SUPPORTING STATEMENT FOR
EPA INFORMATION COLLECTION REQUEST NUMBER 2324.01
REPORTING AND RECORDKEEPING REQUIREMENTS FOR THE PROPOSED RULE ON ADDING PHARMACEUTICALS TO THE UNIVERSAL WASTE RULE (Proposed Rule)

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1. IDENTIFICATION OF THE INFORMATION COLLECTION

1(a) Title and Number of the Information Collection

This information Collection Request (ICR) is entitled "Reporting and Recordkeeping Requirements for the Proposed Rule on Adding Pharmaceuticals to the Universal Waste Rule (Proposed Rule)," EPA ICR Number 2324.01.

1(b) Short Characterization

Section 3001 of the Resource Conservation and Recovery Act (RCRA) of 1976, as amended, requires the Environmental Protection Agency (EPA) to identify which solid wastes are hazardous wastes and therefore must be managed as hazardous waste during treatment, storage, or disposal. Under this authority, EPA established four hazardous waste characteristics (toxicity, reactivity, ignitability, and corrosivity), and listed specific wastes that must be managed as hazardous wastes. Some pharmaceutical wastes are hazardous because they contain listed hazardous waste chemicals or they exhibit one of the four hazardous waste characteristics. As a result, these pharmaceutical wastes are currently subject to strict controls under RCRA Subtitle C hazardous waste regulations. However, health care facilities report that they struggle to familiarize their time-constrained workers with the RCRA hazardous waste regulations. The lack of time and hazardous waste management knowledge on the part of health care workers makes it difficult for them to determine which wastes are RCRA hazardous, whether they are listed or characteristic hazardous wastes, and what the proper management techniques are for those wastes.

After consideration of the issues, EPA is proposing to add hazardous pharmaceutical wastes to the existing universal waste rule (UWR) at 40 CFR Part 273. The existing universal waste regulations, published on May 11, 1995, provide streamlined procedures for certain widely generated wastes identified as universal wastes (60 FR 25492). The universal waste standards are designed to accomplish the following general goals:

• Encourage resource conservation while ensuring protection of human health and the environment.

• Improve implementation of the current RCRA Subtitle C hazardous waste regulatory program.

• Simplify the hazardous waste regulatory requirements and to encourage individuals and organizations to collect the unregulated portion of these wastes and manage them using the same system developed for the regulated portion. That is, this removes otherwise unregulated wastes from the municipal waste stream, minimizing the placement of hazardous constituents into municipal landfills, combustors and composting projects, as well as to wastewater treatment plants.

The UWR is specifically designed to reduce the complexity of the RCRA hazardous waste generator regulations for universal wastes. It streamlines the collection and handling requirements for widely-dispersed hazardous wastes and facilitates their inclusion in the hazardous waste management system. By proposing to incorporate hazardous pharmaceutical waste in the universal waste regulations, EPA expects improved management of hazardous and non-hazardous pharmaceutical wastes, as well as decreased regulatory burden for many hazardous pharmaceutical waste generators. This proposal thus provides a solution to many of the issues facing health care facilities and other pharmaceutical waste generators.

Furthermore, while the UWR regulates only RCRA hazardous wastes, the Agency anticipates that including hazardous pharmaceutical wastes in the UWR will encourage persons to manage other pharmaceutical wastes in the same manner as universal wastes, particularly those wastes that are not hazardous under RCRA but which may nonetheless pose risks. Moreover, EPA expects that including hazardous pharmaceutical wastes in the UWR will ease the regulatory burden on generators that want to collect these wastes, facilitating the implementation of pharmaceutical take-back programs. The proposed rule is also designed to reduce the quantity of RCRA hazardous waste pharmaceuticals managed in municipal solid waste systems. Thus, expansion of the universal waste system to include hazardous pharmaceutical wastes would lead to better management of these wastes by providing a more streamlined, but effective waste management system.

This ICR is a comprehensive description of the information collection requirements for handlers of hazardous pharmaceutical wastes under the universal waste requirements.

