Relay: 711
Fax 206-263-3070
www.govlink.org/hazwaste/

Publication Number SQG-PHARM-2(12/03)


Alternate Formats Available

Voice: 206-263-3050 or TTY Relay: 711
# CONTENTS

Acknowledgements.................................................................................................................1

Introduction and Objectives.................................................................................................2
  Survey Objectives ..............................................................................................................2
  Reverse Distributors and the Returns Industry .................................................................3

Survey Methods ....................................................................................................................4

Findings ...................................................................................................................................5
  General Information ..........................................................................................................5
  Reverse Distributors with Services in King County ..........................................................5
  Service Limitations ............................................................................................................5
  Drug Acceptance Policies ................................................................................................6
  Disposition of Drugs .........................................................................................................7
  Types of Permits ................................................................................................................7
  How Clients Can Make Reverse Distribution Work Smoother .........................................8

Reverse Distributor Operational Models .............................................................................9
  No Credit Processing .........................................................................................................9
  Pre-shipment Screening .....................................................................................................9
  Pre-shipment Segregation .................................................................................................9
  Hazardous Waste Identification Number .........................................................................10
  Destruction-Only Service .................................................................................................10

Summary and Conclusions ................................................................................................11

Appendix A Resource Directory for the Management of Pharmaceuticals in King County 13

Appendix B Definition and Registration of Reverse Distributors .......................................35

Appendix C Reverse Distributor Survey Questionnaire .......................................................55

Appendix D Environmental Protection Agency Guidance ................................................59

Appendix E Washington State Guidance ..........................................................................67

Appendix F Florida State Guidance ..................................................................................75

Appendix G How Clients Can Improve Reverse Distribution, Survey Responses ..........101
Package Drugs to Prevent Breakage ................................................................. 103
Improve Inventory Management ..................................................................... 103
Identify All Pharmaceuticals ......................................................................... 103
Complete DEA Controlled Substance Paperwork .......................................... 104
General Comments about Drug Management .................................................. 104

Bibliography ....................................................................................................... 105

Tables

Table 1, Facilities Receiving Drugs from Reverse Distributors ....................... 7
Table 2, Destruction-only Services Available through Reverse Distributors .... 10
ACKNOWLEDGEMENTS

The author gratefully acknowledges the following individuals for their assistance with the survey:

- Tiffany Yelton, Washington State Department of Ecology, provided technical resources needed to complete the survey and generated interest in the survey results with a national audience.

- Charlotte Smith, R. Ph., M.S. and President of PharmEcology Associates, LLC, provided the reference to the Drug Enforcement Administration regulations for reverse distributors and answered questions about the industry as a whole.

- Debra Oliver, Local Hazardous Waste Management Program in King County, completed some of the surveys and compiled the Resource Directory.

- The survey respondents spent time describing reverse distributor services and addressing follow-up questions.

This report is one part of a larger effort, the Pharmaceutical Workgroup of the Interagency Regulatory Analysis Committee (IRAC). Funded by the Local Hazardous Waste Management Program in King County, IRAC was formed to address issues of regulatory conflict and improve coordination between regulatory agencies. To learn more about IRAC, write 130 Nickerson St, #100, Seattle, WA 98109, call 206-263-3087, or visit the Web site at http://www6.metrokc.gov/hazwaste/irac/index.html.
INTRODUCTION AND OBJECTIVES

Reverse distributors are companies that arrange for recycling or destruction of unwanted pharmaceuticals, including controlled substances. Financial incentives (credits for returned pharmaceuticals) offered by drug manufacturers encourage dispensers to track inventories and return drugs. This product stewardship system provides a needed service to the medical community and the public.

In 2003 a national survey of reverse distributors was conducted to gather information about services available in King County, Washington. This report summarizes the results. Previous surveys gathered information about services offered by hazardous waste incinerators and hazardous waste brokers. The results of both surveys have been combined into a Resource Directory (see Appendix A) for King County businesses with unwanted drugs.

Survey Objectives

- Identify reverse distributors with services available to clients located in King County, Washington.
- Determine service limitations, such as minimum quantities or type of drug.
- Clarify acceptance policies for various types of drugs.
- Identify the scope of service, including the ultimate disposition of drugs.
- Ask about the types of permits reverse distributors maintain.
- Learn steps clients can take to help reverse distribution run smoothly.
- Record other notes and comments of interest.

These telephone surveys were not compliance audits. The survey respondent was typically a customer service representative, not a compliance manager or business owner. Financial data, number of employees and business volume data were outside the scope of the survey.

In addition to answering questions related to the survey objectives, reverse distributors provided valuable suggestions on best management practice and offered comments about the challenges of the business. Reverse distributors work with many operational models and acceptance policies. These can affect where drugs are first declared waste, the client’s generator status, and/or hazardous waste permit requirements for shippers or receivers of drugs. Federal or state (for the state where the reverse distributor processes drugs) hazardous waste regulations can be confusing and businesses may not be aware of the regulatory impact of some policy decisions.
Reverse Distributors and the Returns Industry

Although the terms “reverse distributor” and “returns industry” are used interchangeably, they actually have somewhat different meanings. “Reverse distributor” has a regulatory definition while “returns industry” does not. The Drug Enforcement Administration (DEA) regulatory definition of reverse distributor refers only to management of controlled substances. In practice, reverse distributors also accept drugs that are not controlled substances, so use of the term is actually broader than the regulatory reference. “Returns industry” refers to companies that return drugs to the manufacturer for credit. While some “reverse distributors” return drugs to the manufacturer for credit, others simply destroy the drugs.

Reverse distributors are defined by the DEA at 21 CFR 1300.01 (b)(41) as follows (see also Appendix B):

(41) The term reverse distributor means a registrant who receives controlled substances acquired from another DEA registrant for the purpose of—

(i) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer’s agent; or

(ii) Where necessary, processing such substances or arranging for processing such substances for disposal.

The Returns Industry Association provides resources for reverse distribution companies at http://www.returnsindustry.com/. A brief summary of the industry is provided in the Mission Statement:

The pharmaceutical returns industry is an integral element of the U.S. healthcare system. Reverse distributors handle a large percentage of those pharmaceutical products that become outdated before use. They assist pharmacies and drug wholesalers in returning these items for credit or assuring environmentally responsible disposal. They assist pharmaceutical manufacturers by providing an economical outsourcing alternative to return goods processing. And, by providing efficient reverse supply chain management, they reduce total cost in the healthcare system.

A returns company fee is often based on a percentage of the credits received from drug manufacturers. By accepting drugs as product and making the decision about whether the drug is waste, reverse distributors are in the position of designating drug waste, and thus become the waste generator. If some drug wastes designate as hazardous under Federal or state hazardous waste regulations, the reverse distributor can separate them from other drugs for proper disposal at permitted hazardous waste facilities. Federal and state guidance in Appendices D, E and F provide the foundation for reverse distributor operations under hazardous waste regulations.
SURVEY METHODS

A list of thirty-four national reverse distributors was obtained from the Washington State Department of Ecology. Companies were contacted by telephone and surveyed using a preprinted questionnaire (see Appendix C). For companies with telephone numbers no longer in service, an internet search was conducted to locate current company information, if possible.

Microsoft Access 97 was used to compile and analyze data. In some cases, data gaps were identified and follow-up calls made to complete the surveys. A final list of companies in a format suitable for distribution to businesses with drugs was then prepared (see the Resource Directory in Appendix A).
FINDINGS

General Information

Reverse distributor operations ranged from small family-owned companies to large national companies with multiple locations and trucking fleets. Most companies were located in midwest, northeast or southeast states. Only four were in western states and just one of these in Washington.

Out of thirty-four surveys attempted, twenty-seven were completed. The remaining seven companies were out of business, not found, did not respond to inquiries or were not reverse distributors.

Reverse Distributors with Services in King County

Of the twenty-seven companies surveyed, twenty-three provided services in King County. All twenty-three provide mail-in service and seven also provide on-site pick up services.

Service Limitations

Companies were asked about general classes of drugs for which they provide service. In addition to the types of drugs summarized below, other classes of drugs (over-the-counter drugs, health, beauty or cosmetic products and diagnostics) may be accepted by some companies; these were not summarized for the survey. Out of the twenty-seven companies surveyed, the number of companies accepting four general drug classes are listed below.

<table>
<thead>
<tr>
<th>Drug Class</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Controlled substances</td>
<td>27</td>
</tr>
<tr>
<td>Legend drugs¹</td>
<td>27</td>
</tr>
<tr>
<td>Sharps</td>
<td>22</td>
</tr>
<tr>
<td>Household (patient returns)</td>
<td>7</td>
</tr>
</tbody>
</table>

Services for each general class of drugs may be limited by individual company policies or permits. Examples are:

¹ Legend drugs are those labeled, "caution: Federal law prohibits dispensing without prescription," in conformance with Section 503(b)(1) of the Federal Food, Drug and Cosmetic Act.
• Most reverse distributors are permitted to handle Schedule II through V controlled substances but not Schedule I (these drugs are not approved for medical use). See also the finding titled “Types of Permits.”

• Some companies accept drugs only within specified periods before and/or after shelf-life expiration.

• Most reverse distributors accept unused sharps packaged with a drug, but do not accept used sharps.

• Some companies accept over-the-counter drugs only from large stores or pharmacy chains.

• One company does not accept drugs from veterinary offices (stating that these drugs don’t have the National Drug Code needed for their computer tracking system.)

• Household drugs (also called patient returns) were typically accepted only under certain conditions: the drug was returned through the pharmacy that dispensed it; the drug was not a controlled substance (DEA registrants may not accept controlled substances from non-registrants, such as patients); patient health information subject to privacy laws was protected; and the reverse distributor held the contract as the “returns department” for the manufacturer of the returned drug.

