STATE OF CONNECTICUT
DEPARTMENT OF ENVIRONMENTAL PROTECTION

March 4, 2009

RCRA Docket
Environmental Protection Agency
Mailcode: 2822T
1200 Pennsylvania Avenue NW
Washington, DC 20460

Attention: Docket ID No. EPA-HQ-RCRA-2007-0932

Dear Sir or Madam:

The Connecticut Department of Environmental Protection ("CTDEP") has reviewed the December 2, 2008 proposed rule entitled "Amendment to the Universal Waste Rule: Addition of Pharmaceuticals." CTDEP's comments on the proposed rule are detailed in the following numbered sections.

1.) CTDEP Supports the General Approach of the Proposed Rule.

CTDEP supports the general approach of the proposed rule, and believes that, if made final, the proposed rule would result in a number of benefits, including, most notably: (1) the safer and more environmentally-sound management of pharmaceutical wastes (especially by smaller generators of such wastes); and, (2) the reduction of barriers to the implementation of household pharmaceutical take-back programs. However, CTDEP is concerned about specific aspects of the proposed rule, as elaborated in more detail below.

2.) Chemotherapy Drugs Should Be Listed as Hazardous Wastes.

On page 73523 of the proposed rule preamble, EPA notes that the proposed rule is intended to cover a wide class of pharmaceuticals, and specifically mentions chemotherapy drugs as one of the types that are intended to be captured by the proposed rule. However, only a small portion of the chemotherapeutic or antineoplastic agents that are currently in use in the field of oncology would be classified as hazardous wastes when discarded. These are primarily limited to a few Commercial Chemical Products that are listed at 40 CFR 261.33 (i.e., the so-called "U" and "P" lists). Because of their high toxicity, CTDEP believes that all such agents currently in use should be evaluated as potential hazardous wastes, and listed as appropriate. While it might be a daunting task to evaluate all unlisted chemotherapeutic or antineoplastic agents for listing as U or P-wastes, another option that EPA should consider is listing such drugs as a group under a single listing. Specifically, CTDEP believes that EPA could list such drugs under the "hazardous wastes from non-specific sources" in 40 CFR 261.31.

CTDEP understands that, by streamlining the requirements for the management of discarded pharmaceuticals, the proposed rule would encourage some generators of discarded chemotherapeutic or antineoplastic agents to voluntarily manage such drugs as hazardous waste. However, for these particularly toxic drugs, CTDEP does not believe that voluntary management under the proposed universal waste requirements by even a substantial portion of the generators of these wastes would be sufficient to properly protect human health and the environment. In particular, CTDEP believes that without being listed as hazardous waste, many chemotherapeutic and antineoplastic agents would be disposed of in solid waste containers, where they may leak out with accumulated rainwater or other liquids, or be disposed of at solid waste disposal facilities, resulting in exposures to sanitation and disposal facility workers.

3.) Epinephrine Salts Should Be Added to the P042 Definition.

Footnote 12 on page 73524 of the proposed rule preamble makes reference to EPA's October 15, 2007 policy which stated that epinephrine salts are not covered by the P042 definition. However, CTDEP believes that EPA should not maintain this policy, but instead modify the P042 definition to cover both base epinephrine and epinephrine salts. The salts, being much more water-soluble, are therefore more amenable to absorption by the human body than base epinephrine. Indeed, the available toxicology data on common epinephrine salts, such as epinephrine hydrochloride and epinephrine bitartrate, shows that epinephrine salts are of comparable toxicity and in some cases *more toxic* than base epinephrine. For example, the intravenous LD50 for base epinephrine in rats is 5mg/kg. The corresponding LD50 for epinephrine bitartrate is 0.0082 mg/kg, a difference of nearly three orders of magnitude.

CTDEP understands that medical formulations of epinephrine salts typically contain very low concentrations of the active ingredient, mitigating the toxicity hazard that they represent. However, in the absence of proper regulation, even these low-concentration medical formulations can present significant hazards to human health. As an example, consider discarded unused EpiPens. These devices contain a high dose of epinephrine salt intended to provide an emergency dose of epinephrine during a severe life-threatening allergic reaction. These devices include an auto-injection device that is known to cause accidental injections when mishandled. If unused EpiPens are not regulated as hazardous waste, they may easily find their way into solid waste containers, where sanitation and disposal facility workers may be exposed to potential needle sticks and an unintended administration of a high dose of epinephrine (perhaps without even being aware of what has happened). A single therapeutic dose of epinephrine can cause serious side effects even in healthy individuals. In persons with pre-existing medical conditions or that are on certain medications, these side effects can be very serious, or even life-threatening. Consider the following warning, which is taken directly from the Material Safety Data Sheet produced by Dey Pharmaceutical, manufacturer of the EpiPen (emphasis added):

