United States
Environmental Protection
Agency

DRAFT Data Request for Unused Pharmaceuticals Disposal at Veterinary Hospitals in the Health Services Industry

Facility ID: [Pre-Populated]

23 July 2008

INTRODUCTION

The U.S. Environmental Protection Agency (EPA) is collecting data from veterinary hospitals about unused pharmaceuticals disposal. This questionnaire solicits information from veterinary hospitals. The technical data in Part A of this questionnaire will be used to obtain a national picture of unused pharmaceuticals management and disposal practices at veterinary hospitals including: (1) the factors driving current disposal practices, (2) information on the amount and identities of unused pharmaceuticals currently disposed of via the drain or flushing, and (3) the alternatives to drain disposal and flushing. The financial and economic data collected in Part B of this questionnaire will be used to characterize the economic status of the industry and to estimate the possible economic impacts of disposal policies.

In addition, EPA requests information on alternative management options for unused pharmaceuticals and the costs associated with alternative management practices.

This questionnaire is being conducted under the authority of Section 308 of the Clean Water Act (Federal Water Pollution Control Act, 33 U.S.C. Section 1318). **All companies that receive this questionnaire must respond within 60 days of receipt**. Failure to respond, late filing, or failure to comply with the instructions may result in criminal fines, civil penalties, and other sanctions, as provided by law.

INSTRUCTIONS FOR COMPLETING THE QUESTIONNAIRE

DEFINITIONS

EPA has provided definitions for key terms **at the end of this questionnaire (see PART D). These terms are** shown in ***bold italics*** **as they are used throughout** the questionnaire.

QUESTIONNAIRE OVERVIEW

Please complete one copy of the questionnaire for your *facility* for calendar year 2007 or a recent calendar year. Please use Part C of the questionnaire if you have additional comments.

The questionnaire should be completed by the person(s) most knowledgeable about the information requested (e.g., Veterinarian or Medical Director). Different people may complete different portions of the questionnaire as your ***facility*** deems appropriate.

EPA plans to use the data collected to determine the range of pharmaceutical management and ***disposal*** practices across the U.S. and to produce a nation-wide estimate of the amount of unused ***pharmaceuticals*** disposed to ***wastewater***. As indicated in the questions, EPA is interested in collecting information for **calendar year 2007. If information for 2007 is unavailable, then please provide available records from the most recent year with available data.**

FILLING OUT THE QUESTIONNAIRE

If you need further assistance while filling out this questionnaire, please contact Eastern Research Group, Inc. (ERG) via email at HealthServicesStudy@erg.com.

The questionnaire is divided into the following parts:

PART A: FACILITY INFORMATION;
PART B: FINANCIAL AND CLASSIFICATION INFORMATION;
PART C: COMMENTS; and
PART D: DEFINITIONS.

Each section should be completed by the person(s) most knowledgeable about the information requested. The technical data collected from PART A will be used to evaluate an estimated amount of ***unused pharmaceuticals disposed*** and to review the related ***disposal*** practices. The financial data collected from PART B will be used to evaluate costs currently incurred by facilities to manage their ***unused pharmaceuticals***.

Information collected in Part A and B is for **calendar year 2007,** unless otherwise specified.

Please use the following guidelines for filling out the questionnaire:

- Use **black ink** or **type** in the spaces provided.
- **Mark responses for each question and do not leave blanks.** Fill in the appropriate response(s) to each question unless instructed to skip the question. Check the boxes that apply to your answers. Answer the questions in sequence unless you are directed to SKIP. Do not leave any entry blank. If the answer is zero, enter “0" or “zero”.
- Enter “N/A” if a question is not applicable to your ***facility***. EPA prepared the questionnaire to be applicable to a variety of ***facilities***; therefore, not all of the questions will apply to every ***facility***. Please complete each relevant item in the questionnaire and enter “N/A” if a question is not applicable to your ***facility***.

- **Include any clarifying attachments.** If additional pages are required to clarify a response, please place the associated question number, as well as your facility name (if applicable) in the top right corner of each attachment page. The following list contains examples of items that may be included as attachments to a response to this questionnaire:

  — ***Organization*** brochure, pamphlet, and/or general description;
  — Hard copy or electronic copy of ***disposal*** records; or
  — Pollution prevention or best management practices (BMPs) policies or data.

- If you are completing the questionnaire in hard copy, some pages of the questionnaire may need to be photocopied before you respond. Indicate how many copies of the page(s) you are submitting by completing the entry "Copy ___ of ___" in the top right corner, unless instructed otherwise.

- **Indicate information that should be treated as confidential.** You may claim as confidential all information included in the response to a question by checking the Confidential Business Information (CBI) box next to the question number. Note that you may be required to justify any claim of confidentiality at a later time. See the CONFIDENTIAL BUSINESS INFORMATION section on page v.

- **Indicate atypical data in PART C - COMMENTS.** The information requested in the questionnaire is for calendar year 2007. Year-to-year operations are expected to change, but note in PART C if the information for 2007 is not representative of normal operations and why.

- **Data collection.** If you do not already maintain records for at least one month of disposal data, then record disposal data for one month in 2009 and indicate this in Part C – Comments.

- **Certification**. After completion of this questionnaire, a responsible official or an authorized representative must sign the certification statement on page vi. The corporate official or designee responsible for directing or supervising the response to the questionnaire, must sign one of the Certification Statements on page vi to either (1) verify and validate the information provided, or (2) certify that the facility did not engage in ***pharmaceutical*** distribution during the 2007 calendar year.