While most mail-in services have no minimum quantity requirements, they often have a minimum charge. On-site service typically consists of reverse distributors reviewing drug inventories for excess stocks, preparing paperwork and transferring excess drugs to the reverse distributor’s credit processing center.

One company expressed interest in establishing household drug collection events similar to household hazardous waste collections, under contract with local governments.

**Drug Acceptance Policies**

The Environmental Protection Agency and some states (Washington and Florida) have issued guidance (see Appendices D, E, and F) concerning types of drugs that may be considered “waste.” Drugs that designate as federally regulated hazardous waste or state regulated dangerous waste should be handled through facilities with hazardous waste permits. The twenty-seven reverse distributors were asked about acceptance policies for drugs that may meet the regulatory definition of “waste,” at least in some states.

Accept samples: 25
Accept partially used, opened bottles: 25
Accept dropped pills, broken containers or vials, drugs that fell on the floor, or IV bags: 18

According to many respondents, credit may be issued by manufacturers for some or all of these items. Returned samples may still be in-date and reusable. Several companies
stated that if a National Drug Code was visible on a pill, it was returnable for credit even if it had dropped on the floor.

It should be noted that drug manufacturers change their return policies constantly. Clarification of regulatory guidance and education of both regulators and the reverse distribution industry would be helpful in identifying potentially regulated waste.

**Disposition of Drugs**

The few reverse distributors that hold “returns department” contracts from drug manufacturers stated that the disposition of drugs received is controlled by the manufacturer, as specified in the contract. Most reverse distributors appear to have developed a business relationship with one or two convenient disposal sites, using them on a regular basis. Two companies did not provide disposal data. Types of facilities receiving drugs are listed in Table 1.

<table>
<thead>
<tr>
<th>Table 1, Facilities Receiving Drugs from Reverse Distributors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Facilities Receiving Drugs</td>
</tr>
<tr>
<td>-----------------------------</td>
</tr>
<tr>
<td>Hazardous waste incinerator¹</td>
</tr>
<tr>
<td>Waste-to-energy incinerators²</td>
</tr>
<tr>
<td>Incinerator (type not specified)</td>
</tr>
<tr>
<td>Medical waste incinerator</td>
</tr>
<tr>
<td>Medical waste microwave facility</td>
</tr>
<tr>
<td>Transferred to another reverse distributor</td>
</tr>
</tbody>
</table>

¹ Nine reverse distributors segregate drugs so only non-hazardous drugs go to waste-to-energy incinerators and hazardous drugs go to hazardous waste incinerators. Two reverse distributors send all drugs to hazardous waste incinerators.

² The same nine reverse distributors that segregate drugs and were counted under Hazardous waste incinerators are counted again here. Three reverse distributors accept both hazardous and non-hazardous drugs and send all drugs to waste-to-energy plants. Three reverse distributors do not accept drugs that could designate as hazardous and therefore send only non-hazardous drugs to waste-to-energy incinerators.

* One company may use more than one disposal facility.

**Types of Permits**

Reverse distributors need various permits to operate. For this survey, only general permit information was collected. All survey respondents believed that they held all permits necessary to operate. Permits mentioned by survey respondents included:

- Drug Enforcement Administration controlled substance registration. Most were permitted to handle schedule II through V drugs; only two were registered for schedule I drugs. One reverse distributor was registered to handle schedule III-V drugs only and subcontracted schedule II drug management to another registered reverse distributor.
• State Board of Pharmacy license. Licensing requirements vary by state. Many reverse distributors were licensed in multiple states.

• Environmental Protection Agency hazardous waste identification number. Reverse distributors were small quantity generators, fully regulated large quantity generators or hazardous waste transporters. A few facilities had no hazardous waste identification number (see discussion in the chapter titled “Reverse Distributor Operational Models.”)

• Local solid waste management permit.

• Local medical waste management permit.

**How Clients Can Make Reverse Distribution Work Smoother**

This section summarizes responses to the question, “What should your clients do to make this service run smoother?” It was also phrased as follows: “While we are visiting sites with pharmaceuticals, what practices should we reinforce that will help the reverse distribution process run smoother?” Responses were grouped into several recurring themes that can be incorporated into best management practices. For details about each theme, see Appendix G.

• Package drugs, especially liquids, ampoules and inhalers, to prevent breakage
• Improve inventory management for timely return of drugs
• Identify all drugs returned
• Properly itemize and complete paperwork for controlled substances

General comments about the system of reverse distribution, environmental requirements, incineration and costs of proper drug management are listed in Appendix G.
REVERSE DISTRIBUTOR OPERATIONAL MODELS

Reverse distributors work with different operational models based on their own business policies and market conditions. Their policies can affect where drugs are first declared waste, the client’s generator status, and/or hazardous waste permit requirements for shippers or receivers of drugs. Existing federal or state guidance (see Appendices D, E and F) does not necessarily account for the variety of current practices. Based on responses from the twenty-seven companies surveyed, this chapter summarizes key issues that may be helpful to those agencies revising guidance or outreach materials in the future.

No Credit Processing

Four licensed reverse distributors do not manage credit processing through drug manufacturers. (A “zero credit invoice” may be issued for every pickup or clients are encouraged to process manufacturer credits themselves.) Some companies clearly market themselves as providing destruction service only. Some may specialize in witnessed destruction of controlled substances only and others may pick up drugs and transport them directly to the incinerator, without stopping at a reverse distributor location.

Two of these four companies do not have a hazardous waste identification number. One of them screens out potentially hazardous drugs to ensure only non-hazardous drugs are accepted for disposal; the other does not.

Pre-shipment Screening

Six companies ask clients to submit drug lists prior to shipment and use a screening criteria to determine acceptance. If drugs not meeting the screening criteria are shipped anyway, they are returned to the client. Screening criteria, with the number of companies using the criteria, include:

- Whether the drug designates as a federally regulated hazardous waste (used by two companies).
- Whether the drug has credit value (used by one company).
- Whether the drug is made by specified manufacturers (used by two companies).
- Client type (one company doesn’t accept drugs from veterinarians because they lack a National Drug Code.)

Pre-shipment Segregation

One company provides pre-labeled shipping boxes for use at the client’s location. While being collected on-site the client segregates drugs that would designate as federally regulated hazardous waste, chemotherapy drugs and biohazardous (infectious) waste into
separate containers. The reverse distributor may take the drugs directly to an incinerator or to a credit processing center (if they have value).

**Hazardous Waste Identification Number**

Seven of twenty-seven respondents either did not have Environmental Protection Agency hazardous waste identification numbers (5) or did not know if they had one (2). Some were not aware that some waste drugs are federally-regulated hazardous waste and dispose of all drug wastes at facilities without hazardous waste permits. One respondent requested a list of drugs that designate as hazardous waste. (One company does not accept drugs that would be federally regulated hazardous waste when disposed and thus needs no identification number.)

It’s possible that some companies actually have hazardous waste identification numbers, unknown to survey respondents. If this occurred, however, it underscores the difficulty potential clients may experience in choosing qualified service providers.

All survey respondents knew their Drug Enforcement Administration and Board of Pharmacy license status.

**Destruction-Only Service**

Fifteen of the twenty-seven reverse distributors offer some form of “destruction-only” service (i.e., certain types of drugs accepted by the reverse distributor will not be evaluated for credit or recycling potential). Destruction-only services are summarized in Table 2 below.

<table>
<thead>
<tr>
<th>Destruction-only Service</th>
<th>Number of Reverse Distributors With the Service</th>
<th>Additional comments made by survey respondents.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug samples</td>
<td>6</td>
<td>Company accepts no waste, only products.</td>
</tr>
<tr>
<td>Pills dropped on the floor</td>
<td>1</td>
<td>Company accepts no waste, only products.</td>
</tr>
<tr>
<td>Samples and pills dropped on the floor</td>
<td>2</td>
<td>NA.</td>
</tr>
<tr>
<td>Small quantities (amount not defined in response)</td>
<td>1</td>
<td>No returns service available for small amounts.</td>
</tr>
<tr>
<td>All drugs accepted are destroyed</td>
<td>4</td>
<td>Two of these companies accept no drugs that could designate as hazardous waste.</td>
</tr>
<tr>
<td>Determined individually for each client</td>
<td>1</td>
<td>If waste at the time of pickup, it goes straight to the incinerator; if it has value, it goes to the credit processing center.</td>
</tr>
</tbody>
</table>
SUMMARY AND CONCLUSIONS

A national telephone survey of twenty-seven pharmaceutical reverse distributors was conducted to identify services offered, acceptance policies and other general information about the industry. From these and prior surveys of hazardous waste companies, a Resource Directory (see Appendix A) was completed to help businesses in King County get rid of unwanted pharmaceuticals.

Of the twenty-three reverse distributors available to King County businesses, most provide only mail-in service. All of them accept controlled substances and legend drugs. Most can accept unused sharps packaged with drugs. Options for patient-returned drugs are limited, and Drug Enforcement Administration regulations prohibit return of controlled substances by patients. Most reverse distributors accept small quantities of drugs although some charge a minimum fee per shipment.

Reverse distributors establish individual acceptance criteria and business policies that affect whether a client receives credit for returned drugs. In some cases, the policies may cause the client to become the “generator” of hazardous wastes because a decision that a drug is “waste” occurs while the drug is on the client’s property. Some reverse distributors do not have hazardous waste identification numbers.

Some confusion exists among hazardous waste regulators and reverse distributors concerning which types of drugs are inherently waste-like and which can be received as “product.” Further clarification of requirements and outreach to the industry would be helpful.