2. NEED FOR AND USE OF THE COLLECTION

2(a) Need and Authority for the Collection

The requirements covered in this ICR are necessary for EPA to obtain general information on universal pharmaceutical waste regulated entities and to facilitate enforcement of Part 273 regulations. The notification requirements are needed to assist the Agency in identifying and tracking large quantity handlers of universal pharmaceutical waste. EPA requires large quantity handlers to mark and track pharmaceutical waste shipments to help ensure these wastes are being accumulated responsibly. EPA also requires tracking of universal pharmaceutical waste shipments to help ensure these wastes are being properly treated, recycled, or disposed.

2(b) Practical Utility and Users of the Data

EPA will use the collected information to ensure that universal pharmaceutical wastes are being managed in a protective manner. This information aids the Agency in tracking universal pharmaceutical waste shipments and identifying improper management practices. In addition, information kept in facility records will help handlers demonstrate, and on-site inspectors ensure, that facilities are managing pharmaceutical wastes properly. Information marked on

pharmaceutical waste containers will assist handlers and transporters in ensuring proper management during storage and shipment.

3. NONDUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

3(a) Nonduplication

None of the information required by the proposed rule would duplicate information required by existing RCRA regulations.

3(b) Public Notice

In compliance with the Paperwork Reduction Act of 1995, EPA will open a 60-day public comment period at the time that this proposed rule is published in the *Federal Register*. To assist the public in commenting on the proposal, EPA raised a number of issues in the preamble to the proposed rule and asked for the public to comment on them. At the end of the comment period, EPA will review public comments received in response to the notice and will address comments received, as appropriate.

3(c) Consultations

EPA consulted and collected information from interested parties over several years to support the amendment to the UWR. EPA staff made site visits to hospitals and other pharmaceutical waste generators, met with reverse distributors, and communicated with states and other interested parties. The summaries of the site visits, meetings, and telephone conversations with interested parties are available in the docket for the proposed rule (Docket ID No. EPA-HQ-RCRA-2007-0932).

3(d) Effects of Less Frequent Collection

EPA has carefully considered the burden imposed upon the regulated community by the proposed rule. EPA is confident that those activities required of respondents are necessary, and to the extent possible, the Agency has attempted to minimize the burden imposed. EPA believes strongly that, if the minimum information collection requirements of the proposed rule are not met, neither the industry nor EPA will be able to ensure that pharmaceutical wastes are being managed in a manner protective of human health and the environment.

3(e) General Guidelines

This ICR adheres to the guidelines stated in the Paperwork Reduction Act of 1995, OMB's implementing regulations, EPA's ICR Handbook, and other applicable OMB guidance.

3(f) Confidentiality

Section 3007(b) of RCRA and 40 *CFR* Part 2, Subpart B, which defines EPA's general policy on public disclosure of information, contain provisions for confidentiality. However, the Agency does not anticipate that businesses will assert a claim of confidentiality covering all or part of the proposed rule. If such a claim were asserted, EPA must and will treat the information in accordance with the regulations cited above. EPA also will assure that this information collection complies with the Privacy Act of 1974 and OMB Circular 108.

3(g) Sensitive Questions

No questions of a sensitive nature are included in the information collection requirements associated with the proposed rule.

4. THE RESPONDENTS AND THE INFORMATION REQUESTED

4(a) Respondents and NAICS Codes

The following is a list of North American Industrial Classification System (NAICS) codes associated with the facilities most likely to be affected by the information collection requirements covered in this ICR.

NAICS	Facility Type
44611	Pharmacies
622	Hospitals
6211	Physicians' Offices
6212	Dentists' Offices
6213	Other Health Practitioners (e.g., chiropractors)
6214	Outpatient Care Centers
6219	Other Ambulatory Health Care Services
623	Residential Care Facilities
Various NAICS[3]	Reverse Distributors
54194	Veterinary Clinics

4(b) Information Requested

This section describes information collection requirements applicable to universal pharmaceutical waste regulated entities that would be affected by the rule.