TIMEFRAME FOR COMPLETING QUESTIONNAIRE

The response to this questionnaire is due **60 days** after receipt.

If you wish to request an extension, you must do so **in writing** within 21 days of receipt of this questionnaire. Written requests may be e-mailed to **Meghan Hessenauer** care of Eastern Research Group, Inc. at HealthServicesStudy@erg.com or mailed to:

United States Postal Service	**One- or Two-Day Delivery (e.g., FedEx)**
Meghan Hessenauer	Meghan Hessenauer
USEPA Headquarters	USEPA Headquarters
Ariel Rios Building	Engineering and Analysis Division
1200 Pennsylvania Avenue, N.W.	Room 6231 (Connecting Wing)
Mail Code: 4303T	1301 Constitution Avenue, N.W.
Washington, DC 20460	Washington, DC 20004

Extension requests will be evaluated on a case-by-case basis. Submittal of an extension request to EPA does **not** alter the due date of your questionnaire unless and until EPA agrees to the extension and establishes a new date.

SUBMITTING THE QUESTIONNAIRE TO EPA

After completing the questionnaire and certifying the information that it contains, please use the enclosed mailing label to mail the completed questionnaire to:

U.S. Environmental Protection Agency
Questionnaire for Health Services Industry
c/o Eastern Research Group, Inc.
14555 Avion Parkway, Suite 200
Chantilly, VA 20151-1102

EPA recommends that *organizations* and *facilities* keep a copy of the completed questionnaire, including attachments. EPA will review the information submitted and may request your cooperation in answering follow-up questions, if necessary, to complete our analyses.

CONFIDENTIAL BUSINESS INFORMATION

EPA provides you the opportunity to claim information as confidential. If no business confidentiality claim accompanies the information when it is received by EPA, EPA may make the information available to the public without further notice.

Regulations governing the confidentiality of business information are contained in the Code of Federal Regulations (CFR) at Title 40 Part 2, Subpart B. You may assert a business confidentiality claim covering part or all of the information you submit, other than effluent data and information or data that is otherwise publicly available, as described in 40 CFR 2.203(b):

> "(b) *Method and time of asserting business confidentiality claim.* A business which is submitting information to EPA may assert a business confidentiality claim covering the information by placing on (or attaching to) the information, at the time it is submitted to EPA, a cover sheet, stamped or typed legend, or other suitable form of notice complying language such as 'trade secret,' 'proprietary,' or 'company confidential.' Allegedly confidential portions of otherwise nonconfidential documents should be clearly identified by the business, and may be submitted separately to facilitate identification and handling by EPA. If the business desires confidential treatment only until a certain date or until the occurrence of a certain event, the notice should so state."

You may claim as confidential all information included in the response to a question by checking the Confidential Business Information (CBI) box next to the question number. Note that you may be required to justify any claim of confidentiality at a later time. Note also that facility effluent data are not eligible for confidential treatment, pursuant to Section 308(b) of the ***Clean Water Act***, and thus will be treated as nonconfidential even if the CBI box is checked. In addition, information that is publicly available should not be claimed confidential.

Information covered by a claim of confidentiality will be disclosed by EPA only to the extent of, and by means of, the procedures set forth in 40 CFR Part 2, Subpart B. In general, submitted information protected by a business confidentiality claim may be disclosed to other employees, officers, or authorized representatives of the United States concerned with implementing the ***Clean Water Act***.

Information covered by a claim of confidentiality will be made available to EPA contractors to enable the contractors to perform the work required by their contracts with EPA. All EPA contracts provide that contractor employees use the information only for the purpose of performing the work required by their contracts and will not disclose any CBI to anyone other than EPA without prior written approval from each affected business or from EPA's legal office.

Facility Name: _____

Facility ID: _____

CERTIFICATION STATEMENT

The individual responsible for directing or supervising the preparation of the questionnaire must read and sign the Certification Statement listed below. The certifying official must be a responsible corporate official or his/her authorized representative.

Check Certification Statement #1 if the ***veterinary hospital*** distributed ***pharmaceuticals*** during the 2007 calendar year and the ***veterinary hospital*** has completed the questionnaire.

Check Certification Statement #2 if the ***veterinary hospital*** did not distribute ***pharmaceuticals*** during the 2007 calendar year.

Sign the bottom of this Certification Statement page after checking the appropriate certification statement.

☐ **Certification Statement #1**

*I certify under penalty of law that the attached questionnaire was prepared under my direction or supervision and that qualified personnel properly gathered and evaluated the information submitted. The information submitted is, to the best of my knowledge and belief, accurate and complete. In those cases where we did not possess the requested information for questions applicable to our company, we provided best estimates. We have to the best of our ability indicated what we believe to be company confidential business information as defined under 40 CFR Part 2, Subpart B. We understand that we may be required at a later time to justify our claim in detail with respect to each item claimed confidential. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment as explained in Section 308 of the **Clean Water Act**.*

☐ **Certification Statement #2**

*I certify under penalty of law that this **facility** did not distribute **pharmaceuticals** during the 2007 calendar year. I am aware that there are significant penalties for submitting false information, including the possibility of fines and imprisonment as explained in Section 308 of the **Clean Water Act**.*

_____ _____

Signature of Certifying Official Date

_____ ( ) _____

Printed Name of Certifying Official Telephone Number of Certifying Official

_____

Title of Certifying Official

_____

Facility Name

Facility Name: _____

Facility ID: _____

PART A: FACILITY INFORMATION

INSTRUCTIONS: Complete PART A of the questionnaire for operations at your *facility* in calendar year 2007.