Reverse distributors offer a needed service to the medical community and the public by arranging for recycling or destruction of unwanted pharmaceuticals, including controlled substances. Financial incentives (credits for returned pharmaceuticals) offered by drug manufacturers encourage dispensers to track inventories and return drugs. Overall, this product stewardship system seems to work well.
APPENDIX A

RESOURCE DIRECTORY FOR THE MANAGEMENT OF PHARMACEUTICALS IN KING COUNTY

<http://www.govlink.org/hazwaste/publications/PharmBib_03.pdf>
APPENDIX B

DEFINITION AND REGISTRATION OF REVERSE DISTRIBUTORS
DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Parts 1300, 1301, 1304, 1305, and 1307

[Docket No. DEA-108I] RIN 1117-AA19

Definition and Registration of Reverse Distributors

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Interim final rule with request for comment.

SUMMARY: DEA is amending its regulations to define the term "reverse distributor" and to establish a category of registration for persons handling controlled substances. The amendments establish regulatory standards under which reverse distributors may handle unwanted, unusable, or outdated controlled substances acquired from another DEA registrant. These standards ensure the proper documentation and recordkeeping necessary to prevent diversion of such controlled substances for legitimate purposes. Since this amendment mostly codifies DEA's existing practices, it will have no significant impact on existing reverse distributors.

DATES: Effective Date: August 11, 2003. Comment Date: Written comments must be postmark

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

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

**SUPPLEMENTARY INFORMATION:**

Overview of and Benefits of This Interim Final Rule

As is more fully discussed in this preamble, this interim final rule mostly codifies existing practices reverse distributors follow under memorandums of understanding (MOUs) with the Drug Enforcement Administration. This approach is consistent with the comments received (also discussed more fully in this preamble) that stated that reverse distributors would be significantly and adversely impacted by the proposal, they were classified as manufacturers. In recognizing this activity as a separate registrant category of distributors, DEA believes the entire controlled substances industry will benefit. Existing distributors operating under MOUs will become fully recognized registrants under DEA rules. The other registrants who need to dispose of unneeded or outdated inventories will be able to turn to a registered group of distributors. Furthermore, by essentially codifying existing practices these benefits can be achieved with minimal need for change or for disruption to the affected industry.

Background

The overall goal of the Controlled Substances Act (CSA) and of DEA’s regulations in Title 21, C

Federal Regulations (CFR), parts 1300-1316 is to provide a closed distribution system so that a substance is at all times under the legal control of a person registered, or specifically exempted from registration, by the Drug Enforcement Administration until it reaches the ultimate user or is destroyed. Thus, any movement of controlled substances between these registered persons is covered by regulations,

[[Page 41223]]

which ensure that all controlled substances are accounted for from their creation until their consumption or destruction. When a controlled substance has become outdated or otherwise unusable, the registrant who possesses the substance must dispose of it. However, over the past decade, environmental concerns and regulatory changes have caused drug manufacturers and government agencies (DEA and State authorities) to become increasingly reluctant to be involved in the disposal process; many disposal options are no longer available. Nonetheless, disposal of controlled substances may be accomplished in several ways:

1. The distributor or dispenser can return the controlled substances to the pharmaceutical manufacturers who, as a service to their customers, accept returns of outdated/damaged substances. Distributors, dispensers, and manufacturers are all registered with DEA.

2. The distributor, dispenser, or manufacturer can itself dispose of the controlled substances in accordance with procedures outlined in 21 CFR 1307.21. Under 21 CFR 1307.21, anyone may request
to dispose of controlled substances without the benefit of a DEA or State witness. In many
blanket permission for disposal of controlled substances is granted to registrants who have
ongoing need to dispose of unwanted controlled substances. The disposal must be authorized
DEA in writing, and DEA may require that a set schedule be established. Other registrants
granted disposal authority on a case-by-case basis. DEA normally requires that the registra
tion designate responsible individuals to accompany the drugs to the disposal site and observe
destruction. This achieves DEA's goal of assuring the controlled substances are rendered
nonrecoverable. Disposal under the authority of 21 CFR 1307.21 maintains the closed dis-
sposal system because the controlled substances remain under the legal control of a registered
registrant.

3. The distributor, dispenser, or manufacturer can distribute the controlled substances to a
distributor to take control of the controlled substances for the purpose of returning them to
the manufacturer or, if necessary, disposing of them.

For many years, DEA opposed granting DEA registrations to firms solely or primarily engaged in
disposal (whether the transportation portion, actual disposal, or both) of controlled substances
they were not considered an essential link in the closed distribution system that the Controlled Substances
Act established to control the flow of drugs from the manufacturer to the ultimate user. In recent
years, however, increasingly stringent requirements imposed by the U.S. Environmental Protection
Agency resulted in fewer and fewer approved disposal facilities. As a result, a new type of business has
developed that collects controlled substances from registrants and either returns them to the manufacturer
for their disposal. The businesses performing this middleman service refer to themselves as "reverse distributors" or "returns processors."

This interim final rule deals only with the distribution of controlled substances to reverse distribu-
tors. The first two categories--direct returns of controlled substances by distributors or dispensers to man-
ufacturer and disposals by the distributor, manufacturer or dispenser--are already covered by the existing
regulations, although DEA has regulated reverse distributors for many years as distributors generally, and second, as reverse distributors specifically under the terms of Memoranda of Understanding (MOUs), through which they are granted DEA registrations. This rule will eliminate
regulatory standards governing disposers of controlled substances. DEA proposed to accompli-
achieve DEA's goal of assuring the controlled substances are rendered
nonrecoverable. Disposal under the authority of 21 CFR 1307.21 maintains the closed dis-
sposal system because the controlled substances remain under the legal control of a registered
registrant.

On August 23, 1995, DEA issued a Notice of Proposed Rulemaking (NPRM) (60 FR 43732) the
regulatory standards governing disposers of controlled substances. DEA proposed to accomplish
amending its regulations to define the term "Disposer" to account for this middleman function in
registrations and establish a new category of manufacturer registration under which persons performing
function would be registered. DEA also proposed amending the regulations to exempt disposers
from quota requirements; to identify the records and reports required of disposers; and to establish
procedures for disposers. Finally, DEA proposed amendments to a number of gender-specific sections
make them gender neutral.

DEA originally based its decision to define the persons performing the reverse distribution function
disposers on the definition of "manufacturer." In 21 CFR 1300.01(b)(27), DEA defines manufactur-
the producing, preparation, propagation, compounding, or processing of a drug or other sub-
section further defines a manufacturer as "a person who manufactures a drug or other sub-
In the proposed rule, DEA stated that by its nature, a disposer processes a drug or other sub-
Therefore, DEA proposed to place disposers within the definition of manufacturer, under a new
subcategory. Commenters to the proposed rule objected to being categorized as disposers and manufacturers for the reasons explained below under "Comments." Therefore, in this interim final rule DEA is establishing a definition for "reverse distributor" and is establishing a new category of registrants: reverse distributors.

DEA is using an interim final rule because it will give interested persons an additional opportunity to comment even though the substance of this interim final rule is consistent with the purpose of the 1995 NPRM, the comments submitted in response to that NPRM, and with current DEA and industry practice.

Currently DEA registers persons performing reverse distributor functions as distributors. Since reverse distributors are not specifically identified in the current regulations, DEA enters into a Memorandum of Understanding (MOU) with the person performing the reverse distribution function. The Memorandum of Understanding (MOU) specifies conditions which the reverse distributor must follow in addition to the regulations that apply to distributors. These registrations must be renewed annually and operate them are limited to products in schedules listed on the registration. DEA has not experienced any difficulties in treating reverse distributors as distributors for purposes of registration and other requirements. Any reverse distributor that was registered under the terms of a MOU will be reregistered as a reverse distributor under the terms of this interim final rule in the next renewal cycle and will be specifically identified in DEA's records as a reverse distributor. Persons currently conducting reverse distribution operations must notify DEA by no later than the time of renewal of their registration so that they are properly identified as reverse distributors in DEA's records.

The requirements for a reverse distributor in this interim final rule are similar to those currently in place for 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 in accordance with the existing standards of 21 CFR 1301.71 and 1301.72.

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

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

- **Reports**: Reports are required under the Automation of Reports and Consolidated Orders System (ARCO) 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 16038, March 24, 1997) that reorganized and clarified the regulations that would have been affected by the NPRM. The 1997 rulemaking also addressed the gender-specific and other editorial changes that contained in the 1995 NPRM. Therefore, proposed changes to 21 CFR 1301.26 (now 21 CFR 1301.26)
Exemption of law enforcement officers; 21 CFR 1301.32 (now 21 CFR 1301.13), Application for contents; signature; and 21 CFR 1304.34 (now 21 CFR 1304.33(a)), Reports generally, are not 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 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 currently operating under Memoranda of Understanding (i.e., facilities such as incinerators 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. This 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 disposing or manufacturing and stated that doing so would subject them to unnecessary and burdensome requirements.

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 authority to regulate these companies as manufacturers. Another commenter stated that the purpose of disposers is not to render a controlled substance unusable, but, rather, it is to sort, inventory, 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 manufacturer 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 distributors establishing a new category of registration as reverse distributors. In this interim final rule, DEA has amended the definition for "reverse distributors" to 21 CFR 1300.01(b). Reverse distributors are defined as a company who receives controlled substances acquired from another DEA registrant for the purpose of return to an unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer or, where necessary, processing such substances or arranging for processing such substances for disposal." When reverse distributors return unwanted, unusable, or outdated controlled substances, they must follow the same DEA requirements as distributors do. If they 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 1301.67 "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 exempt dentists and other small disposers by quantity, or state that they are not members of the 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 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 on behalf of manufacturers provided that the manufacturer's representatives bring the controlled substances to the 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. Those procedures are designed to ensure that controlled substances are under control of a DEA registrant until they are destroyed or rendered unusable. If a disposal company 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 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.