Notification

(i) Data items:

The proposed rule, based on the existing UWR regulations for large quantity handlers, requires that large quantity handlers of universal pharmaceutical waste must send written notification of their universal waste management to the Regional Administrator, and receive an EPA identification number. Specifically, the large quantity handlers must send written notification before meeting or exceeding the 5,000 kilogram accumulation limit of universal waste. Large quantity handlers who have already notified EPA of their hazardous waste management activities under RCRA or pesticide management under FIFRA and have received an EPA Identification number are not required to re-notify.

The notification must include the following data items:

- The universal waste handler's name and mailing address;
- The name and business telephone number of the person at the universal waste handler's site who should be contacted regarding universal waste management activities;
- The address or physical location of the universal waste management activities;
- A list of all types of universal waste managed by the handler; and
- A statement indicating that the handler is accumulating 5,000 kilograms or more of universal waste at one time.

(ii) Respondent activities:

Large quantity handlers of universal pharmaceutical waste must prepare and submit written notification of their universal waste management to the Regional Administrator. However, it is reasonable to assume that large quantity handlers have previously notified EPA of their hazardous waste management activities under RCRA or pesticide management under FIFRA and have received an EPA Identification number. Therefore, they would not be required to re-notify under the proposed rule.

Labeling/Marking

(i) Data items:

Small and large quantity handlers are required to mark or label their universal pharmaceutical waste materials in accordance with the following procedures:

- All containers must be marked with the words “Universal Waste - Pharmaceuticals” or “Waste Pharmaceuticals.”

(ii) Respondent Activities:

- Handlers must mark or label the universal pharmaceutical waste or the containers holding universal pharmaceutical waste. However, the small and large quantity generators under RCRA Subtitle C requirements must also mark all containers with the words "Hazardous Waste" and the accumulation start date. Therefore, the labeling requirements under the proposed rule would not result in any additional burden to the handlers.

Accumulation Time Limits

(i) Data items:

- Small quantity and large quantity handlers are required to demonstrate the length of time that the pharmaceutical material has been accumulated from the date it was received or became a waste.

(ii) Respondent Activities:

Handlers must demonstrate the length of time that pharmaceutical material has been accumulated from the date it was received or became a waste. As with the Labeling/Marking requirements for small and large quantity generators under RCRA Subtitle C that are described above, the handlers can continue to mark all containers with the accumulation start date. Therefore, this activity should not result in any additional burden to the handlers.

Tracking Pharmaceutical Waste Shipments

(i) Data items:

The rule requires large quantity handlers to keep records of each incoming or outgoing universal pharmaceutical waste shipment. Records of shipments must be kept for a period of three years from the day of receipt or the day the shipment left the facility.

The data items required are:

- Records of incoming and outgoing shipments must contain the following information:
    - Name and address of the originating or destination facility;
    - Quantity of universal pharmaceutical waste received or sent; and
    - Date the shipment was sent or received.

(ii) Respondent activities:

- Large quantity handlers must:

- Maintain records of all shipments for a period of three years.

Exports

(i) Data Items:

The proposed rule, based on the existing UWR regulations for exports, requires that shipments of universal pharmaceutical waste to a foreign destination must comply with the same requirements as shipments of hazardous waste (i.e., 40 CFR 262, Subparts E or H). These reporting and recordkeeping activities are not evaluated in this ICR because they already are addressed in the "Requirements for Generators, Transporters, and Waste Management Facilities under the RCRA Hazardous Waste Manifest System" (ICR No. 801) and in the "Exports from and Imports to the U.S. under the Organization for Economic Cooperation and Development (OECD) Decision" (ICR No. 1647).

5. THE INFORMATION COLLECTED --AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

5(a) Agency Activities

Most of the information that is required of universal pharmaceutical waste handlers would be kept on site and not be submitted to EPA for review. The exception is a notification requirement for large quantity handlers of universal pharmaceutical waste. However, as stated earlier, it is being assumed that large quantity handlers have previously notified EPA of their hazardous waste management activities under RCRA or pesticide management under FIFRA and have received an EPA Identification number. Therefore, they would not be required to re-notify the Agency under the proposed rule, and the Agency does not have to review any new notifications.