A-1. What is the name of your ***facility***?

_____
Facility Name

A-2. What is physical address of your ***facility***?

_____
Facility Street Address

_____
Facility City

_____ _____
State Zip Code

A-3. What is mailing address of your ***facility***?

☐ Check here if mailing address is same as above.

_____
Facility Mailing Address

_____
Facility City

_____ _____
State Zip Code

A-4. What is the name, title, telephone and fax numbers, and e-mail address of the **primary contact** at your company for the information supplied in Part A of this questionnaire? (Note: We suggest that the Director of Veterinary Medicine or a Medical Director fill out this information.)

_____ (____) _____
Primary Contact Name Telephone Number

_____ (____) _____
Primary Contact Title Fax Number

_____ Convenient time to call between:
Street Address _____ ☐ am / ☐ pm and
_____ ☐ am / ☐ pm (Eastern Time)

_____ _____
City, State, Zip Code Email

Facility Name: _____

Facility ID: _____

A-5. What is the name, title, telephone and fax numbers, and e-mail address of the **secondary contact** at your company for the information supplied in Part A of this data request?

_____ (____) _____
Secondary Contact Name Telephone Number

_____ (____) _____
Secondary Contact Title Fax Number

_____ Convenient time to call between:
Street Address _____ ☐ am / ☐ pm and
_____ ☐ am / ☐ pm (Eastern Time)

_____ _____
City, State, Zip Code Email

CBI? ☐ Yes A-6. What types of services does your ***veterinary hospital*** provide? Check all that apply.

- ☐ Emergency/critical care
- ☐ Surgery
- ☐ Radiology
- ☐ Clinical pathology
- ☐ Oncology
- ☐ Dental
- ☐ 24-hour patient surveillance
- ☐ Medication dispensary
- ☐ Boarding
- ☐ Diagnostic laboratory
- ☐ Other (specify)_____
- ☐ Other (specify)_____
- ☐ Other (specify)_____

CBI? ☐ Yes A-7. How many ***patient*** visits does your ***facility*** typically have in one year? _____

CBI? ☐ Yes A-8. How many months did this ***facility*** accept ***patients*** in calendar year 2007?

_____

CBI? ☐ Yes A-9. What type of pharmacy supplied ***pharmaceuticals*** for ***patients*** of your facility in 2007? Check all that apply.

- ☐ ***Facility*** has an on-site pharmacy
- ☐ Retail pharmacy
- ☐ Mail-order pharmacy
- ☐ Other (*specify*) _____
- ☐ Other (*specify*) _____
- ☐ Other (*specify*) _____

Facility Name: _____

Facility ID: _____

CBI?
☐ Yes

A-10. Question A-10 requests information on how ***pharmaceuticals*** were transferred from the pharmacy(ies) indicated in Question A-9 to the ***patients*** at your ***facility*** in 2007.

Where were ***pharmaceuticals*** stored at your ***facility*** upon receipt from the pharmacy, if applicable?

☐ Med room or storage room
☐ Satellite pharmacy
☐ Automatic dispensing system (e.g., Pyxis®, Omnicell, Baxter)
☐ Other (*specify*) _____
☐ Other (*specify*) _____
☐ Other (*specify*) _____
☐ N/A medications are not stored at this ***facility***.

Indicate in Table A-1 who is responsible for the ***pharmaceuticals*** during the transfer of ***pharmaceuticals*** from the pharmacy to the ***patient*** and from ***patient*** to ***disposal***.

Table A-1. *Pharmaceuticals* Transfer from Pharmacy to *Disposal*

Transfer Step	Pharmacist/ Veterinarian	Veterinary Technician	*Patient Owner*	Other (specify)
Who obtains ***pharmaceuticals*** from the pharmacy?	☐	☐	☐	☐ _____
Who maintains ***pharmaceuticals*** while they are stored at the ***facility***?	☐	☐	N/A	☐ _____
Who has ownership of the ***pharmaceuticals*** while being stored in your ***facility***?	☐ (Pharmacy)	☐ (Facility)	N/A	☐ _____
Who collects ***unused pharmaceuticals*** from the ***patient***?	☐	☐	N/A	☐ _____
Who maintains the ***unused pharmaceuticals*** while they are stored at the ***facility***?	☐	☐	N/A	☐ _____
Who is responsible for disposal or offsite transfer of ***unused pharmaceuticals***?	☐	☐	N/A	☐ _____

Facility Name: _____

Facility ID: _____

☐ **CBI?** Yes

A-11. What was the average number of doses administered per month to all ***patients*** at your ***facility*** in 2007? Example: 4,000 tablets.

Tablets or Capsules (Example: dose is one tablet or capsule) _____

Liquid (administered orally) _____

Liquid (administered by IV/infusion) _____

Patches _____

Topical creams or ointments _____

☐ **CBI?** Yes

A-12. What was the average number of doses administered per month to all ***patients*** at your ***facility*** that were unused in 2007? Example: 1,000 tablets or X% of 300 IVs.