[[Page 41225]]

Usually this involves obtaining authority and instructions from the local DEA field office as specified in 21 CFR 1307.21. Such registrants also have the option of returning controlled substances to the manufacturer or to a reverse distributor.

Appropriateness of Security and Other Requirements That Apply to Manufacturers

Commenters recommended creating a separate category for reverse distributors, as a subcategory of distributors, who would be subject to the existing registration and other requirements for distributors. Commenters stated that reverse distributors should, therefore, not be subject to the security, inventory, recordkeeping, and reporting requirements of the proposed rule that apply to manufacturers.

DEA’s Response

Since DEA has decided to create a completely separate category for reverse distributors, persons under this category will be required to comply with the same security, reporting, and other requirements that apply to distributors rather than the requirements that apply to manufacturers.

Proposed Security Requirements: Monitoring Systems

DEA received one comment on the language in proposed 21 CFR 1301.71(b)(14) which requires an applicant or registrant to document the adequacy of its system for monitoring the receipt, manual...
distribution, and disposal of controlled substances. The commenter stated that all of the "waste facilities that it operates have demonstrated that the implementation of supervised monitoring o and disposal process, by the disposer, has proven effective and that it would be physically impc them to construct the vaults or other security barriers that the regulations require for storage at manufacturer's locations (under 21 CFR 1301.72). Instead, this commenter recommended that be required to develop a set of Standard Operating Procedures, to be approved by DEA, for the disposal of controlled substances.

**DEA Response**

With respect to the issue of physical security, it should be noted that the commenter does not t possession of the controlled substances that are to be destroyed. Instead, the commenter main incineration facilities at which DEA registrants carry out witnessed destruction of their controlled substances. As a result, the commenter is not subject to DEA's requirements and does not have establish or maintain physical security as required under 21 CFR 1301.72 of the regulations.

**Proposed Security Requirements: Compliance With Other Laws**

One commenter commented on proposed 21 CFR 1301.71(b)(15), which would require DEA to the applicability of the security requirements contained in all Federal, State, and local laws and governing the management of waste, as they would apply to applicants and registrants. The co stated that this requirement would be inappropriate because it would exceed DEA's statutory au While DEA inspectors should be concerned with compliance with DEA statutes and regulations audits, the inspectors should not be empowered to look for violations of other Federal, State, ar governing the management of waste. Enforcement of those laws should be left to the other Fed agencies and individual jurisdictions. Therefore, the commenter requested DEA clarification on

**DEA Response**

With respect to this comment, the items listed in 21 CFR 1301.71(b)(1) through new (b)(15) are the Administrator may consider in evaluating whether the security controls provided by a DEA n adequate to guard against theft and diversion of controlled substances and appropriate to the re business. Not all of the factors may be relevant for evaluation of a particular registrant's oper adding a new factor regarding the applicability of other Federal, State, or local laws, not as an e issue for those specific laws, but only as guidance to the registrant that DEA may consider how registrant is complying with such laws in making an evaluation of the adequacy of the registrant system. DEA has the statutory authority under 21 U.S.C. 823 applicable State and local laws before granting a registration.

**Proposed Inventory Requirements**

A commenter that provides disposal facilities at which registrants may conduct witnessed destrn recommended that additional language be added to the end of proposed 21 CFR 1304.20 (curr 1304.11) to require that the information required under 21 CFR 1304.15(a), (c), and (d) be prov manufacturer or its agent when tendering the substances for disposal.

**DEA Response**

The commenter's suggested change is not necessary because in witnessed destructions the re conducting the destruction must accurately document the controlled substances being destroye
Form 41. Further, a disposal facility of the type operated by the commenter does not take possession of controlled substances being destroyed and, thus, is not subject to the registration, inventory, and recordkeeping requirements under the law.

**Proposed Recordkeeping Requirements**

Several commenters made recommendations to change the language of proposed 21 CFR 130 (current 21 CFR 1304.22) to make the specific requirements clear.

A commenter also expressed concern about proposed paragraph (b) and stated that the disposal facility should not be expected to recount and itemize the individual dosage units and containers for each substance being delivered for disposal. This would put their employees at possible risk for exposure to the substances, increase opportunities for diversion, and significantly slow down the disposal operation. Instead, the commenter recommended that sufficient controls be placed on the manufacturer or representatives prior to disposal so that the disposer can focus on rapid and effective disposal.

**DEA Response**

The comments primarily address problems that could have arisen if the reverse distribution function included under manufacturing, as proposed. These concerns are mostly addressed by treating reverse distribution as a separate category of registration. The concerns expressed by disposers are, as discussed, not relevant as long as legal control of the controlled substances remains with a person registered with DEA.

Recordkeeping requirements for reverse distributors are set forth in new paragraph (e) of 21 CFR 130. These requirements are tailored to the reverse distributor role and address recordkeeping for controlled substances in both bulk and finished form. These requirements are consistent with existing practices.

[[Page 41226]]

**Witness Requirement**

A commenter stated that DEA would require two responsible individuals to accompany the drug disposal site and actually witness the destruction. The commenter stated that this would significantly increase the costs of controlled substances destruction for all registrants and that the rule should, therefore, require a regulatory flexibility analysis.

**DEA Response**

The requirement to have two responsible individuals accompany the drugs to the disposal site is consistent with existing practice. DEA Form 41, Registrants Inventory of Drugs Surrendered, may be completed by a registrant's representative and witnessed by a second representative of the registrant to document the disposal of controlled substances. This form must be sent to DEA.

**Proposed Reporting Requirements**

A commenter stated that ARCOS reporting becomes difficult and costly when a disposer receives a quantity of a controlled substance listed in Schedule I and II and a narcotic controlled substance in Schedule III which is contained in a compound, mixture or preparation which is not assigned an identification number. The commenter stated that this reporting "will become more difficult as more returns are submitted."
from Pharmacies, Home Infusion Pharmacies, Provider Pharmacies to Long Term Care Facilities, Hospitals, and dispensers."

The commenter recommended adding a new paragraph (e) to current 21 CFR 1304.33 (former 1304.39) that would provide for the following exception: "Exceptions. Any controlled substance Schedule I and II and on each narcotic controlled substance listed in Schedule III which material compounded, mixture or preparation containing a quantity of a substance from a registered dispensers, researchers, and analytical registrants, e.g., prescription, IV mixture or non NDC m be exempted from filing reports under this section to ARCOS Units of the Administration." The commenter also stated that proposed paragraphs (b) and (c) (with regard to ARCOS reports being filed no l the 15th day of the month or no later than January 15th) would have a significant economic imp lead to ARCOS delays. This is because disposers (unlike manufacturers or distributors) deal with containers that need validation (by count, weight, and/or volume) before the containers can be inventory; this can be a slow and tedious process. The commenter added that the economic impo ARCOS delays would increase as the disposer class registration utilization grows.

**DEA Response**

While the commenter addressed the reporting requirements in proposed 21 CFR 1304.39(b) an commenter's real concern appears to be related to inventory requirements currently in 21 CFR. This interim final rule will allow reverse distributors to follow the inventory requirements that cur to dispensers and researchers. This would mean that in the circumstances described in 21 CFR (3)(ii), it would not be necessary to make an exact count or measure of the contents in all cases controlled substance is listed in Schedule III, IV, or V, and the container holds fewer than 1,000 capsules, the reverse distributor could make an estimated count or measure.

Notwithstanding this change, a reverse distributor is required to know what it has on hand from it is received. It is the reverse distributor's responsibility to have the proper documentation and accountability for any controlled substances in his or her possession. The best way for reverse to accomplish this is by doing the following: (1) Require customers to provide a list of the contro substances to be sent in advance of the shipment; (2) Complete a form or invoice indicating the that the customer will be sending, keep a copy of this document, and send 2 copies to the cust (3) Require the customer to keep one copy of the document and put the other copy in the pack shipment. This procedure would maintain a paper trail and provide the data on inventory from the shipment is received by the reverse distributor. Reverse distributors who follow this procedu not have difficulty preparing the ARCOS reports that are required by current 21 CFR 1304.33 for substances listed in Schedules I and II, and for narcotic controlled substances listed in Schedule and V.

With respect to the issue of non-NDC material, such as compounded prescription products or ir products, DEA's ARCOS Unit has established a listing of generic codes that can be used to ide products that do not have an NDC number assigned. If a product being handled does not have code, please contact the ARCOS Unit of the Administration for assistance.

Reverse distributors are encouraged to make use of electronic identification and tracking syster bar codes, to aid in meeting the inventory and reporting requirements. Also, reverse distributors electronic versions of DEA Form 41 if the electronic version is an exact reproduction of the form. electronic version is not identical to the paper version, it is not the official form, and may not be

DEA invites manufacturers, reverse distributors, and other distributors to work with the Admini
establish standard operating procedures so there is a standard recordkeeping system for transfer receiving, and inventorying partial containers. With a standardized system there would be fewer inconsistencies among the records of each registrant when controlled substances are transferred to another.

**Proposed Order Form Requirements**

A commenter stated that in the preamble, DEA stated that "Order Forms must be completed for Schedule I and III items received and transferred." The commenter stated that this is incorrect and a correct statement should be: "Order Forms must be completed for all Schedule I and II items received and transferred."

**DEA Response**

DEA agrees that there was a typographical error in the preamble and is clarifying that order forms (Form 222) required by part 1305 are for Schedule I and II controlled substances received and transferred.