> "Large doses or accidental intravenous injection of epinephrine may result in cerebral hemorrhage due to sharp rise in blood pressure. Fatalities may also result from pulmonary edema because of peripheral vascular constriction together with cardiac stimulation. Do not inject into intravenously or into buttock. Side effects of epinephrine may include palpitations, tachycardia, sweating, nausea and

vomiting, respiratory difficulty, pallor, dizziness, weakness, tremor, headache, apprehension, nervousness and anxiety."

CTDEP therefore believes that EPA should revise the P042 definition to include epinephrine salts. Although the revision of the P042 definition would require that partially-used epinephrine IV bags, unused EpiPens, and other similar wastes be classified as hazardous wastes, CTDEP believes that the reduced requirements of the proposed Universal Waste Rule for pharmaceutical wastes would greatly mitigate the effects of such classification. In particular, generators of such wastes would not experience an adverse effect on their generator status, or have to deal with the logistical problems associated with satellite storage of these materials, both of which have created problems in the absence of a Universal Waste Rule for pharmaceuticals.

4.) Pharmaceuticals Being Sent to Return Centers Should Be Subject to Regulation as Wastes from the Point of Origin.

On pages 73525 and 73531 of the proposed rule preamble, EPA states that unused or expired pharmaceuticals that are returned to a manufacturer-sponsored reversed distribution center (often referred to simply as a "return center") would not be considered solid or hazardous wastes. EPA cites as its reason for this conclusion that the unused or expired pharmaceuticals are "being returned ... for possible manufacturer credit" and therefore "still have potential value to the pharmacy or hospital..." This statement appears to be consistent with prior EPA policy, in particular a May 16, 1991 letter to Pharmaceutical Services, Inc. (RCRA On-Line document # 11606), which stated that unused or expired pharmaceuticals that are sent to return centers are not wastes until they are received at the return center and evaluated to determine if they may be reused or recycled. That is, EPA assumes there is a legitimate presumption that the returned pharmaceuticals will be recycled, therefore justifying their not being a solid or hazardous waste.

While Connecticut does not have one of these return centers in Connecticut, it does have many generators of unused or expired pharmaceuticals that send their unwanted materials to return centers located in other states. In discussing these facilities with neighboring states that have such facilities, we have found that essentially all of the pharmaceuticals sent to return centers are not reused or recycled, but rather consolidated and sent for disposal. Hence any presumption of reuse or recycling that the May 16, 1991 policy was based on is not valid (indeed, if there is any presumption to be made, it must be that returned pharmaceuticals will be disposed of, not reused or recycled). As for the issue of the supposed value of the returned pharmaceuticals, the proposed rule preamble discussion on page 73525 notes that the manufacturers' main reason for providing these return arrangements is not for the purposes of facilitating recycling or reuse, but rather merely as a "financial incentive to pharmacies, hospitals, and other health care facilities to stock their products." In fact, the pharmaceuticals have no inherent value (indeed, due to the cost of disposal, they would actually have negative value). The only "value" that these returned pharmaceuticals have is the result of a marketing artifact. CTDEP does not believe that EPA should acknowledge or accept such artificial values as legitimate, and believes that doing so would establish a precedent that could be abused in other, more traditional, industrial waste management scenarios.

In addition CTDEP is aware that there have been serious waste mismanagement issues at some of these return centers, including storing materials for excessive periods of time before sending them for disposal, and the physical mismanagement of wastes while in storage at these facilities. In light of these facts, CTDEP believes that EPA should not consider unused or expired pharmaceuticals that are sent to return centers as being exempt from solid and hazardous waste requirements. Rather, CTDEP believes that these pharmaceuticals should be subject to regulation from the point that they are determined to be unwanted or unusable by the generating facility. While interpreting the regulatory status of these materials in this manner would present numerous problems under the current regulatory structure (i.e., full regulation as hazardous wastes), CTDEP believes that this approach would be appropriate and workable under the proposed Universal Waste Rule for pharmaceuticals. In particular, requiring the management of returned pharmaceuticals as waste would ensure that generators of these pharmaceuticals manage them properly, and would also ensure that return centers are appropriately accountable for their management of the returned pharmaceuticals. Both of the parties in these transactions would be regulated only as universal waste handlers, with the generators most likely being small quantity handlers. As a result, the regulatory burden would be low, while at the same time ensuring proper management of waste pharmaceuticals at all levels of the management chain. As for the transportation of these wastes, many universal wastes are already being transported by common carriers (e.g., mercury-containing equipment, lamps, etc.). Hence, regulation of returned pharmaceuticals as universal wastes should not hinder the transportation of these materials to the return centers.