Tablets or Capsules (Example: dose is one tablet or capsule). _____

Liquid (administered orally) _____

Liquid (administered by IV/infusion) _____

Patches _____

Topical creams or ointments _____

Facility Name: _____

Facility ID: _____

CBI? ☐ Yes

A-13. Why were some of the ***pharmaceuticals*** brought into your ***facility*** not used? Check all that apply and provide the approximate percentage for each reason.

Example – In your facility, approximately 20% of the ***unused pharmaceuticals*** results from ***patients*** changing medications. Check the box by ☒ Medication no longer prescribed or required and write 20 %

☐	***Patient*** no longer at ***facility*** and/or deceased	_____ %
☐	Allergic and/or adverse reaction	_____ %
☐	Contraindicated (drug interaction problem)	_____ %
☐	Medication expired	_____ %
☐	Medication no longer prescribed or required	_____ %
☐	***Patient owner*** refused to continue treatment	_____ %
☐	Excess dosage (e.g., medication available in 75 mL container but ***patient*** was only prescribed 50 mL)	_____ %
☐	Samples from drug companies	_____ %
☐	Medication dropped/spilled	_____ %
☐	Other (*specify*) _____	_____ %
☐	Other (*specify*) _____	_____ %
☐	Other (*specify*) _____	_____ %
	TOTAL =	100 %

CBI? ☐ Yes

A-14. How did your ***facility*** determine how to ***dispose*** of ***unused pharmaceuticals*** that require special ***disposal*** (e.g., hazardous waste) in 2007? Check all that apply. *Note: If your **facility** has composed disposal guidelines, please attach a copy to this questionnaire and check the box here.* ☐

☐ Environmental management staff identifies special disposal requirements
☐ Trained technician or other medical staff identifies special disposal requirements
☐ ***Pharmaceutical*** waste database (e.g., PharmE® Waste Wizard) identifies special disposal requirements
☐ Waste contractor identifies special disposal requirements
☐ Other (specify) _____
☐ Other (specify) _____
☐ Other (specify) _____

Facility Name: _____

Facility ID: _____

CBI? ☐ Yes

A-15. How did your ***facility*** communicate ***disposal*** practices for ***unused pharmaceuticals*** that require special ***disposal*** (e.g., hazardous waste) to its staff in 2007? Check all that apply.

- ☐ Bar code system for pharmaceutical containers (e.g., EcoRex™)
- ☐ Labeling system for pharmaceutical containers
- ☐ Disposal method is displayed by automatic dispensing system (e.g., Pyxis®, Omnicell, Baxter)
- ☐ Training
- ☐ Posters, booklets, flyers
- ☐ Other (specify) _____
- ☐ Other (specify) _____
- ☐ Other (specify) _____

CBI? ☐ Yes

A-16. What practices did your ***facility*** use in 2007 to collect and sort ***unused pharmaceuticals*** that require special ***disposal*** (e.g., hazardous waste)? Check all that apply.

- ☐ ***Unused pharmaceuticals*** are collected and stored in a central area for sorting
- ☐ ***Unused pharmaceuticals*** are placed into separate bins for different types of ***disposal*** in satellite collection areas throughout the ***facility***
- ☐ Automated sorting and ***disposal*** of ***unused pharmaceuticals*** (e.g., EcoRex™)
- ☐ ***Unused pharmaceuticals*** are not collected and sorted prior to ***disposal***
- ☐ Other (specify) _____
- ☐ Other (specify) _____
- ☐ Other (specify) _____

Facility Name: _____

Facility ID: _____

CBI?
☐ Yes

A-17. Complete Table A-2, below, to indicate which practices your ***facility*** used in 2007 to manage ***unused pharmaceuticals.*** Provide the relative percentage that each management practice was used for each ***pharmaceutical*** category.

Table A-2. Practices your *Facility* used in 2007 to Manage *Unused Pharmaceuticals*

Management Practice	***Pharmaceutical* Category**					
	Hazardous *Pharmaceuticals* (not *controlled substances*)	**Hazardous *Pharmaceuticals* (*controlled substances*)**	**Bulk Chemotherapy Waste**	**Trace Chemotherapy Waste**	**Non-Hazardous (not *controlled substances*)**	**Non-Hazardous (*controlled substances*)**
Disposal via drain or toilet flushing						
Disposal via trash (regular dry or wet garbage)						
Disposal via medical waste (biohazard bag/sharps container)						
Disposal via hazardous waste						
Disposal via non-hazardous witnessed incineration						
Returned directly to onsite ***facility*** pharmacy						
Returned directly to offsite retail pharmacy						
Shipped to ***reverse distributor***						
Other (specify): _____						
Other (specify): _____						
Other (specify): _____						
Total	100%	100%	100%	100%	100%	100%

Facility Name: _____

Facility ID: _____

CBI? ☐ Yes

A-18. Please comment on any ***disposal*** practices listed in Question A-17 that your ***facility*** does not use because they are unavailable or subject to restrictions.

Example: Cannot use reverse distributor for hydrocodone because it is a DEA-controlled substance.

_____

_____

_____

_____

CBI? ☐ Yes

A-19. How much does it cost your ***facility*** each month to manage ***unused pharmaceuticals***? Please provide the average monthly cost (in either dollars or hours as appropriate) for each method and the labor descriptions and percentages of the time spent on each method noted in Question A-17 in Table A-3. The average monthly cost in dollars should include disposal fees and/or contractor fees in addition to any ***facility*** costs.