**Reverse Distributor Receipt of Controlled Substances From Non-registrants**

Under the interim final rule, reverse distributors may only receive controlled substances from DEA registrants. Non-registrants, such as long term care facilities, do not have direct authority to have controlled substances. Further, the substances in their possession are no longer part of the closed system of distribution and are no longer subject to DEA's system of corresponding accountability. In case of a drug shortage, long term care facilities must dispose of controlled substances, they should follow the guidelines by State for disposing of the drugs and maintain appropriate documentation of the disposal. Likewise, a registrant, such as a pharmacy, whose registration has expired or has been surrendered, would coordinate with the local DEA office to develop a procedure to dispose of any controlled substances on hand.

**Why Is DEA Publishing This Action as an Interim Final Rule?**

As discussed previously, the goal of the NPRM was to give codified status to reverse distributor DEA initially proposed doing this by registering reverse distributors in the manufacturer category (comments on the NPRM made it clear that this approach would adversely affect the existing industry by subjecting reverse distributors to certain EPA and FDA regulations). By registering reverse distributors, DEA accomplishes its original goal in a manner that is consistent with the intent of the NPRM and with public comments on the NPRM. Also, this approach is beneficial rather than detrimental to the entire controlled substances industry. However, recognizing the time which has elapsed since publication of the NPRM and this action, as well as the growth and evolution of the reverse distributor industry during that time, DEA has determined that, rather than publishing final regulations on this industry evolution and concerns, it is in the best interest of industry that DEA publish an interim final rule. Publishing an interim final rule will permit further comment from the affected industry, ensuring that final regulations appropriately reflect industry evolution and concerns.

**Summary**

In summary, the registration and other requirements for reverse distributors under this interim final rule...
the same as those currently imposed on distributors and the same as currently imposed on reverse distributors under MOUs; Registration requirements under existing 21 CFR 1301.13; Security requirements under existing 21 CFR 1301.71 and 1301.72; Inventory requirements under existing 21 CFR 1301.72; Recordkeeping requirements under existing 21 CFR 1304.22; Reporting requirements under existing 21 CFR 1304.33 (ARCOS reports); Order form requirements under existing 21 CFR 1305.08 (Persons to fill order forms). In some cases these rules have been modified to apply specifically to reverse distributors. In addition, DEA is amending 21 CFR 1307.11 and 1307.12 to clarify that registrant controls substances to a reverse distributor, even if the registrant is not registered as a distributor. As a result of DEA’s decision to classify reverse distributors as a new category of registrant, instead of as a manufacturer, proposed 21 CFR 1303.12 on quotas is not applicable.

The closed system of distribution established under the CSA for controlled substances relies on fundamental principles, including registration, security, and accountability (i.e., inventories, record-keeping, and reporting), to achieve a system of controls that allows for legitimate commerce while minimizing potential for diversion. The fact that reverse distributors engage in a unique activity within the controlled substances chain and are faced with certain challenges that other registrants do not normally encounter does not override the fundamental principles of DEA’s controls. Reverse distributors must register, maintain security, and maintain accurate records for all controlled substances in their possession. However, the regulatory structure does provide some flexibility and, where possible, DEA has made adjustments to address some of the problems the industry has encountered, including use of a separate category of registration and application of the inventory requirements for dispensers and researchers.

Because of the length of time since the NPRM was published and the evolving nature of this industry, DEA is using an interim final rule to give an additional opportunity for comment. DEA will consider the appropriateness and the practical application of these rules to current industry practice and will make the rules as flexible as possible in developing final rules.

**Application for Registration for Reverse Distributors**

As has been previously noted in this rulemaking, persons wishing to conduct reverse distributor activities must register with DEA to do so. To apply for registration, persons must complete a DEA Form Application for Registration. To renew a DEA registration, persons must complete a DEA Form Application for Registration Renewal. As DEA has not yet issued updated forms specifically referring to reverse distributor business activity, persons wishing to register as reverse distributors must check the box for reverse distributor business activity on the form and then must attach a written statement signed by the registrant acknowledging that the applicant is conducting reverse distributor activities.

**Regulatory Certifications**

**Regulatory Flexibility Act**

The Deputy Assistant Administrator hereby certifies that this interim final rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), and by approving it certifies that this regulation will not have a significant economic impact upon a substantial number of small entities. Therefore, no regulatory flexibility analysis is required.

**Executive Order 12866**

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in acc
with the principles of Executive Order 12866 Section 1(b). DEA has determined that this rule is regulatory action. Therefore, this action has been reviewed by the Office of Management and B

Executive Order 12988

The Deputy Assistant Administrator further certifies that this regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

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, of $100,000,000 or more in any one year, and will not significantly or uniquely affect the public sector. 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, 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

21 CFR Part 1300

Definitions, Drug traffic control.

21 CFR Part 1301

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

21 CFR Part 1304

Drug traffic control, Reporting requirements.

21 CFR Part 1305
Drug traffic control, Reporting requirements.

21 CFR Part 1307

Drug traffic control.

- For the reasons set out above, 21 CFR parts 1300, 1301, 1304, 1305, and 1307 are amended as follows:

PART 1300--DEFINITIONS

- 1. The authority citation for part 1300 continues to read as follows:

  Authority: 21 U.S.C. 802, 871(b), 951, 958(f).

- 2. Section 1300.01 is amended by redesignating paragraphs (b)(41) through (b)(43) as paragraphs (b)(42) through (b)(44), and adding a new paragraph (b)(41) to read as follows:

  § 1300.01 Definitions relating to controlled substances.
  *

  (b) *

  (41) The term reverse distributor means a registrant who receives controlled substances acquired from another DEA registrant for the purpose of--

  (i) Returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent; or

  (ii) Where necessary, processing such substances or arranging for processing such substances for disposal. *

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

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

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

- 4. Section 1301.13 is amended by revising paragraph (c), redesignating paragraphs (e)(1)(ix) as paragraphs (e)(1)(v) through (e)(1)(x) and adding a new paragraph (e)(1)(ix) to read as follows:

  § 1301.13 Application for registration; time for application; expiration date; registration for independent activities; application forms, fees, contents and signature; coincident activities.
(c) At the time a manufacturer, distributor, reverse distributor, researcher, analytical lab, importer or narcotic treatment program is first registered, that business activity shall be assigned to one of groups, which shall correspond to the months of the year. The expiration date of the registration registrants within any group will be the last date of the month designated for that group. In assigning these business activities to a group, the Administration may select a group the expiration date of less than one year from the date such business activity was registered. If the business activity is assigned to a group which has an expiration date less than three months from the date of which the business is registered, the registration shall not expire until one year from that expiration date; in all other cases registration shall expire on the expiration date following the date on which the business activity was registered.

* * * * *

(e) **

(1) **

(iii) Reverse distributing Schedules I-V New -- 225

Renewal -- 225a 438

* * * * *

- 5. Section 1301.71 is amended by revising paragraphs (b)(13) and (b)(14) and adding a new paragraph (b)(15) to read as follows:

§ 1301.71 Security requirements generally.

* * * * *

(b) * * *

(13) The availability of local police protection or of the registrant's or applicant's security person

(14) The adequacy of the registrant's or applicant's system for monitoring the receipt, manufacture, distribution, and disposition of controlled substances in its operations; and

(15) The applicability of the security requirements contained in all Federal, State, and local laws regulating the management of waste.

* * * * *

- 6. Section 1301.72 is amended by revising paragraph (b)(7) to read as follows:

§ 1301.72 Physical security controls for non-practitioners; narcotic treatment programs; compounds for narcotic treatment programs; storage areas.

* * * * *

(b) * * *

(7) Such other secure storage areas as may be approved by the Administrator after considering...
listed in § 1301.71(b);

PART 1304--RECORDS AND REPORTS OF REGISTRANTS

7. The authority citation for part 1304 continues to read as follows:

Authority: 21 U.S.C. 821, 827, 871(b), 958(e), 965, unless otherwise noted.

8. Section 1304.11 is amended by revising paragraph (e)(2) and the introductory text of paragraph (3) to read as follows:

§ 1304.11 Inventory requirements.
* * * *

(e)
* *

(2) Inventories of distributors. Except for reverse distributors covered by paragraph (e)(3) of this section, each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section.

(3) Inventories of dispensers, researchers, and reverse distributors. Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs (e)(1)(iii) and (iv) of this section. In determining the number of units of each finished form of a controlled substance in a container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:

9. Section 1304.22 is amended by revising paragraph (b) and adding new paragraph (e) to read as follows:

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, and exporters.
* * * *

(b) Records for distributors. Except as provided in paragraph (e) of this section, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

[Page 41229]

or reverse distributor shall do as follows:
* * * *

9. Section 1304.22 is amended by revising paragraph (b) and adding new paragraph (e) to read as follows:

§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, and exporters.
* * * *

(b) Records for distributors. Except as provided in paragraph (e) of this section, each person registered or authorized to distribute controlled substances shall maintain records with the same information required of manufacturers pursuant to paragraphs (a)(2)(i), (ii), (iv), (v), (vii), (viii) and (ix) of this section.

[Page 41229]
(e) Records for reverse distributors. Each person registered to distribute controlled substances reverse distributor shall maintain records with the following information for each controlled subs

(1) For each controlled substance in bulk form the following:

   (i) The name of the controlled substance.
   (ii) The total quantity of the controlled substance to the nearest metric unit weight consist with unit size.
   (iii) The quantity received from other persons, including the date and quantity of each rece and the name, address, and registration number of the other person from whom the contr substance was received.
   (iv) The quantity returned to the original manufacturer of the controlled substance or the manufacturer's agent, including the date of and quantity of each distribution and the name address and registration number of the manufacturer or manufacturer's agent to whom the controlled substance was distributed.
   (v) The quantity disposed of including the date and manner of disposal and the signatures two responsible employees of the registrant who witnessed the disposal.