In addition, there are many pharmaceutical products that are <u>not</u> eligible for manufacturer return credits (in particular, many generic drugs). These pharmaceuticals have no "return value" as described above, and would therefore not be eligible for an exemption from being classified as solid or hazardous wastes under the rationale provided in the proposed rule preamble, as discussed above. CTDEP is aware that generators of unused or expired pharmaceuticals of this type often send them to the same return centers that they send their pharmaceuticals that are eligible for return credit. Hence, such pharmaceuticals would have to be managed as solid and hazardous wastes beginning at the point that they are determined to unusable or expired. CTDEP believes that it makes no sense to manage two sets of pharmaceuticals in a different manner, and believes that, both for the purpose of simplicity as well as to ensure protection of human health and the environment, both pharmaceuticals that are eligible for a return credit and those that are not eligible for such credit should be managed in the same manner – namely, as universal waste pharmaceuticals – from the point that they are determined to be unwanted or expired.

5.) <u>The Proposed Rule Would Encourage Take-Back Programs.</u>

On page 73526 of the proposed rule preamble, EPA seeks comment on how the proposed rule might affect community take-back programs. CTDEP agrees with EPA that the proposed rule would have a positive effect on such programs. In particular, DEP agrees with the statement in the proposed rule preamble that such wastes are typically managed as hazardous wastes after the point of collection, even though they originated from household sources. Hence, the proposed rule would allow collected wastes to be more efficiently and easily managed after collection, while at the same time ensuring their proper management and disposal.

6.) CTDEP Agrees with EPA that the Management of Pharmaceutical Waste is Difficult Under the RCRA Regulations, and Supports the Creation of a More Streamlined Approach under the Universal Waste Rule.

In Section IV.D. of the proposed rule preamble (pages 73526 - 73527), EPA outlines its understanding of why the management of pharmaceutical wastes is difficult under current RCRA regulations. CTDEP agrees with all of EPA's points in this area. Based on the experience that CTDEP has had with hospitals and other health care facilities in Connecticut, we have observed first hand almost all of the issues raised by EPA in this preamble discussion. In particular, CTDEP has directly observed the following problems and issues:

- Waste pharmaceuticals are often generated at non-industrial sites that would otherwise be subject to minimal regulation under hazardous waste requirements. These include hospitals, walk-in clinics, individual physicians' offices, dentists' offices, long-term health care facilities, institutional facilities, and veterinary facilities. These types of facilities would normally be subject to regulation as Conditionally-Exempt Small Quantity Generators of hazardous waste ("CESQGs"), or perhaps only as Small Quantity Handlers of Universal Waste ("SQHUWs") owing to generation of items such as spent mercury lamps or spent batteries.

- Certain pharmaceutical wastes (particularly certain "P" listed pharmaceuticals) can very quickly make such facilities subject to regulation as Large Quantity Generators of Hazardous Waste ("LQGs"). These facilities often do not have the familiarity with RCRA regulations that industrial facilities do, and often do not have the personnel or expertise in order to develop the detailed regulatory programs required under RCRA regulations for LQGs.

- The generation of waste pharmaceuticals, particularly in acute-care facilities, does not lend itself to management in strict accordance with RCRA regulations. For example, these wastes are sometimes generated in operating rooms or on hospital floors in areas where compliance with satellite accumulation requirements may present significant logistical problems. CTDEP has worked with hospitals in order to develop such systems, and it is often an inordinately difficult task to do so in a manner that is workable for the facility staff, that is practical given the many competing priorities these workers face, and that is consistent with other requirements such as biomedical waste or controlled substance requirements.

- Especially for facilities that become subject to regulation as LQGs, the 90-day accumulation limit requirement can be burdensome. Often, the amounts of waste generated are small, and the frequent pickup of these small-volume wastes can be especially costly.