Table A-3. Monthly *Unused Pharmaceuticals* Management

Management Practice	Average Monthly Cost		Labor Allocation and Percent of Time Spent on Management Practice					
	Amount	Unit (hours or dollars)	Pharmacist	Veterinarian	Technician	Other: _____	Other: _____	Total
Disposal via drain or toilet flushing			%	%	%	%	%	100%
Disposal via trash (regular dry or wet garbage)			%	%	%	%	%	100%
Disposal via medical waste (biohazard bag/sharps container)			%	%	%	%	%	100%
Disposal via hazardous waste			%	%	%	%	%	100%
Disposal via non-hazardous witnessed incineration			%	%	%	%	%	100%
Returned directly to onsite ***facility*** pharmacy			%	%	%	%	%	100%
Returned directly to offsite retail pharmacy			%	%	%	%	%	100%
Shipped to ***reverse distributor***			%	%	%	%	%	100%
Other (specify): _____			%	%	%	%	%	100%
Other (specify): _____			%	%	%	%	%	100%
Other (specify): _____			%	%	%	%	%	100%

Facility Name: _____

Facility ID: _____

CBI? ☐ Yes

A-20. Please attach a copy of your ***facility's*** records of the amounts of ***unused pharmaceuticals disposed*** and the ***disposal*** method for one representative month in 2007 or for another calendar year if 2007 records are not available. Please see Table A-4 for an example of the information that EPA is requesting; however, you may provide records in any available format. If your ***facility*** does not have these records available, please complete Table 1 in Attachment A for one month.

Table A-4. Example Records for Monthly *Disposal* of *Unused Pharmaceuticals*

Name of *Pharmaceutical*	*Pharmaceutical* Classification	*Controlled Substance?*	Hazardous Waste?	Chemotherapy Waste? (e.g., Yes - Trace, Yes - Bulk, No)	Estimated Number of *Unused Pharmaceuticals Disposed*	Unit of Measure (e.g., tablets, vials, capsules, patches, ounces, grams, mL)	Amount of *Pharmaceutical* Active Ingredient per Dose	Method of *Disposal*
Epinephrine	Cardiac Drug	No	Yes	No	20	vials	35 mg	Hazardous Waste
Oxytocin	Hormone	No	No	No	50	vials	variable	Down the Drain
Captopril	Cardiac Drug	No	No	No	5	tablets	12.5 mg	Trash

CBI? ☐ Yes

A-21. With regards to flushing unused pharmaceuticals down a drain or toilet in 2007, check all that apply.

☐ No ***Unused Pharmaceuticals*** Flushed Down the Drain or Toilet
☐ Drug Enforcement Administration (DEA) Policy (Controlled Substances Act)
☐ State or Local Policy
☐ ***Organization*** and/or ***Facility*** Guidelines
☐ Ease of ***Disposal***
☐ Cost of ***Disposal*** Alternatives
☐ Staff Time Constraints
☐ Other (*specify*) _____
☐ Other (*specify*) _____
☐ Other (*specify*) _____

CBI? ☐ Yes

A-22. If you checked "DEA Policy" or "State or Local Policy" in Question 0, please explain why these policies caused your ***facility*** to dispose of ***unused pharmaceuticals*** by flushing down the drain or toilet.

DEA Policy: _____

_____

State or Local Policy *(provide citation to regulation)*: _____

_____

Organization and/or ***Facility*** Guidelines: _____

_____

Facility Name: _____

Facility ID: _____

CBI? ☐ Yes

A-23. If your ***facility disposed*** of ***unused pharmaceuticals*** down a drain or toilet in 2007, please indicate the destination of the ***wastewater*** from your ***facility***.

☐ ***Wastewater*** is sent to a sewage treatment plant.

_____

Name of Company on your Sewer Bill (Example: *City of Springfield Public Works)*

☐ Our ***facility*** does not have a sewer bill because our facility is a ***direct wastewater discharger***:

_____

Name of River, Lake, or ***Surface Water***

_____

NPDES Permit Number

☐ ***Wastewater*** is sent to another destination: _____

Explain: _____

☐ Septic System

☐ Unknown

CBI? ☐ Yes

A-24. How often do you dispose of unused pharmaceuticals at your facility?

☐ Daily
☐ As Necessary *(specify):* _____
☐ Once/Week
☐ Once/Month
☐ Other *(specify)*: _____
☐ Other *(specify)*: _____
☐ Other *(specify)*: _____

CBI? ☐ Yes

A-25. What management practices or ***pollution prevention*** activities does your ***facility*** use to reduce the amount of ***unused pharmaceuticals*** at your ***facility***? Check all that apply and attach a copy of any literature if available.

☐ Use of an automatic dispensing system (e.g., Pyxis®, Omnicell, Baxter)
☐ Central collection system for companies with multiple facilities
☐ Render ***controlled substances*** inert by combining with solvent waste, such as chloroform, for ***disposal*** as hazardous waste with a licensed off-side hazardous waste provided
☐ Inventory analysis
☐ Stock rotation
☐ Order medication in smaller quantities to avoid excess (e.g., fewer tablets or doses)
☐ Order medication in smaller doses to avoid excess (e.g., 5 mg instead of 10 mg)
☐ Other *(specify)*: _____
☐ Other *(specify)*: _____
☐ Other *(specify)*: _____

Facility Name: _____

Facility ID: _____

CBI? ☐ Yes

A-26. If your ***facility*** were prevented from ***disposing*** of ***unused pharmaceuticals*** down the drain or toilet, what alternative management method(s) would your facility likely use? Check all that apply.