(2) For each controlled substance in finished form the following:

   (i) The name of the substance.
   (ii) Each finished form (e.g., 10-milligram tablet or 10-milligram concentration per fluid oun milliliter) and the number of units or volume of finished form in each commercial container 100-tablet bottle or 3-milliliter vial).
   (iii) The number of commercial containers of each such finished form received from other persons, including the date of and number of containers in each receipt and the name, ad and registration number of the person from whom the containers were received.
   (iv) The number of commercial containers of each such finished form distributed back to t l original manufacturer of the substance or the manufacturer's agent, including the date of a number of containers in each distribution and the name, address, and registration number manufacturer or manufacturer's agent to whom the containers were distributed.
   (v) The number of units or volume of finished forms and/or commercial containers dispose including the date and manner of disposal, the quantity of the substance in finished form disposed, and the signatures of two responsible employees of the registrant who witnesses disposal.

* 10. Section 1304.33 is amended by revising paragraph (c) to read as follows:

§ 1304.33 Reports to ARCOS.

(c) Persons reporting. For controlled substances in Schedules I, II or narcotic controlled substar Schedule III, each person who is registered to manufacture in bulk or dosage form, or to package, repackage, label or relabel, and each person who is registered to distribute, including each person registered to reverse distribute, shall report acquisition/distribution transactions. In addition to acquisition/distribution transactions, each person who is registered to manufacture controlled substance in bulk or dosage form shall report manufacturing transactions on controlled substances in Schedule each narcotic controlled substance listed in Schedules III, IV, and V, and on each psychotropic substance listed in Schedules III and IV as identified in paragraph (d) of this section.
PART 1305--ORDER FORMS

11. The authority citation for part 1305 continues to read as follows:

Authority: 21 U.S.C. 821, 828, 871(b), unless otherwise noted.

12. Section 1305.08 is amended by revising paragraph (b) to read as follows:

§ 1305.08 Persons entitled to fill order forms.

(b) A person who has obtained any controlled substance in Schedule I or II by order form may re- 

substance, or portion thereof, to the person from whom he/she obtained the substance, to the n 

of the substance, or to a registered reverse distributor pursuant to the order form of the latter p 


PART 1307--MISCELLANEOUS

13. The authority citation for part 1307 continues to read as follows:

Authority: 21 U.S.C. 821, 822(d), 871(b), unless otherwise noted.

14. Section 1307.11 is revised to read as follows:

§ 1307.11 Distribution by dispenser to another practitioner or reverse distributor.

(a) A practitioner who is registered to dispense a controlled substance may distribute (without b r 

registered to distribute) a quantity of such substance to--

(1) Another practitioner for the purpose of general dispensing by the practitioner to patienti 

provided that--

(i) The practitioner to whom the controlled substance is to be distributed is registered unde 

Act to dispense that controlled substance;

(ii) The distribution is recorded by the distributing practitioner in accordance with § 1304.2 

this chapter and by the receiving practitioner in accordance with § 1304.22(c) of this chap 

(iii) If the substance is listed in Schedule I or II, an order form is used as required in part 1 

this chapter; and

(iv) The total number of dosage units of all controlled substances distributed by the practit 

pursuant to this section and § 1301.25 of this chapter during each calendar year in which 

practitioner is registered to dispense does not exceed 5 percent of the total number of dos 

units of all controlled substances distributed and dispensed by the practitioner during the s 

calendar year.

(2) A reverse distributor who is registered to receive such controlled substances.
(b) If, during any calendar year in which the practitioner is registered to dispense, the practitioner has reason to believe that the total number of dosage units of all controlled substances which will be by him pursuant to paragraph (a)(1) of this section and § 1301.25 of this chapter will exceed 5 pa this total number of dosage units of all controlled substances distributed and dispensed by him in the calendar year, the practitioner shall obtain a registration to distribute controlled substances.

- 15. Section 1307.12 is amended by revising the title and revising paragraph (a) to read as

[[Page 41230]]

§ 1307.12 Distribution to supplier or manufacturer.

(a) Any person lawfully in possession of a controlled substance listed in any schedule may distribute (without being registered to distribute) that substance to the person from whom he/she obtained the manufacturer of the substance, or, if designated, to the manufacturer's registered agent for accessing returns, provided that a written record is maintained which indicates the date of the transaction, form and quantity of the substance, the name, address, and registration number, if any, of the person making the distribution, and the name, address, and registration number, if known, of the supplier making the distribution. In the case of returning a controlled substance in Schedule I or II, an order form used in the manner prescribed in part 1305 of this chapter and be maintained as the written record of the transaction. Any person not required to register pursuant to sections 302(c) or 1007(b)(1) of the U.S.C. 822(c) or 957(b)(1)) shall be exempt from maintaining the records required by this section.

*   *   *   *   *


Laura M. Nagel,
Deputy Assistant Administrator, Office of Diversion Control.

[FR Doc. 03-17578 Filed 7-10-03; 8:45 am]
BILLING CODE 4410-09-P

NOTICE: This is an unofficial version. An official version of these publications may be obtained directly from the Government Printing Office (GPO).
APPENDIX C

REVERSE DISTRIBUTOR SURVEY
QUESTIONNAIRE
Date of Contact:

Reverse Distributor Survey Questionnaire

«Company» Contact: «FirstName» «LastName»
«Address1» Contact Phone: «ContactPhone»
«City», «State» «PostalCode» Other contacts: «Additional_contacts»
Customer Service: «Customer_Phone» Fax: «Fax»
e-mail/web site: «Email» «WebSite»

Company Profile: «Company_Profile»
Notes: «Notes»

Introductions; describe purpose of call; find the person who can answer these questions.

Does your company accept pharmaceuticals?
   If no, do you know a company that does?
   If yes, clarify the following:
   □ accept shelf-life expired drugs?
   □ accept partially used drugs, opened bottles, etc.
   □ accept pills that dropped on the floor or broken containers?
   □ accept samples?
   □ are manufacturer’s credits processed & returned to clients?

Service available in King County, Washington?

Quantity or service limitations (service available to small generators)?

Describe service for these wastes, including a cost estimate (designation? packaging? transportation? processing? final disposal?)
• DEA-controlled substances? Witnessed destruction?

• Legend drugs?

• Sharps?

• Infectious waste?

• Drugs returned by patients or from households?
Date of Contact:

**What permits do you have?**
RCRA ID#:  
DEA licensee or other authorization:  
Health dept:

**What should your clients do to make this service run smoother?**

**Other Notes:**

*Confirm/update contact information on top of the page.*
APPENDIX D

ENVIRONMENTAL PROTECTION AGENCY
GUIDANCE
MAY 13, 1981

Mr. Steven C. Wittmer
Environmental Facilities Engineer
MERCK SHARP & DOHME
West Point, Pennsylvania 19486

Dear Mr. Wittmer:

Your letter of March 26, 1981 requests our interpretation of the RCRA hazardous waste regulations as applied to products eventually discarded at your West Point plant.

40 CFR §261.33 is the controlling provision: the materials you describe, including U245, become hazardous wastes "if and when they are discarded or intended to be discarded...". [Emphasis added]. We underscore the word "when" because the event of discard, or the time of decision to discard, is determinative. Until a material referenced by section 261.33 is actually discarded, or the decision is made to discard the material, it is not subject to RCRA regulation.

As we understand, the decision by Merck Sharp & Dohme whether to discard a given product is not made until after the product has been returned to the West Point plant, following a check by your Security Department. Moreover, as we understand, your procedures for segregating returned goods for reclamation or disposal via either incineration or landfill take place only at the West Point plant. Given these facts, and assuming that your branch operations have no role in the decision to discard a particular material, we conclude, as to materials in the form of commercial chemical products on the P or U lists of 40 CFR §261.33, that the materials are not yet within the RCRA regulatory system when shipped to West Point from the branch operations. We agree with your reasoning that West Point is "the place where the goods become a waste."

I trust this interpretation will be helpful. If I can be of further assistance, please let me know.

Sincerely yours,

Alan S. Corson
Chief
Waste Characterization Branch
Hazardous and Industrial Waste Division (WH-565)
March 26, 1981

Mr. Alan Corson,
Chief-Waste Characteristics Branch
Hazardous Waste Management Division (AW-465)
Office of Solid Waste
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Dear Mr. Corson:

I recently had the opportunity to meet with Ms. Claire Welty from your office, at our plant on March 6, 1981. During her visit, I briefly summarized a matter concerning hazardous waste management that has been of concern to our Company. Ms. Welty recommended that we submit this matter in writing to your office for consideration.

Merck Sharp & Dohme, Division of Merck & Co., Inc., is located in West Point, Pennsylvania where we manufacture ethical pharmaceutical and biological products. Finished goods are shipped to sixteen branch operation facilities located throughout the country. The finished goods are then distributed to customers from the branch operation facilities. A small percentage of the finished goods are returned to the branch operation facilities on a regular basis. Usually returns occur when a pharmacist has kept a product beyond the expiration date. Occasionally, a pharmacist may return a product for some other reason, such as lack of sales. Also, a product may be returned if we initiate a recall for any one of numerous reasons. These return goods are shipped from all sixteen branches to our West Point plant.

Most return goods shipped to West Point are discarded either for business reasons or because Food and Drug Administration regulations prevent us from recovering them. Once they reach the plant, return goods are disposed, but only after they have been checked at our plant under the supervision of our Security Department. They are either incinerated or transferred to a solid waste crusher for destruction prior to being landfilled. In this manner, we can account for and control the disposal of all return goods in a uniform manner at a central location. The centralized control of our return goods has been practiced effectively for over 30 years. It is essential to our standards of practice to assure uniformity in handling products, even when discarded.