5(b) Small Entity Flexibility

By adding hazardous pharmaceutical waste to the federal list of universal wastes, the proposed rule will provide regulatory relief from the full Subtitle C management requirement for entities involved in pharmaceutical waste management. These entities include generation and transportation facilities. Small quantity generators (SQGs) of hazardous pharmaceutical waste will become small quantity handlers (SQHs) of universal pharmaceutical waste. Regulatory requirements for small quantity handlers of universal waste are considerably simpler than those applicable to small quantity generators of hazardous waste.

Further, EPA relieved small quantity handlers from several administrative requirements applicable to large quantity handlers. For example, the proposed rule does not require small quantity handlers to submit notifications of universal pharmaceutical waste management or to obtain an EPA identification number. EPA also does not require small quantity handlers to keep records of their universal pharmaceutical waste shipments. EPA believes these exemptions would encourage small businesses to safely manage universal pharmaceutical waste in

compliance with the regulation. In addition, EPA allows conditionally exempt small quantity generators (CESQGs) to manage their hazardous pharmaceutical waste either under the specific provisions of the proposed rule or under the existing CESQG exemption in 40 CFR 261.5.

Finally, the proposed rule to add pharmaceuticals to the universal waste rule is a regulatory relief initiative that should reduce regulatory burden and costs for all universal waste handlers, but should particularly benefit small entities.

6. ESTIMATING THE HOUR AND COST BURDEN OF THE COLLECTION

6(a) Estimating Respondent Burden

In exhibit 1, EPA estimates the respondent burden associated with the new paperwork requirements in the proposed rule. As shown in the exhibit, EPA estimates that the total annual respondent burden for the new paperwork requirements in the rule is approximately 960 hours per year.

6(b) Estimating Respondent Costs

EPA also estimates in Exhibit 1 that the total annual respondent cost for the new paperwork requirements in the rule is approximately $54,000. This cost includes annual labor, capital, and operation and maintenance (O&M) costs to be incurred by respondents affected by the information collection requirements covered in this ICR. Specific data and/or assumptions used in developing these costs are described below.

Labor Costs

For purposes of this analysis, EPA estimates an average hourly respondent labor cost of $102 for legal staff, $71 for managerial staff, $48 for technical staff, and $26 for clerical staff. These hourly labor costs were obtained from the economics background document developed for the proposed rule.

Annual Capital and Operation & Maintenance Costs

Capital costs usually include any produced physical good needed to provide the needed information, such as machinery, computers, and other equipment. EPA does not anticipate that respondents will incur capital costs in carrying out the information collection requirements of the proposed rule.

O&M costs are those costs associated with paperwork requirements incurred continually over the life of the ICR. They are defined by the EPA as “the recurring dollar amount of costs associated with O&M or purchasing services.” For this ICR, O&M costs would be from photocopying shipping papers.

6(c) Estimating Agency Burden and Costs

The annual burden and costs to the Agency for collecting information under the rule would be negligible. This is because the Agency is not requiring pharmaceutical universal waste handlers to submit any information for its review and approval under the proposed rule. Under the proposed rule, large quantity handlers (LQHs) of universal waste must notify EPA and obtain an EPA identification number. However, a LQH is not required to notify if it has previously notified EPA and obtained an identification number as a large quantity generator (LQG) under RCRA Subtitle C hazardous waste requirements. We are assuming that all existing/new LQHs of universal pharmaceutical waste have previously notified EPA and obtained an identification number. The pharmaceutical universal waste handlers would keep all records required under the proposed rule on site.