- ☐ Hire management company to organize and track disposal
- ☐ Work with local/state law enforcement and regulatory agencies for more flexible controlled substances disposal
- ☐ Increase and/or improve storage and sorting to have less frequent, more organized disposal
- ☐ Change dispensing practices to minimize dose distribution
- ☐ Other *(specify)*: _____
- ☐ Other *(specify)*: _____
- ☐ Other *(specify)*: _____

CBI? ☐ Yes

A-27. What is the basis of your policy regarding ***unused pharmaceutical disposal***? Check all that apply.

- ☐ Hazardous waste (RCRA) requirements
- ☐ State requirements
- ☐ Waste minimization
- ☐ Cost reduction
- ☐ Drug Enforcement Agency (DEA)
- ☐ OSHA compliance
- ☐ Other *(specify)*: _____
- ☐ Other *(specify)*: _____
- ☐ Other *(specify)*: _____

A-28. For the purpose of training staff in proper ***pharmaceutical disposal***, what is best type of material the Environmental Protection Agency (EPA) can provide you (i.e., brochure, CD/DVD)? Check all that apply.

- ☐ CD
- ☐ DVD
- ☐ Internet downloads of written material
- ☐ Web-based training
- ☐ Internet
- ☐ Hard Copy
- ☐ Outreach meetings
- ☐ Other *(specify)*: _____
- ☐ Other *(specify)*: _____
- ☐ Other *(specify)*: _____

Facility Name: _____

Facility ID: _____

PART B: FINANCIAL AND CLASSIFICATION INFORMATION FACILITY AND ORGANIZATION

CBI? ☐ Yes B-1. How many employees (full- and part-time) work at this ***facility***?

Full time (35+ hours/week) _____full-time employees

Part time (<35 hours/week) _____part-time employees

CBI? ☐ Yes B-2. What were the 2005, 2006, and 2007 revenues for this ***facility***? (Round to nearest thousand; the zeros are already in the table.)

Facility **Revenues**

2005	2006	2007
$ _ _ _, _ _ _, 0 0 0	$ _ _ _, _ _ _, 0 0 0	$ _ _ _, _ _ _, 0 0 0

CBI? ☐ Yes B-3. What were the 2005, 2006, and 2007 operating costs for this ***facility***? (Round to nearest thousand; the zeros are already in the table.)

Facility **Operating Costs**

2005	2006	2007
$ _ _ _, _ _ _, 0 0 0	$ _ _ _, _ _ _, 0 0 0	$ _ _ _, _ _ _, 0 0 0

CBI? ☐ Yes B-4. What is this ***facility's*** ownership?

- ☐ Government
  - ☐ Federal
  - ☐ State
  - ☐ Indian Nation
  - ☐ Community (County, City, Town, etc.)
    The population served by this facility is:
    - ☐ 50,000 or fewer
    - ☐ More than 50,000
- ☐ Not-For-Profit (including religious)
- ☐ For-Profit (Investor-owned)

If the *facility* belongs to a government entity, you have completed the questionnaire.
THANK YOU FOR YOUR TIME AND PARTICIPATION

If the *facility* belongs to a NOT-FOR-PROFIT or a FOR-PROFIT entity, continue with Question B-5.

For assistance, please contact ERG at HealthServicesStudy@erg.com.

Facility Name: _____

Facility ID: _____

CBI? ☐ Yes B-5. What is the name of the ***organization*** that owns this ***facility***?

_____

Organization Name

CBI? ☐ Yes B-6. What is the physical address of the ***organization*** that owns this ***facility***?

_____

Street Address

_____

City

_____ _____

State Zip Code

CBI? ☐ Yes B-7. What is the mailing address of the ***organization*** that owns this ***facility***?

☐ Check here if mailing address is same as above.

_____

Mailing Address

_____

City

_____ _____

State Zip Code

CBI? ☐ Yes B-8. What is your ***organization's*** ownership?

☐ Publicly traded
☐ Privately owned

CBI? ☐ Yes B-9. How many pet health care service ***facilities*** are owned by this ***organization***? _____

CBI? ☐ Yes B-10. How many employees (full- and part-time) work at this ***organization***? _____

Full time (35+ hours/week) _____ full-time employees

Part time (<35 hours/week) _____ part-time employees

CBI? ☐ Yes B-11. What were the 2005, 2006, and 2007 revenues for this ***organization***? (Round to nearest thousand; the zeros are already in the table.)

***Organization* Revenues**

2005	2006	2007
$ _ _ _, _ _ _, 0 0 0	$ _ _ _, _ _ _, 0 0 0	$ _ _ _, _ _ _, 0 0 0

Facility Name: _____

Facility ID: _____

CBI?
☐ Yes

B-12. What were the 2005, 2006, and 2007 operating costs for this ***organization***? (Round to nearest thousand; the zeros are already in the table.)