After careful review of the Part 261 regulations, Identification and Listing of Hazardous Waste, we have determined that some of our return goods should be
ultimately disposed of as a hazardous waste. Accordingly, we have established procedures to segregate the return goods so that proper disposal can be assured.

One of our products was listed as an acutely hazardous waste (P025) on May 9, 1980 but was reclassified as a toxic waste (U245) on November 25, 1980. Since it was unknown at the time the regulations went into effect whether or not the return goods shipment to West Point contained more than 1 kilogram of that product each month, it was determined that each of our branch operations facilities should register as a generator and a treatment, storage, disposal facility (TSDF). This included notification of all ten EPA Regional Administrators. The TSDF portion of the notification has since been withdrawn based on an evaluation of our standard operating procedures. We have not withdrawn the generator notification because we are not sure if the branch operation facility is a generator of hazardous waste or if the West Point plant is the generator of hazardous waste for that fraction of return goods ultimately disposed as hazardous waste.

In the comments preceding the regulations, the EPA stated that "any material which is intended to be or is in fact thrown away, abandoned or destroyed is a "waste". (emphasis added). Because most return goods are discarded, it remains unclear to us whether or not the "intent to discard" language in the preamble to the regulations means that the branches' return shipments to West Point, in the absence of the small quantity provisions, would be subject to the requirements of Parts 263 and 264. If branches are generators we face the probability that we will have to establish different return goods procedures for branches located in states whose regulations vary from the federal ones. The resulting loss in uniformity would present increased potential of security and administrative problems.

However, since branches have authority only to return the goods to West Point and only the West Point site has authority to actually discard the goods, we believe that it is reasonable to regard West Point as the place where the goods become a waste. This interpretation is consistent with the regulations' purpose of assuring proper disposal of wastes, since all return goods are tracked under our internal system and the disposal of goods would be managed in compliance with hazardous waste regulations where applicable. Following this approach, we would not have to establish different compliance procedures in different states according to their generator standards, and we could maintain a uniform procedure. Uniformity in procedures results in better security and control, which, in turn, helps to assure compliance with the hazardous waste regulations.

As it is our objective to comply with the hazardous waste regulations, we would appreciate your review of our situation to determine whether our interpretation is correct that insofar as returned goods are concerned, our branch operation facilities are not subject to the hazardous waste generator standards of the regulations. Thank you for your cooperation in this matter.
Very truly yours,

Steven C. Wittmer,
Environmental Facilities Engineer,
Facilities Engineering

SCW:cg
Mark J. Schulz  
President  
Pharmaceutical Services, Inc.  
Browning-Ferris Industries  
757 N. Eldridge  
Houston, Texas 77079

Dear Mr. Schulz:

This responds to your February 22, 1991 letter to David Bussard requesting a determination regarding the regulatory status of pharmaceutical products that are returned by the dispensers of these products to the manufacturers, wholesalers, or to a third-party service company that will facilitate the processing, crediting, and, if needed, appropriate disposal of the returned products. Currently, such products are returned directly to the manufacturer or wholesaler, who credits the dispenser for the products and determines whether the products are to be reused, reclaimed, or appropriately disposed. BFI Pharmaceutical Services, Inc. (BFI-Pharm) intends to provide this reverse distribution service to the pharmaceutical industry.

As I understand your letter, pharmaceutical products may be returned for many reasons, including, among others: 1) an oversupply at the dispenser, 2) expiration of the recommended shelf life, 3) a recall has been initiated by the manufacturer, 4) the product was received as a result of a shipping error, and 5) the product has been damaged. You state that, in general the dispensers of the pharmaceutical products do not know whether the returned products will be reused, reclaimed, sold overseas, or disposed (i.e., they are not able to determine whether these materials are solid wastes). Because the dispensers receive credit for the returned products (either because the products actually have real value to manufacturer or because such credits are part of a competitive marketing approach), the products have a monetary value to the dispensers and they would not normally assume such materials to be wastes.

Under our current regulations, such returned products are not considered solid wastes until a determination is made to discard these materials. The returned products themselves (being "commercial chemical products" under our classification system) are considered more product-like than waste-like (until a determination is made to dispose of them) because recycling by use/reuse is generally a viable option. If the underlying assumption is that the returned products will be recycled, until the manufacturer or wholesaler...
determines otherwise (assuming that this determination is beyond the ability of the dispenser), then those products managed within the reverse distribution system are not solid wastes until the manufacturer or wholesaler makes the determination to dispose of them. This view is based on our understanding that the system is established as a means to facilitate the recycling of reusable pharmaceutical products, rather than a waste management system. We will be interested to learn if your data, which will be computerized, will support this assumption. At the current time there does not appear to be any reason for EPA to change its policy regarding this type of reverse distribution system simply because a third-party service company is involved rather than the manufacturers themselves.

I would like briefly to bring to your attention two issues that bear generally upon reverse distribution systems, although neither appear to be of concern in the BFI-Pharm situation. First, EPA does not intend for hazardous waste brokers to use a reverse distribution system to relieve generators of the responsibility for making determinations about the discarding of materials as wastes. It remains the generator's responsibility to properly identify secondary materials. Second, a reverse distribution system cannot be used as a waste management service to customers/generators without the applicable regulatory controls on waste management being in place. Of course, as I discussed above with respect to the BFI-Pharm situation, to the extent that the materials involved are unused commercial products with a reasonable expectation of being recycled in some way when returned, the materials are not considered as wastes until a determination has been made to discard them.

This interpretation is based on the current set of Federal RCRA regulations. However, as you know, authorized States may regulate or interpret the regulations differently, and State requirements are the applicable standards in authorized States. You should contact the appropriate State regulatory agencies for a more definitive regulatory determination for their respective jurisdictions.

I hope this has sufficiently answered your questions. Should you have any further questions regarding EPA's policies, you may contact David Bussard at (202) 382-4637.

Sincerely,

Original Document signed

Sylvia K. Lowrance
Director
Office of Solid Waste

King County – Pharmaceutical Reverse Distributor Survey
APPENDIX E

WASHINGTON STATE GUIDANCE
February 13, 2002

CERTIFIED MAIL
7001 0320 0000 4654 1177

Mr. Phil Schoeneman R. Ph.
PS Industries Inc.
1100 Second Ave., Suite B1
Seattle, WA 98101

Dear Mr. Schoeneman:

Re: Regulatory status of your reverse distribution company under Chapter 173-303 of the Washington Administrative Code (Dangerous Waste Regulations)

This letter is to clarify your company's status under the Dangerous Waste Regulations and to give you some guidance in complying with those regulations. This letter will focus on the controlled substances you handle.

Your company accepts pharmaceuticals from hospitals, clinics, doctor's offices and other sites, for processing or reverse distribution. This includes drugs that are controlled substances, under both state and federal law, which are returned to you in their original product state for processing. The controlled substances are sent to you in accordance with the applicable state and federal law on the shipment of controlled substances. You can accept these controlled substances from facilities that are allowed to possess them because of your status with the US Drug Enforcement Agency (DEA).

According to the United State Environmental Protection Agency (EPA), other companies can return pharmaceuticals to reverse distributors as product. The Washington State Department of Ecology's Hazardous Waste and Toxics Reduction Program concurs with EPA's findings.

When you receive controlled substances, you follow the regulations of the United States Drug Enforcement Agency (DEA) and Washington State Department of Health's Board of Pharmacy (Board of Pharmacy). One of the requirements of those regulations is the destruction of the controlled substance beyond reclamation. To achieve this destruction, you have worked with the

---

1 EPA letter – Lowrance to Schulz, May 16, 1991
Seattle office of the DEA to get approval for a process that you created as a proprietary business activity. The result after the destruction process is a waste product. You began this process in the summer of 2001.

Washington’s “Dangerous Waste Regulations,” Chapter 173-303 WAC, apply to the waste that results from your destruction process. Your company is the generator of this waste, and as such, you are subject to the regulations. The first step in compliance is to determine if the waste from your process meets the definitions of dangerous waste in our regulations. This is referred to as designation and is detailed in sections -090 and -100 of the Dangerous Waste Regulations. From my meetings with you, I understand that you have determined that the waste is a dangerous waste due to our state’s criteria for toxicity (see section -100). You put the waste into containers and use the services of a hazardous waste transporter to prepare the waste for transport. The waste is then shipped to a permitted treatment, storage and disposal facility.

You have told me that you keep a log of each batch of controlled substance you process. This information will be helpful to you in determining your generator status and the subsequent regulations that apply to your company. You have asked for assistance in determining your generator status and we will meet on February 20, 2002, to do this and to assist you in filling out your Annual Dangerous Waste Report for calendar year 2001.

Enclosed is comparison chart of how the regulations apply to dangerous waste generators, depending on their generator status. You will need to comply with these additional regulations depending on your generator status.

Please contact me if you have questions or concerns. I can be reached at (425) 649-7055.

Sincerely,

Tiffany Yelton
Hazardous Waste Compliance Inspector

cc: Alfred Cheeseman, Diversion Program Manager, US Dept. of Justice, Drug Enforcement Agency
Donald H. Williams, Executive Director, WA Dept. of Health, Board of Pharmacy
Rod Shafer, R. Ph., Chief Executive Officer, Washington State Pharmacists Association
David Lundstrom, Manager, Hazardous Materials and Waste Management, University of Washington
Jerry French, Hazardous Waste and Toxics Reduction Program, WA Dept. of Ecology, Eastern Regional Office
Peggy Rice, King Co. Industrial Waste Management Program
Fred Miller, Environmental Health and Safety, Washington State University

December 6, 2002

Linda L. Baetz  
Program Manager  
Hazardous and Medical Waste  
Department of the Army  
CDR, USACHPPM  
Attn: MCHB-TS-EHM  
Bldg E1677  
APG, MD 21010-5403

Dear Ms. Baetz:

RE: Letter to the Department of Ecology dated April 17, 2002 on the use of reverse distributors

Thank you for your letter to the Department of Ecology. I apologize for the delay in responding to your letter, but we needed some time to discuss this issue.