In light of the above, CTDEP agrees that the proposed rule is appropriate, and will result in appropriate regulatory relief for a large number of facilities that generate waste pharmaceuticals, while at the same time ensuring their proper management and requiring that such wastes be sent to destination facilities that are properly permitted under RCRA. In addition, CTDEP agrees

with EPA that the proposed rule will result in more pharmaceutical wastes being sent for proper disposal, rather than disposed of in the solid waste stream or into sewage or septic systems.

7.) Comments on the Management of Pharmaceutical Wastes that Are Subject to Regulation under Both Hazardous Waste and Controlled Substances Requirements.

On page 73532 of the proposed rule preamble, EPA solicits comment regarding how hazardous wastes that are also controlled substances are currently being managed, and if the inclusion of federally controlled substances in the federal universal waste program will change how these co-regulated wastes are being managed.

CTDEP's experience in Connecticut is that, historically speaking, many generators of hazardous, federally-controlled substances have complied with the "witnessed destruction" requirements for controlled substances by disposing of them to the on-site sewer. In recent years, however, CTDEP has coordinated with controlled substances officials in Connecticut's Department of Consumer Protection to find alternatives to drain disposal. Although such efforts have seen some success, drain disposal is still practiced in many facilities in Connecticut, especially long-term health care facilities (e.g., nursing homes). CTDEP and its partners in state government continue to work to minimize this practice. Toward that end, CTDEP believes that designation of hazardous controlled substances as universal wastes would support the reduction of drain disposal in a number of ways. Most importantly, it would highlight the fact that these wastes are subject to regulation, but at the same time would provide a workable, efficient, and easy-to-understand regime under which they may be managed.

Based on the above, CTDEP supports the inclusion of hazardous pharmaceuticals that are also federally-controlled substances in the proposed pharmaceutical Universal Waste Rule. However, at the same time, CTDEP believes that EPA should coordinate with the U.S. Drug Enforcement Agency ("DEA") concerning the types of methodologies that are considered acceptable to meet controlled substance witnessed destruction requirements. In particular, efforts should be made to expand the types of methodologies that are considered acceptable to include new types that would be consistent with containerization and shipment to a TSDF for destruction.

8.) Comments on the Likely Management of Pharmaceutical Wastes by Pharmaceutical Waste Generators if the Proposed Rule Is Finalized.

On page 73532 of the proposed rule preamble, EPA requests comment on whether health care facilities, reverse distributors and other hazardous pharmaceutical waste generators will choose to manage their pharmaceutical wastes as universal wastes if the proposed rule is finalized. EPA also poses a number of specific management scenarios and seeks feedback on how those managing pharmaceutical are likely to manage their waste under each of these scenarios.

CTDEP believes that the vast majority of such facilities will choose to manage their hazardous pharmaceutical wastes as universal wastes. CTDEP believes that the advantages of doing so as opposed to management as fully-regulated hazardous wastes are clear, and that generators and other handlers of such wastes will learn about the rules through simple word of mouth between colleagues in the industry, through trade association publications and meetings, and through

outreach efforts by governmental agencies, such as those that CTDEP is already conducting.

In response to the more specific inquiries posed by EPA regarding certain particular pharmaceutical waste management scenarios, CTDEP provides the following additional comments:

a.) Would facilities choose to manage both their hazardous and non-hazardous pharmaceutical wastes as universal wastes?

CTDEP believes that some pharmaceutical waste generators will choose to co-manage their hazardous and non-hazardous pharmaceuticals for a number of reasons, including:

- Many pharmaceutical waste generators, especially smaller facilities, are currently serviced by waste hauling companies that are able to offer several waste management needs simultaneously, as a way of providing convenience, efficiency, and lower cost. For example, there are several waste haulers doing business in Connecticut that will remove a health care facility's biomedical waste, dental amalgam, spent photo fixer and developer, and other wastes as part of a package arrangement. CTDEP believes that many generators will choose to use such haulers to remove their hazardous and non-hazardous pharmaceuticals as well, especially since Connecticut law places certain restrictions on the disposal of CESQG waste and non-hazardous pharmaceuticals in the solid waste stream.

- Some pharmaceutical waste generators may find it more convenient and economical to manage all their pharmaceutical wastes as a single (i.e. hazardous) waste stream, rather than establish and enforce protocols for their staff to segregate hazardous and non-hazardous pharmaceuticals. CTDEP believes that this is especially true for facilities that may not have dedicated hazardous waste management staff, or for whom it may be impractical to train facility staff to effectively keep hazardous and non-hazardous pharmaceuticals separate.