6(d) Estimating the Respondent Universe and Total Burden and Costs

Respondent Universe

In Exhibit 1, EPA provides estimates of the annual number of respondents that will likely choose to comply with the new paperwork requirements in the proposed rule. This is because the respondent paperwork requirements for the existing small and large quantity handlers under the UWR will be more streamlined (resulting in lower burden) compared to the RCRA Subtitle C hazardous waste regulations. In the same exhibit, EPA estimates respondent burden and costs associated with the new paperwork requirements. Table 1 presents the number of respondents that could potentially be affected by the proposed rule.[1] It shows that EPA estimates 634,552 small and large facilities handle hazardous pharmaceutical waste each year. The conditionally-exempt small quantity generators (CESQGs) of hazardous pharmaceutical waste are already subject to very minimum waste management requirements under the existing RCRA Subtitle C hazardous waste regulations. Because the burden from new paperwork requirements for CESQGs under the amended UWR would be higher than the existing paperwork requirements, we are assuming that CESQGs are unlikely to choose to manage their pharmaceutical wastes under the amended UWR.

1These universe assumptions are based on the document, "Assessment of the Potential Costs, Benefits, and Other Impacts of Adding Pharmaceuticals to the Universal Waste Rule, as Proposed."

TABLE 1

NUMBER OF FACILITIES POTENTIALLY AFFECTED BY THE PROPOSED RULE

Type of Respondent	Number of Facilities
Small Quantity Handlers (CESQGs under Subtitle C regulations)	633,433
Small Quantity Handlers (SQGs under Subtitle C regulations)	1,083
Large Quantity Handlers (LQGs under Subtitle C regulations)	36
Total	634,552

Respondent Burden and Cost

Based on the universe data presented in Table 1, EPA estimated the respondent burden associated with all of the new information collection requirements covered in this ICR in Exhibit 1. A discussion of the assumptions used in developing these burden estimates follows.

Reading the Regulations

As shown in Exhibit 1, EPA estimates that 1,119 potentially affected facilities will read the rule on adding pharmaceuticals to the universal waste rule (facilities that are currently classified as CESQGs are unlikely to read the rule because the proposed rule would not decrease their paperwork burden). In estimating the annual respondent burden and cost over the three year period covered by this ICR, EPA annualized the burden and cost of this one-time activity by dividing the number of hours required for this activity by three.

Record of Shipments for Generators

The SQHs of universal waste are not required to maintain any records of universal waste shipments. LQHs, however, must record all shipments received or shipped. Logs, invoices, bills of lading, or other shipping documents constitute acceptable forms of records. These records must be maintained for at least three years. Based on the quantity of universal pharmaceutical waste managed by LQHs, it was estimated that an average of about eight shipments of universal pharmaceutical waste would be made annually by each LQH. The cost to complete and maintain a record of universal waste shipment was estimated to be $10 per shipment in the economics background document developed for the proposed rule.

Total Respondent Burden and Cost

In Exhibit 2, EPA presents a summary of the total annual respondent burden and costs associated with both new and existing paperwork requirements. The specific information collection activities of the new paperwork requirements are described throughout this ICR, and the total annual burden and cost estimates associated with them are calculated in Exhibit 1, summarized in Exhibit 2, and briefly described below. The existing paperwork requirements are those that are contained in the current RCRA regulations and that apply to generators of hazardous pharmaceutical wastes. These existing requirements, the existing ICRs with which they are associated, and the total annual burden and cost associated with them also are summarized in Exhibit 2 and briefly described below.

New Paperwork Requirements

EPA presents the total respondent burden and costs for all of the new information collection activities associated with the proposed rule in exhibit 1. As noted above, this exhibit presents the annual burden and costs over the three-year effective life of the ICR. The exhibit calculates the burden and cost of one-time activities by dividing the total number of burden hours by three. In Exhibit 2, EPA summarizes the total annual respondent burden and cost of these new paperwork requirements derived in Exhibit 1.

Existing Paperwork Requirements

In addition to the new paperwork requirements in the proposed rule, EPA also estimated the burden and cost savings that hazardous pharmaceutical waste handlers would expect for no longer following the existing RCRA information collection requirements. In Exhibit 2, EPA presents the total annual respondent burden and cost savings under the existing paperwork requirements, broken out by the four existing EPA ICRs that are affected by the proposed rule. In developing Exhibit 2, EPA reviewed each of the affected ICRs to identify the existing information collection activities that are currently undertaken by hazardous pharmaceutical waste handlers, calculated the associated burden and costs (or savings), and presented the totals in the exhibit.