In your letter you made the following request: “We request that the Department of Ecology’s Hazardous Waste and Toxics Reduction Program describe allowable options for the disposal of returned or expired pharmaceuticals, to include legend drugs and controlled substances as defined and regulated by the DEA and the Washington State Department of Health’s Board of Pharmacy, that designate as Dangerous Waste under the Dangerous Waste Regulations (WAC 173-303), and Hazardous Waste regulated under the Resource Conservation and Recovery Act-Subtitle C (RCRA-C) when they meet the criteria for listed(characteristic HW as described in Subparts C and D of 40 CFR 261.”

We have been referring to the third party service companies that take back pharmaceuticals as reverse distributors and I will use that term in this letter. Ecology currently allows the use of reverse distributors for the return of pharmaceuticals due to oversupply, recall, damaged shipments, and the passing of the expiration date. Ecology has been leaning more about how reverse distributors operate and we agree with the statement in your letter that “a dispenser of such products (pharmaceuticals) generally does not know if the returned item will be reused, reclaimed, sold or disposed of.” We understand this to be the case because the reverse
distributor works with the manufacturer to decide the fate of the pharmaceutical and that cannot be done until after the reverse distributor receives the pharmaceutical.

In contrast to our 1998 letter to you on this topic, we will allow expired drugs to be returned to a reverse distributor. We understand that expiration dates on drugs may not indicate the drug is not usable and those drugs may be tested for quality by the manufacturer or reverse distributor and deemed usable.

We still, like the EPA, do not want to see reverse distributors used as a waste disposal mechanism. It is a system to return products. To prevent abuse, we would encourage continuing with the inventory controls you describe in your letter that reduce the amount of pharmaceuticals your facilities stock. Further, we would feel that the reverse distribution system was being used as a disposal option if pharmaceuticals that the reverse distributor does not accept were included in the shipment. As an example, it would not be appropriate to send back a pharmaceutical that had spilled or one that was in secondary packaging (such as a single dose unit) that the reverse distributor will not accept. It would also be an abuse of this system if a waste generator were to try to leverage a reverse distributor into taking a pharmaceutical that is a waste if they take the other pharmaceuticals that are the result of oversupply, recall, damaged shipment or expiration.

It should be noted that if a reverse distributor was found to be mismanaging regulated waste, the facilities that used that reverse distributor may have some liability, as would the reverse distributor itself.

Please contact me at (425) 649-7055 if you have any questions about this letter.

Sincerely,

Tiffany Yelton, Hazardous Waste Compliance Inspector
Hazardous Waste and Toxics Reduction Program

TY:sd

cc: Central Files
Institutional Memory
Returns Industry Association
December 10, 2002

CERTIFIED MAIL
7002 2030 0006 2248 3955

Mr. Dave Jenkins, Executive Director
Returns Industry Association
1821 Michael Faraday Drive
Suite 400
Reston, VA 20190

Dear Mr. Jenkins,

The Hazardous Waste and Toxics Reduction Program at the Washington State Department of Ecology (Ecology) has been asked by users of pharmaceutical reverse distributors if our program allows this practice. We do allow the use of reverse distributors for the return of pharmaceuticals, but like the USEPA, we do not want to have a system that was intended to facilitate the return of products abused by illegal disposal of hazardous waste.

This letter is intended to help your association and its members join us in a common understanding. We expect that reverse distributors have a working definition of what is and what is not waste. Returns made to reverse distributors as the result of oversupply, recall, damaged shipments or expiration are well within the concept of reusable products. Pharmaceuticals that have been spilled, mixed or removed from their original packaging would not be products because there is little potential that they could be reused. We would instruct hospitals, pharmacies and related facilities that these are waste and that those organizations, as the generators of the waste, can not send them to a reverse distributor and must handle those pharmaceuticals appropriately.

Ecology would support the use of internal policies by reverse distributors for accepting returns that help both the reverse distributor and their clients determine what is product and what is not. If any reverse distributor offering service to clients in the state of Washington has questions about what is a waste and what is not, we would be happy to advise them. Ecology is aware of opportunities that reverse distributors have to learn more about the federal Resource Conservation and Recovery Act (RCRA) and we see the reverse distributor as having a role in instructing clients about the characteristics of RCRA waste. In Washington, we have added to RCRA to create the “Dangerous Waste Regulations”, Chapter 173-303 of the Washington Administrative Code (WAC). We would be happy to educate any reverse distributor about the additional criteria we use in our state to determine what is a hazardous waste.
Mr. Dave Jenkins  
December 10, 2002  
Page 2

Ecology understands that reverse distributors may have to make decisions to dispose of materials that come to them as product. When these occasions arise, we expect that the reverse distributor will comply with the applicable laws and ordinances in their specific area regarding proper management and disposal of hazardous wastes. At all times, we advise businesses to use companies that are in compliance with their local regulations.

Thank you for sharing this information with your members. If you have questions, please call Tiffany Yelton at (423) 649 7055. We look forward to working with you.

Sincerely,

Tiffany Yelton, Hazardous Waste Compliance Inspector  
Hazardous Waste and Toxics Reduction Program

cc: Institutional Memory  
Charlotte Smith, Pharm-e-cology
APPENDIX F

FLORIDA STATE GUIDANCE

<http://www.floridacenter.org/brochures_bulletins/rcra_pharmacies.pdf>
APPENDIX G

HOW CLIENTS CAN IMPROVE REVERSE DISTRIBUTION, SURVEY RESPONSES
Appendix G lists individual survey responses to the question “How can clients make reverse distribution run smoother?” Survey responses are grouped by theme.

**Package Drugs to Prevent Breakage**

- Apply common sense to packaging corrosives, inhalants, etc. Don’t hide these items in boxes of pills.
- Pack pharmaceuticals correctly so containers don’t break, especially liquids. Ensure tops are securely on bottles. Line shipping box with plastic bag (don’t use a red bag) in case of leakage.
- Use good packaging
- Work on improving packaging. Don’t use a worn box. Choose sound packaging materials and pack securely.
- Segregation of drugs is important. Pharmacies need to separate controls from non-controls. Hospitals need to clearly identify chemotherapy products. Properly package and place drugs in bins, especially liquid ampoules which may break in transit.

**Improve Inventory Management**

- Package all expired drugs quarterly as a batch. Customers shouldn’t try to presort.
- Third party “shelf sweepers” can be problematic in paperwork accounting for credits. Otherwise, products received are in good shape, very little refused due to leaking or damage.
- Encourage shipment of drugs before credit expires.
- Most clients are pretty good about following procedures. Occasionally account forms need revision. Clients are encouraged to return product before shelf-life expiration to ensure credit; keep up on inventory turnover, clean shelves more often.
- Inventory the drugs – especially the descriptive information. Even DEA allows some estimating of drug quantities. Fax or call in the inventories prior to shipment. Keep inventories rotating so drugs stay current.
- For mail-in service, be thorough in scanning shelves. A pharmacy tech spending 20 minutes checking inventory isn’t enough. For a typical pharmacy, spend 2-3 hours; for a typical doctor’s office, 30 minutes. Otherwise, expired drugs are missed and end up being returned too old for credit.

**Identify All Pharmaceuticals**

- Effectiveness of returns gets down to individuals at the site & their specific drugs. Need individual pre-approval and screening of proposed shipments before sending them off.
- Please provide product label or National Drug Codes for spilled pills. Must identify every pill.
• Work with customer service department & sales rep to follow procedures. Get paperwork done, use shipping labels. Clients aren’t supposed to send wastes now but they do anyway (especially nursing homes & pharmacies).
• Client needs to request an authorization label before mailing product. Don’t just mail drugs without advance notice.
• Label merchandise, call first for return authorization labels and complete inventory forms before shipping.
• Need good inventories of containers, especially if the site is packaging drugs on their own.

Complete DEA Controlled Substance Paperwork
• Controlled substances are a problem: itemize them all, no guesses, send controlled substances with an inventory, don’t just dump drugs in a box, count everything.
• Keep controls itemized. In other areas the service is so easy that not too many problems are seen.
• Always encourage DEA compliance, provide advance notice of shipments.
• Call first, get paperwork completed and procedures explained, then ship materials.

General Comments about Drug Management
• Samples accepted but company charges a fee. Doctor’s offices and clinics don’t want to pay a fee so this company rarely sees samples.
• Clients should consider, “Is your pharmaceutical waste handled in an environmentally conscious manner?”
• Contact read about King County IRAC pharmaceutical workgroup activities on our web site. Interested in the project and future products such as Best Management Practices.
• Contact expressed both concerns about incineration as a good long-term option and also concern about local incinerators & hospital incinerators being shut down. Has seen both questionable practices and very well-run incinerators. Some hospital incinerators were high-tech and even returned energy to the facility. Now hospitals face higher costs. Contact wondered if the broad shutdown was overkill -- an over-reactation to potential dioxin risks from burning plastics.
• Contact observed that Pyxis is expensive, requires extra employees to operate & maintain inventory, wonders if it is worth the cost. (“Pyxis” is a computerized pharmacy management and drug dispensing system used in hospitals.)
• Contact was concerned that existing environmental regulations encourage other reverse distributors to cheat. It’s not fair for a reverse distributor sorting drugs in a van to be hit with a fine for hazardous waste transport because the “waste determination” was made in the van rather than at the warehouse. Need to operate business efficiently.
• Not a member of Returns Industry Association; considers it too costly.
BIBLIOGRAPHY