- Some pharmaceutical waste generators may generate only small amounts of such waste, and the additional cost of co-disposal may be minimal compared to the cost of properly classifying and segregating the hazardous and non-hazardous pharmaceutical wastes.

b.) Would facilities choose to manage their hazardous pharmaceutical waste and only certain categories of pharmaceutical wastes not currently regulated as hazardous wastes (such as chemotherapy drugs) as universal wastes?

CTDEP believes it is likely that some facilities will only handle a limited number of non-hazardous pharmaceuticals as universal waste if the proposed rule were finalized. CTDEP believes that generators might choose to do so for numerous reasons, including:

- Some non-hazardous pharmaceuticals (in particular chemotherapy and antineoplastic agents) are especially toxic, and may present exposure hazards to

health care workers. Health care facilities that use such pharmaceuticals typically have special procedures in place to ensure the safety of their workers, particularly those that may be frequently exposed to such drugs (e.g., oncology department staff). As part of these procedures, health care facilities may have special procedures for the management of wastes generated during the use of such drugs. Management of these wastes with the facility's hazardous pharmaceuticals would be a convenient way to ensure that these wastes are properly managed and do not result in releases or exposure to staff.

- Because of the size of our current pharmacopeia and the many different formulations, dosages, and modes of administration of these many drugs, health care facilities often face a daunting task when attempting to properly classify their waste pharmaceuticals for disposal purposes. As a result, new companies have formed to provide health care facilities with informational and consulting services to assist them in the classification process. CTDEP knows of at least one such company, PharmEcology Associates, LLC, that advises its clients to handle certain especially toxic non-hazardous pharmaceuticals as hazardous wastes (e.g., chemotherapeutic/antineoplastic agents), for reasons such as those listed in the previous bullet. It is likely that other such companies offer similar advice, and that health care facilities may heed this advice for the items recommended for disposal as hazardous waste, while disposing of the remaining non-hazardous pharmaceuticals as non-hazardous/non-universal waste.

While CTDEP believes that some generators may pursue this option, CTDEP also believes that EPA should not rely on an expectation of this as a basis for failing to list certain highly toxic drugs as hazardous waste. In particular, as noted in comment 2 above, CTDEP believes that the list of hazardous wastes should be amended to add chemotherapy and antineoplastic agents that are currently not listed as hazardous wastes. Only in this way will EPA ensure that all such drugs are properly managed and do not result in exposure to health care facility workers, sanitation workers, and disposal facility workers, or in releases to the environment. The proper management of these currently unlisted drugs should not be left to chance or to the whims of those generating them.

c.) Would facilities choose to manage only their hazardous pharmaceutical wastes as universal wastes?

CTDEP believes that some facilities would choose to manage only their hazardous pharmaceutical wastes as universal wastes. Possible reasons for taking this approach would include:

- Facilities that generate especially large amounts of pharmaceutical waste may decide to segregate their hazardous from their non-hazardous pharmaceuticals so as to save on the added cost of disposal associated with hazardous waste. However, as noted above, Connecticut state law imposes certain prohibitions on the disposal of non-hazardous pharmaceuticals as ordinary solid waste, and as a result, the economic incentive to segregate may not be very significant for many

generators in this state, since these generators will have to dispose of their non-hazardous drugs as non-hazardous chemical wastes.

d.) Would facilities choose to manage their hazardous pharmaceutical wastes as hazardous wastes (rather than as universal wastes)?

CTDEP believes that some, although not many, facilities would choose to manage their hazardous pharmaceutical wastes as hazardous wastes, even if offered the opportunity of managing them under the streamlined requirements of the Universal Waste Rule. CTDEP believes the facilities most likely to select this option would be facilities that have already spent much time and effort to establish a workable system for the segregation and proper disposal of their hazardous pharmaceuticals, and that may wish to avoid the confusion associated with a change in facility procedures and protocols. In particular, CTDEP believes that the facilities most likely to pursue such an option are large critical-care facilities (e.g., hospitals), that are large-quantity generators of hazardous waste even without counting their hazardous pharmaceutical waste. For such facilities, the benefits of the Universal Waste Rule in terms of generator status reduction and the associated elimination of the need for comprehensive facility plans (i.e., contingency plans, etc.) are less than for smaller facilities that do not generate much if any hazardous waste other than waste pharmaceuticals.