The total costs in Exhibit 2 are broken down into labor and operation and maintenance (O&M) costs. In Section 6(b), EPA presents a discussion of the capital and O&M costs associated with new paperwork requirements from the proposed rule. In the following paragraph, EPA presents a brief discussion of the O&M costs associated with each of the existing ICRs that are affected by the proposed rule.

For the Manifest ICR (ICR No. 801), the O&M costs are associated with postage for sending and returning copies of the manifest form. For the Generator Standards ICR (ICR No. 820), O&M costs are associated with copying training materials. For the Biennial Report ICR (ICR No. 976), O&M costs are associated with mailing costs and maintaining copies of Waste Generation and Management (GM) and Waste Received from Off-Site (WR) forms. For the

Land Disposal Restrictions ICR (ICR No. 1442), O&M costs are associated with mailing costs and maintaining copies of notification.

6(e) Bottom Line Burden Hours and Costs

Respondent Tally

In Exhibit 2, EPA presents the total annual respondent burden and cost for both new and existing paperwork requirements associated with the proposed rule. As described specifically in Section 6(d) above, these new and existing paperwork requirements apply to universal pharmaceutical waste handlers. As shown in Exhibit 2, the total annual respondent burden for these new paperwork requirements is approximately 960 hours, at an annual cost of approximately $54,000. As also shown in Exhibit 2, the total annual respondent burden savings under the existing paperwork requirements, which are associated with four existing EPA ICRs, is approximately 1,900 hours, at annual cost savings of approximately $93,000. In the same Exhibit 2, EPA then combines the burden and cost impacts under both new and existing paperwork requirements and estimates the total annual respondent burden savings for all information collection activities at approximately 935 hours and an annual cost savings of approximately $39,000.

The bottom line respondent burden hours saved over the three-year period covered by this ICR is approximately 2,805 hours, at a total cost savings of $117,000.

6(f) Reasons for Change in Burden

As shown in exhibit 2, EPA expects that the proposed rule will result in a reduction in burden to the hazardous pharmaceutical waste generators complying with UWR requirements. This is because universal pharmaceutical waste generators no longer would be subject to full Subtitle C requirements. Following is a list of primary RCRA reporting and recordkeeping requirements that hazardous pharmaceutical waste generators may be relieved of:

- Reporting and recordkeeping under the hazardous waste manifest requirements, as covered in ICR No. 801, Manifest ICR;

- Recordkeeping and/or reporting of personnel training, contingency plan, and emergency procedures under the generator standards of 40 CFR Part 262, as covered in ICR No. 820, Hazardous Waste Generator Standards ICR.

- Reporting waste generation data for the EPA's Biennial Report, as covered in ICR No. 976, Biennial Report ICR; and

- Reporting and recordkeeping under the land disposal restrictions (LDRs) program of 40 CFR Part 268, as covered in ICR No. 1442, Land Disposal Restrictions ICR;

6(g) Burden Statement

The annual public reporting and recordkeeping burden for this collection of information is estimated to average 0.8 hours per response for a small quantity handler and 2.5 hours per response for a large quantity handler. However, in addition to the new paperwork requirements in the proposed rule, the Agency also estimated the annual respondent burden savings that generators could expect as result of no longer having to follow information collection requirements under four existing EPA ICRs (Manifest ICR, Generator Standards ICR, Biennial Report ICR, and Land Disposal Restrictions ICR). Taking both the new proposed and existing RCRA information collection requirements into account, EPA expects the proposed rule will result in a net reduction in annual reporting and recordkeeping burden of approximately 0.5 hour per response for a small quantity handler and 11 hours per response for a large quantity handler. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9 and 48 CFR chapter 15.

