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RCRA Docket U.S. Environmental Protection Agency 1200 Pennsylvania Avenue, NW Washington, DC 20460 Docket ID No. EPA-HQ-RCRA-2007-0932

Regarding: Yale University's Comments on EPA's Proposed Rule Amendment to the Universal Waste Rule: Addition of Pharmaceuticals (73 FR 73520-73544)

Dear Sir or Madam:

Yale University submits the following comments on the Environmental Protection Agency's Proposed Rule Amendment to the Universal Waste Rule: Addition of Pharmaceuticals. The proposed rule was published in the 2 December 2008 Federal Register (73 FR 73520-73544). Yale University generates pharmaceutical wastes at approximately forty clinics associated with the Yale Medical School as well as at the Yale Health Plan, which is a medical center on campus that offers health care services to Yale students, employees, retirees and their dependents. Due to our experience, we believe our comments may be valuable to you.

Yale University strongly supports the proposed rule and the amendment to add hazardous pharmaceuticals to the Universal Waste Rule. We agree with EPA that the proposal would facilitate better management of pharmaceutical wastes by streamlining the generator requirements and encouraging generators of hazardous pharmaceutical wastes to manage them under the provisions of the Universal Waste Rule. The Universal Waste Rule ensures that these wastes are treated and disposed of properly.

While hazardous pharmaceutical waste generated at Yale is managed according to EPA's hazardous waste rules, these rules were written for industrial waste. EPA hazardous waste rules fit healthcare poorly. The current rules are too complex and confusing for most entities, especially small organizations, that generate pharmaceutical wastes.

This issue warrants attention because scientists have discovered low concentrations of pharmaceuticals in our Nation's waters. Making the process for managing pharmaceutical wastes simpler will help address these concerns by encouraging more environmentally sound methods of disposal. The universal waste rule has already been effective in improving the disposal of fluorescent light bulbs,

Docket ID No. EPA-HQ-RCRA-2007-0932 Yale University page 2

batteries and computers. We believe the extension of the universal waste rule would have a similarly salutary effect on the handling of pharmaceuticals in the waste stream.

We agree with EPA that the proposed rule would facilitate the implementation of pharmaceutical take-back programs by removing RCRA barriers. By allowing and encouraging generators to manage non-hazardous pharmaceutical wastes under the same regulations, the proposal will encourage the management of non-RCRA pharmaceutical wastes as universal waste. (In our experience, the majority of pharmaceutical waste is not RCRA-regulated.) Furthermore, we agree with EPA that the proposed rule will also reduce hazardous waste in the municipal solid waste stream by making it easier for Universal Waste handlers to collect these items for proper disposal.

We see several other benefits of the proposal:

- The longer accumulation time allowed under the Universal Waste rules will allow all generators to package this waste stream more efficiently and will allow most generators to ship less frequently. More efficient packaging and less frequent shipments will result in cost savings for generators.
- Managing hazardous pharmaceutical waste as universal waste will reduce reporting burdens and may reduce the regulatory burden on generators if it results in a change in their generator status.
- Pharmaceutical waste management will be much simpler for generators: the labeling system will be easier, less segregation will be required, and collection can be more centralized.

In the preamble, EPA requests comment on whether or not handlers should be required to keep individual pharmaceutical waste containers in their original packaging (unless original packaging is leaking or otherwise compromised). We believe pharmaceutical wastes in their original packaging (as long as the original packaging is not leaking or otherwise compromised) should be placed in the collection container as is. This is best because the original packaging includes information that makes identification and segregation easier. If the packaging is leaking, otherwise compromised or not the original packaging, the waste should simply be over packed in another sealable/closable package (such as a plastic Ziploc bag) prior to placing in the universal waste collection container.

EPA also requests comment on the proposed training requirements for Small Quantity Handlers of Universal Waste and Large Quantity Handlers of Universal Waste. We recommend that they have the same training requirements. Training content can accommodate this, and it would further streamline the requirements.

In conclusion, the University supports adding pharmaceuticals to the Universal Waste rule. Because Universal Waste regulations are significantly less complex than but as effective RCRA regulations, this change will provide a more streamlined waste

Docket ID No. EPA-HQ-RCRA-2007-0932 Yale University page 3

management system for pharmaceuticals. As we explain above, the new, streamlined system will have many ancillary benefits to human health and the environment.

Thank you for considering our comments. Should you have questions after you've had an opportunity to review this letter, please contact Peter A. Reinhardt, Director of Yale Environmental, Health and Safety, at (203) 737-2123.

Respectfully submitted,

Sincerely,

/s/

Dorothy Robinson Vice President and General Counsel Yale University