CTDEP is aware of waste generators that have made a similar decision with other universal wastes, such as batteries and lamps. Such facilities were typically larger waste generators that had well-established procedures in place for the management of such wastes as hazardous wastes, and did not wish to create confusion by changing these procedures.

9.) EPA Should Maintain the Current SQHUW Threshold for Pharmaceutical Wastes.

On page 73533 of the proposed rule preamble, EPA notes its intent to maintain the current upper limit of 5000 kilograms for a Small Quantity Handler of Universal waste ("SQHUW"), and requests comment on its intent to do so.

CTDEP agrees that the existing threshold of 5000 kilograms should be maintained, since there does not appear to be any compelling reason to select a different number for universal waste pharmaceuticals than for other types of universal waste.

Hazardous pharmaceuticals do pose a relatively high hazard as hazardous wastes go (many of them being acutely toxic, P-listed wastes), thereby raising the possible argument that a lower threshold should be used for these wastes. However, CTDEP believes that waste pharmaceuticals present environmental risks that are comparable with other currently-listed universal wastes, such as cancelled pesticides and mercury-containing devices. Furthermore, CTDEP believes that the 5000 kilogram threshold will result in the appropriate division of pharmaceutical waste handlers into the small and large quantity handler categories. In particular, CTDEP believes that virtually all generators of universal waste pharmaceuticals will be classified as SQHUWs, even with their other universal wastes taken into account, and that large

aggregation facilities will be classified as LQHUWs.

In addition, CTDEP would note that selecting a different threshold would be difficult simply from a regulatory construction perspective, and would add unnecessary confusion to the entire Universal Waste Rule regarding the SQHUW/LQHUW threshold. CTDEP believes that a different threshold would also make inspections and enforcement of the Universal Waste Rule more difficult, by complicating the handler status determination process.

10.) EPA Should Clarify the Definition of "Pharmaceutical."

On page 73534 of the proposed rule preamble, EPA offers it proposed definition of the term "pharmaceutical" as used in the proposed rule, and requests comment on the proposed definition.

CTDEP generally agrees with the proposed definition, although the preamble discussion regarding the definition is not entirely clear regarding the applicability of the definition to certain types of pharmaceutical delivery systems. In particular, the preamble text mentions that "pharmaceuticals" may include "... any delivery devices with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic." CTDEP is unsure if this is intended to capture delivery systems not specifically mentioned in the preamble language, such as sprays, aerosols, inhalants, autoinjectors, and enemas. CTDEP believes that all of the above should be included in the definition of "pharmaceutical."

11.) Containers of Waste Pharmaceuticals Should Be Required to Be Closed.

On page 73535 of the proposed rule preamble, EPA notes that the proposed rule requires that universal waste pharmaceuticals be placed in containers that are structurally sound and compatible with the wastes placed in them, but does not require that these containers be kept closed. EPA requests comment on this issue.

Although CTDEP agrees with EPA's proposals to require that containers be structurally sound and compatible with the wastes placed in them, we believe that containers of universal waste pharmaceuticals should be required to be kept closed. EPA's reasoning in support of not requiring closed containers is that many waste pharmaceuticals will be in their original packaging, and, when they are not, that the general performance standard of preventing releases will suffice. CTDEP disagrees with this rationale for the following reasons:

- CTDEP believes that there will be many instances where waste pharmaceuticals will not be in their original packaging. Examples include partially-used IV bags, pharmaceuticals that are being disposed of because their packaging has been damaged, and pharmaceuticals that have been shredded. With respect to the shredding of pharmaceuticals, CTDEP is aware of several long-term health care facilities in our state that are planning to shred their waste pharmaceuticals (which are often on large "bingo" cards), as an alternative to drain disposal in order to meet controlled substance witnessed destruction requirements. Our counterparts in the Connecticut Department of Consumer Protection, who have state jurisdiction over controlled substance management in Connecticut, have indicated that this would be an acceptable manner of destroying these

materials, and clearly this method is also clearly advantageous over drain disposal.

- Even for those pharmaceuticals that may be in their original packaging, if they are in liquid, or aerosol/inhaler form, or in the form of autoinjectors, they present an immediate possibility of release. CTDEP believes that relying on a general performance standard to ensure that these types of materials are properly containerized is inappropriate, and will likely result in unproductive, time-consuming disputes between waste generators and state inspection and enforcement staff over whether or not these waste pharmaceuticals are properly contained to prevent releases.

