Connecticut Department of
ENERGY &
ENVIRONMENTAL
PROTECTION

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Dear Stakeholders:

On December 2, 2008, EPA public noticed a proposal to add hazardous pharmaceutical waste to the Universal Waste Rule ("UWR") to facilitate the appropriate management and disposal of such wastes (see 73 Fed. Reg. 73520). Due to extensive and conflicting comments, and concern over the lack of notification and tracking requirements, EPA decided to not finalize the 2008 proposal. EPA is working on a new proposal for the sector-based management of hazardous waste pharmaceuticals. Over at least the past five years, DEEP has been actively working on the issues surrounding the proper management and disposal of hazardous waste pharmaceuticals. DEEP provided comments to EPA in favor of their December 2008 proposal, and in January 2013, concluded lengthy negotiations with a major pharmaceutical retailer concerning, in part, the failure to manage non-dispensable pharmaceuticals in compliance with Connecticut's hazardous waste management regulations. This enforcement action further emphasized the need for national regulatory reform for the management of pharmaceutical waste. DEEP is advocating for this change through a state-initiated universal waste listing. Please find below the key issues for which DEEP would appreciate your input at this time:

1) **Definitions:** For purposes of EPA's proposed rule preamble dated December 2, 2008, "pharmaceutical" and "pharmaceutical universal waste" were defined as, respectively, (see 73 Fed. Reg. 73520):

   a. Pharmaceutical - "Any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or injury in man or other animals; or any chemical product, vaccine or allergenic (including any product with the primary purpose to dispense or deliver a chemical product, vaccine or allergenic), not containing a radioactive component, that is intended to affect the structure or function of the body in man or other animals. This definition includes products such as transdermal patches, and oral delivery devices such as gums or lozenges. This definition does not include sharps or other infectious or biohazardous waste, dental amalgams, medical devices not used for delivery or dispensing purposes, equipment, contaminated personal protective equipment or contaminated cleaning materials.''

      The proposed definition of "pharmaceutical" was meant to include, but was not limited to, pills or tablets, medicinal gums or lozenges, medicinal liquids, ointments and lotions, intravenous (IV) or other compounded solutions, chemotherapy drugs, vaccines, allergenics, medicinal shampoos, antiseptics and medicinal dermal patches, and any delivery devices with the primary purpose to deliver or dispense a chemical product, vaccine or allergenic.

The definition of "pharmaceutical" was not meant to include:

Sharps (*e.g.*, needles from IV bags or syringes), infectious or biohazardous ''red-bag'' waste, waste chemicals from laboratories, medical devices (*e.g.*, blood pressure cuffs, mercury thermometers, x-ray films and fixers), dental amalgams, personal protective equipment contaminated with hazardous pharmaceuticals (*e.g.*, scrubs, gowns, gloves, *etc.*) or any materials used to clean up spills of hazardous pharmaceutical wastes. In addition, residues resulting from the manufacture, production, or distribution of such pharmaceuticals, including off-specification pharmaceutical products were not included.

[**Note**: The definition of "pharmaceutical" was adapted from the Federal Food, Drug and Cosmetic Act's definition of ''drug'' (21 U.S.C. 321(g)(1)(B)).]

DEEP is seeking comment on whether the proposed definition of "pharmaceutical" should be amended and how such definition should be amended. Alternatively, you may propose to DEEP a new definition of "pharmaceutical".

b. Pharmaceutical universal waste - "A pharmaceutical that is a hazardous waste as defined in 40 CFR 261.3, and containers (*e.g.*, bottles, vials, IV bags, tubes of ointment/gels/creams, ampules, etc.) which have held any hazardous pharmaceutical waste and which would be classified as hazardous waste under 40 CFR 261.7."

DEEP is seeking comment on whether the proposed definition of "pharmaceutical universal waste" should be amended and how such definition should be amended. Alternatively, you may propose to DEEP a new definition of "pharmaceutical universal waste".

2) **Inclusion of drugs from NIOSH Publication No. 2012-150:** As noted in number one above, the proposed definition of "pharmaceutical" was meant to include chemotherapy drugs. However, at the present time only a few listed chemotherapy or antineoplastic agents that are used in the field of oncology are classified as hazardous wastes when discarded. These compounds are contained on the "P" and "U" lists.

The Food and Drug Administration ("FDA") approved about fifty (50) new oncology drugs alone since 2008. These drugs are especially toxic and present exposure hazards. DEEP is seeking comment on whether drugs from Appendix A of NIOSH Publication No. 2012-150 and Appendix VI: 2-1 of the OSHA Technical Manual should be managed as universal wastes. If you answer yes, please elaborate on special management standards that need to be considered if any (*e.g.*, training, labeling, tracking, etc.).

3) **Training:** Additional training requirements were not proposed by EPA for either large or small quantity handlers of pharmaceutical universal waste. [A large quantity handler of universal waste is one who handles more than 5,000 kilograms of total universal wastes at one time. A small quantity

handler of universal waste is one who handles 5,000 kilograms or less of total universal wastes at one time.] DEEP is seeking comment on whether additional training should be required for large quantity handlers of universal pharmaceutical waste, small quantity handlers of universal pharmaceutical waste or both. DEEP is also seeking comment on the type(s) of training that should be required.

4) **Container Management:** The preamble to the proposed rule did not require containers of hazardous waste pharmaceuticals be kept closed. DEEP is seeking comment on whether containers of hazardous pharmaceutical waste should be required to be kept closed, except when pharmaceuticals are being added to or removed from the container, as a safeguard against cross-contamination, to minimize pilfering and prevent releases, or if such requirement will pose an undue burden.

5) **Tracking:** Under the proposed rule preamble, EPA was not recommending to change the existing requirements applicable to the tracking of universal waste for shipments of pharmaceutical waste. Specifically, under the federal framework, a uniform hazardous waste manifest would not be required. DEEP is seeking comment on the types of documents that should be used for tracking shipments of universal waste pharmaceuticals between handlers and from handlers to disposal facilities. DEEP is also seeking comment on what specific information should be required in such tracking documents.

6) DEEP is seeking comment on whether there are other key issues that should be considered at this time for our preliminary draft of the regulations.