***Organization* Operating Costs**

2005	2006	2007
$ _ _ _, _ _ _, 0 0 0	$ _ _ _, _ _ _, 0 0 0	$ _ _ _, _ _ _, 0 0 0

THANK YOU FOR YOUR TIME AND PARTICIPATION

Facility Name: _____

Facility ID: _____

Copy ____ of ____

PART C: COMMENTS

Year-to-year operations are expected to change, but note in this table if 2007 information is not representative of normal operations and why. Cross reference your comments by question number and indicate the confidential status of your comment by checking ☒ the box in the column titled "CBI" (Confidential Business Information). If you are completing a hard copy data request and you need additional rows, make copies of this page.

Question Number	CBI?	Comment
	☐ Yes	
	☐ Yes	
	☐ Yes	
	☐ Yes	
	☐ Yes	
	☐ Yes	
	☐ Yes	
	☐ Yes	
	☐ Yes	
	☐ Yes	
	☐ Yes	
	☐ Yes	

PART D: DEFINITIONS

The terms identified below are identified in the text of this data request in bold and italic font.

Best Management Practices (BMPs)* – BMPs include methods to prevent toxic and hazardous pollutants from reaching rivers, lakes and other** *surface water* **and sewage treatment plants. For example, BMPs for this industry could include, but are not limited to, practices to reduce the amount of** *pharmaceuticals* **generated that are not used or alternatives to** *disposal* **of** *unused pharmaceuticals. Example BMPs include dispensing** *pharmaceuticals* **as unit doses and using a** *reverse distributor* **for managing returns of** *unused pharmaceuticals***.**

Clean Water Act (CWA) – Federal legislation enacted by Congress to "restore and maintain the chemical, physical, and biological integrity of the Nation's waters" (Federal Water Pollution Control Act of 1972, as amended, 33 U.S.C. 1251 et seq.).

Controlled Substances – ***Pharmaceuticals*** and certain other chemicals, both narcotic and non-narcotic, whose possession and use are regulated within "schedules" under the Controlled Substances Act.[1]

Direct Wastewater Discharge – The discernible, confined, and discrete conveyance of pollutants to United States ***surface waters*** such as rivers, lakes, and oceans. See 40 CFR 122.2. If you ***discharge*** directly, you have an NPDES permit (see below).

Discharge – The conveyance of ***wastewater*** to: (1) United States ***surface waters*** such as rivers, lakes, and oceans, or (2) a publicly owned, privately owned, federally owned, combined, or other treatment works (i.e., municipal wastewater treatment plant).

Disposal – Intentional placement of ***unused pharmaceuticals*** as waste into drain or toilet or into municipal, medical, or hazardous waste for permanent treatment or disposition.

Facility – Facilities include ***veterinary hospitals***.

Organization – An organization that operates one or more ***veterinary hospitals***. Organizations may include government-owned, religiously affiliated, nonprofit, and for-profit organizations.

Non-Disposal – Return of ***unused pharmaceuticals*** to a pharmacy, take back program, ***reverse distributor***, ***pharmaceutical*** manufacturer or donation site.

NPDES Permit – Permits issued under the National Pollutant Discharge Elimination System (NPDES) program authorized by Sections 307, 318, 402, and 405 of the ***Clean Water Act*** that apply to facilities that ***discharge wastewater*** directly to United States ***surface waters***.

Patient – Any animal receiving medical, surgical, or psychiatric care or treatment at a ***veterinary hospital***.

Patient Owner – The person/caretaker responsible for the animal receiving treatment.

Pharmaceuticals – Any chemical or biological substance, synthetic or non-synthetic, that when taken by the ***facility patient*** will cure or reduce the symptoms of an illness or ongoing medical condition. Additionally, this definition refers to substances taken by the ***facility patient*** for preventive medicine. This includes over the counter medication, as well as those prescribed by a veterinarian. Table 1 in Attachment B includes a list of the ***pharmaceuticals*** most frequently prescribed according to http://www.ahc.umn.edu/rar/umnuser/formulary.html#Miscellaneous. The definition of ***pharmaceuticals*** includes, but is not limited to, the ***pharmaceuticals*** listed in Table 1 in Attachment B.

Pharmacy – Any unit or organization dispensing pharmaceuticals, whether located within the facility or outside of the facility.

[1] See http://www.usdoj.gov/dea/pubs/csa.html for information on the Controlled Substances Act.

Pollution Prevention – The use of materials, processes, or practices that reduce or eliminate the creation of ***pollutants*** or wastes. It includes practices that reduce the use of hazardous and nonhazardous materials, energy, water, or other resources, as well as those practices that protect natural resources through conservation or more efficient use. For example, ***pollution prevention*** for this industry could include but is not limited to reducing the amount of ***unused pharmaceuticals*** generated at ***veterinary hospitals***.

Reverse Distributor – A company engaged primarily in the business of accepting outdated/expired ***pharmaceuticals*** from pharmacies and drug wholesalers for the primary purpose of returning them to the manufacturer for credit.

Surface Waters – Waters of the United States including, but not limited to, oceans and all interstate and intrastate lakes, rivers, streams, creeks, mudflats, sand flats, wetlands, sloughs, prairie potholes, wet meadows, playa lakes, and natural ponds.