To comment on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including the use of automated collection techniques, EPA has established a public docket for this ICR under Docket ID Number EPA-HQ-RCRA-2007-0932, which is available for online viewing at www.regulations.gov, or in person viewing at the RCRA Docket in the EPA Docket Center (EPA/DC), EPA West, Room 3334, 1301 Constitution Avenue, NW, Washington, D.C. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Reading Room is (202) 566-1744, and the telephone number for the RCRA Docket is (202) 566-0270. An electronic version of the public docket is available at www.regulations.gov. This site can be used to submit or view public comments, access the index listing of the contents of the public docket, and to access those documents in the public docket that are available electronically. When in the system, select "search," then key in the Docket ID Number identified above. Also, you can send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street, NW, Washington, D.C. 20503, Attention: Desk Officer for EPA. Please include the EPA Docket ID Number EPA-HQ-RCRA-2007-0932 and OMB Control Number 2050-NEW in any correspondence.

Exhibit 1 - Estimated Annual Respondent Burden and Cost

	Hours and Costs per Respondent								Total Hours and Costs		
INFORMATION COLLECTION ACTIVITY	Leg. $102/Hr	Mgr. $71/Hr	Tech. $48/Hr	Cler. $26/Hr	Respon. Hours/Yr	Labor Cost/Yr	Capital/ Startup Cost	O & M Cost	Number of Respondents	Total Hours/Yr	Total Cost/Yr
RULE FAMILIARIZATION – Read the rule											
Small Quantity Handler	0.0	0.3	0.5	0.0	0.8	$45.00	0.0	0.0	1,083	866	$48,735.00
Large Quantity Handler	0.2	0.3	0.5	0.0	1.0	$66.00	0.0	0.0	36	36	$2,376.00
RECORDKEEPING – Keep records of shipments											
Large Quantity Handlers	0.0	0.0	1.5	0.0	1.5	$72.00	0.0	$29.00	36	54	$2621.00
Total	varies	varies	varies	0.0	varies	varies	0.0	varies	Varies	956	$53,732.00

Agency Data Sources:

Wage Rate Data: "Assessment of the Potential Costs, Benefits, and Other Impacts of Adding Pharmaceuticals to the Universal Waste Rule, as Proposed."

Labor Hours: "Supporting Statement for EPA Information Collection Number 1597.07: Reporting and Recordkeeping Requirements for the final Rule on Adding Mercury-Containing Equipment to the Universal Waste Rule."

O&M Cost: "Supporting Statement for EPA Information Collection Number 1597.07: Reporting and Recordkeeping Requirements for the final Rule on Adding Mercury-Containing Equipment to the Universal Waste Rule."

Exhibit 2 – Estimated Annual Respondent Burden for Existing ICRS (Including Net Impact from Pharmaceutical Rule ICR)						
ICR Name	ICR Number	Respondents	Total Labor Hours	Total Labor Cost	Total O&M Cost	Total Annual Cost
Manifest ICR	801	1,119	(1,591)	($76,368.00)	($2,258.00)	($ 78,626.00)
Generator Standards	820	36	(22)	($572.00)	($360.00)	($932.00)
Biennial Report	976	36	(170)	($8,172.00)	($84.00)	($8,256.00)
Land Disposal Restrictions	1442	36	(108)	($5,184.00)	($48.00)	($5,232.00)
Subtotal Other ICRs			(1,891)	($90,296.00)	($2,750.00)	($93,046.00)
Pharmaceutical ICR	2324.01	Varies	956	$53,703.00	$29.00	$53,732.00
Net Impact (Pharmaceutical ICR + Other ICRs) =			(935)	($36,593.00)	($2,721.00)	($39,314 .00)

Agency Sources:

Labor Hours & Cost: "Assessment of the Potential Costs, Benefits, and Other Impacts of Adding Pharmaceuticals to the Universal Waste Rule, as Proposed."

"Supporting Statement for EPA Information Collection Number 1597.07: Reporting and Recordkeeping Requirements for the final Rule on Adding Mercury-Containing Equipment to the Universal Waste Rule."

O&M Cost: "Supporting Statement for EPA Information Collection Number 1597.07: Reporting and Recordkeeping Requirements for the final Rule on Adding Mercury-Containing Equipment to the Universal Waste Rule."