- Waste pharmaceuticals are potentially a very attractive target for pilfering by persons that might be interested in abusing them, or reselling them for illicit purposes. Although the most attractive pharmaceuticals would typically be classified as controlled substances and subject to witnessed destruction requirements, many pharmaceuticals that are not controlled substances are also sought after for abuse. CTDEP is aware of documented instances of "pharming" in which individuals search trash receptacles, looking for discarded pharmaceuticals for illicit purposes. Consolidating large numbers of pharmaceuticals in one or more open containers would certainly present an even more inviting target than a trash receptacle. CTDEP therefore believes that requiring waste pharmaceuticals to be kept in closed containers would provide an increased level of security for such pharmaceuticals, and help prevent pilfering and abuse.

In consideration of the security issue raised in the above bullet, CTDEP also believes that merely keeping containers closed is not adequate in order to prevent pilfering and abuse of waste pharmaceuticals. CTDEP believes that in addition to being kept in closed containers, waste pharmaceuticals should be stored in a secure area (such as in a locked closet or cabinet, or – for waste pharmaceuticals generated in pharmacies – behind the pharmacy counter where only pharmacy staff would have access to them). CTDEP also believes that, during transportation, waste pharmaceuticals should also be required to be in tamper-resistant containers (i.e., sealed, locked, or similarly rendered difficult to open). CTDEP believes that this is appropriate due to the potential for pilfering that can occur during transportation, especially if the waste pharmaceuticals are self-transported by the generator, or transported by a common carrier.

12.) <u>Incompatible Wastes Should Not be Placed in the Same Container.</u>

On page 73535 of the proposed rule preamble, EPA notes that it is proposing to require that incompatible wastes not be placed in the same container, unless in compliance with 40 CFR 265.17. On the same page, EPA seeks comment on it proposed container management standards (including, presumably, the proposed requirements for separation of incompatible wastes).

CTDEP agrees with EPA's proposed requirement to require the separation of incompatible wastes. Some pharmaceuticals (especially compounding agents) may contain concentrated acids, bases, or oxidizers, and may therefore be incompatible with each other or with other pharmaceuticals. As a result, CTDEP feels that the requirement to ensure that these types of pharmaceuticals are not placed in the same container is very important.

13.) Additional Labeling/Marking or Other Identification Requirements Should Apply to Waste Pharmaceuticals.

On page 73536 of the proposed rule preamble, EPA describes its proposed marking/labeling requirements and requests comment on whether, in order for the destination facility to have sufficient information on the pharmaceutical universal wastes they receive, additional information should be required on the container labeling.

CTDEP agrees with EPA's proposed requirements to mark containers of waste pharmaceuticals, and further believes that additional information should be required, either on the container, or in a shipping paper accompanying the container. Unlike other universal wastes, waste pharmaceuticals include a wide variety of waste codes (i.e., various waste codes in the D001 – D043 characteristic hazardous wastes, and numerous "U" and "P" listed hazardous wastes), each of which in turn requires specific treatment technologies or treatment standards under Land Disposal Restriction ("LDR") requirements which will have to be met at the ultimate destination facility. CTDEP believes that these requirements cannot be realistically satisfied unless the waste pharmaceuticals are somehow identified (again, either on the container itself or in accompanying shipping information). Regardless of the form that this additional information takes, CTDEP believes that it should also be required to accompany the container to the ultimate destination facility.

14.) Different Accumulation Time Limits Are not Necessary or Appropriate for Waste Pharmaceuticals.

On page 73536 of the proposed rule preamble, EPA requests comment on whether universal waste pharmaceuticals should be subject to a different accumulation time limit. CTDEP does not believe that a different accumulation time limit is necessary or appropriate for waste pharmaceuticals. CTDEP further believes that adopting a different accumulation time limit for this one universal waste would introduce a degree of confusion into the Universal Waste Rule that would likely result in misunderstandings by handlers, and result in an unnecessary increase in the number of enforcement actions against such generators.

This concludes CTDEP's comments on the proposed rule. Please contact Ross Bunnell of my staff if you should have any questions on the foregoing. Mr. Bunnell may be reached by phone at (860) 424-3274, or by email at ross.bunnell@ct.gov.

Sincerely,

Robert C. Isner, Director
Waste Engineering & Enforcement Division

Cc: Bill Cass, NEWMOA