Unused Pharmaceuticals – Any ***pharmaceutical*** purchased or prescribed for a ***patient*** that is not taken by or administered to the ***patient***. These ***pharmaceuticals*** may be returned to the pharmacy, taken back by a ***reverse distributor***, ***pharmaceutical*** manufacturer, or an organization accepting donations (***non-disposal***). Alternatively, ***pharmaceuticals*** may be intentionally placed into a drain or toilet at the facility or into the facility's municipal trash, medical waste, or hazardous waste (***disposal***). This definition does not include any ***pharmaceutical*** ingredients or metabolites excreted or washed from patient or residents.

Veterinary Hospital – An institution that provides medical, surgical, or psychiatric care and treatment for sick or injured animals.

Wastewater – Water that is generated from any source at a ***veterinary hospital*** that includes, but not limited to, restrooms, cafeterias, showers, domestic activities, and any healthcare activity.

ATTACHMENT A

Table 1. Example Records for Monthly *Disposal* of *Unused Pharmaceuticals*

Name of *Pharmaceutical*	*Pharmaceutical* Classification	*Controlled Substance?* (Y/N)	Hazardous Waste? (Y/N)	Chemotherapy Waste? (e.g., Yes - Trace, Yes - Bulk, No)	Estimated Number of *Unused Pharmaceuticals Doses Disposed*	Unit of Measure (e.g., tablets, vials, capsules, patches, ounces, grams, mL)	Amount of *Pharmaceutical* Active Ingredient per Dose	Method of *Disposal*

ATTACHMENT B

Table 1. Classifications and Names of Common Pharmaceuticals

Veterinary Pharmaceutical Therapeutic Class	Names of Pharmaceuticals Active Ingredient (Common Name)
Analeptic	Diazepam Midazolam Pentobarbital Phenobarbital Thiamylal/Thiopental
Anesthetics	Alpha Chloralose/Chloral Hydrate Benzocaine Droperidol/Fentanyl (Innovar) Halothane Isoflurane Ketamine Lidocaine Methohexital (Brevital) Methoxyflurane Pentobarbital Quinaldine Sulfate Thiamylal/Thiopental Tiletamine/Zolazepam (Telazol) Tribromoethanol/Trichloroethylene Tricaine
Analgesic- Opiate	Buprenorphine Butorphanol Hydrocodone Meperidine (Demerol) Morphine Nalbuphine Naloxone Oxymorphone Pentazocine (Talwin)
Analgesics- Non-steroidal Anti-inflammatory	Acetaminophen Aspirin Carprofen (Rimadyl) Dipyrone Flunixin (Banamine) Ibuprofen Ketoprofen Meloxicam Phenylbutazone
Muscle Relaxants/Neuromuscular blocker	Gallamine Guaifenesin Methocarbamol (Robaxin-V) Metocurine Iodide Succinylcholine (Anectine) Tubocurarine
Sedative	Acepromazine Azaperone (Stresnil) Diazepam Medetomidine (Domitor) Midazolam Propofol Xylazine

Table 1. Classifications and Names of Common Pharmaceuticals

Veterinary Pharmaceutical Therapeutic Class	Names of Pharmaceuticals Active Ingredient (Common Name)
Anthelminthic/Antiprotozoa	Amitraz Amprolium Dichlorvos Diethylcarbamazine Esiprantel (Cestex) Febantel Fenbendazole Ivermectin Levamisole Mebendazole Metronidazole (Flagyl) Milbemycin Oxime (Interceptor) Piperazine Praziquantel (Droncit) Pyrantel (Strongid-T) Thiabendazole
Antifungal	Amphotericin B Flucytosine Griseofulvin Ketoconazole
Antimicrobial	Amikacin Amoxicillin Cephalosporins Chloramphenicol Chlorhexidine (Nolvasan) Ciprofloxacin Clindamycin (Antirobe) Doxycycline Enrofloxacin (Baytril) Erythromycin Gentamicin Lincomycin Minocycline Neomycin Orbifloxacin (Orbax) Ormetoprim/Sulfadimethoxine (Primor) Oxytetracycline Penicillin Rifampin Sulfonamides Tetracycline Tiamulin Ticarcillin Tilmicosin Trimethoprim/SulfonamideTylosin
Antihistamine	Chlorpheniramine Cimetidine Diphenhydramine
Autonomic Drug	Atropine Bethanechol Glycopyrrolate

Table 1. Classifications and Names of Common Pharmaceuticals

Veterinary Pharmaceutical Therapeutic Class	Names of Pharmaceuticals Active Ingredient (Common Name)
Cardiac Drug	Captopril Digoxin Epinephrine Furosemide (Lasix) Nitroglycerin Procainamide Propanolol
Electrolytes/Nutritional	Calcium Iron Dextran Methionine, D-L Potassium Taurine Vitamin A & D Vitamin B Complex Vitamin C Vitamin D Vitamin K
Gastrointestinal Agent	Chlorpromazine Cimetidine Metoclopramide Pancrealipase (Viokase) Ranitidine Sucralfate
Hormone	Dexamethasone Dinoprost (Lutalyse) Estradiol Cypionate Fludrocortisone Gonadorelin Levothyroxine Methylprednisolone Misoprostol Oxytocin Prednisone/Prednisolone Stanozolol (Winstrol-V) Triamcinolone
Respiratory	Aminophyline Dextromethorphan Doxapram Hydrocodone
Miscellaneous	Atapimazole (Antisedan) Beuthanasia Bromosolfophthalein Formaldehyde Heparin Insulin Methimazole (Tapazole) Propylene Glycol Protamine Sulfate Yohimbine