



January 15, 2009

Lisa Lauer
Office of Solid Waste (5304P)
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Via lauer.lisa@epa.gov and WWW.REGULATIONS.GOV

Re: Docket ID No. EPA-HQ-RCRA-2007-0932. Proposed Rule: “Amendment to the Universal Waste Rule: Addition of Pharmaceuticals,” 73 Fed. Reg. 73520 (Dec. 2, 2008). Request for Extension of Comment Period.

Dear Ms. Lauer:

On behalf of the Healthcare Distribution Management Association (HDMA) this letter is to request an extension of the public comment period for the proposed rule: “Amendment to the Universal Waste Rule: Addition of Pharmaceuticals.” (“proposed rule” or “proposal”). Specifically, we request that the Environmental Protection Agency (EPA) allow the public an additional 60 days so that the comment period, currently set to close on February 2, 2009 would close on April 2, 2009.

HDMA represents the nation’s primary, full-service healthcare distributors. Our members are large national companies and regional, family-owned businesses. Each and every day, HDMA member companies safely and efficiently deliver nine million healthcare products to more than 144,000 pharmacies, hospitals, nursing homes, physician offices, and clinics across the United States. The products our members distribute include the very type of pharmaceutical products that would be subject to this rule should they be determined to meet the definition of “waste” during their life cycle.

Furthermore, HDMA’s membership includes pharmaceutical reverse distributors. EPA specifically solicits comment from this segment of the pharmaceutical supply chain. Thus, we have considerable interest in the rule’s outcome and can contribute to EPA’s understanding of pharmaceutical waste handling practices.


Under the proposal, hazardous pharmaceutical wastes would be added to the Universal Waste Rule. Among the hoped for results of the proposal are better management of pharmaceutical wastes, encouragement of generators of hazardous pharmaceutical wastes to manage them under the provisions of the Universal Waste Rule, and facilitation of pharmaceutical take-back programs.

HDMA was pleased to see the publication of this proposal and fully appreciates the opportunity to provide public comments. In reviewing the proposal, however, HDMA must fully consider the potential implications for both the forward and reverse distribution processes, which have substantial differences both in business models and in potential impacts of the rule. Moreover, these pharmaceutical distribution processes are critical to the patients we serve and can be, literally, life saving steps in the provision of medical care. We must also fully consider the interplay between EPA's proposal and other regulations such as those of the Department of Transportation (DOT), the Drug Enforcement Administration (DEA) and the Food and Drug Administration (FDA). Further, the pharmaceutical distribution community is particularly interested in examining the proposal's potential impact on our current "closed-loop," tightly controlled system of pharmaceutical distribution that is designed to prevent the theft, diversion, and counterfeiting of drugs and drug packaging.

Thus, the proposal has more wide-spread implications for the pharmaceutical supply chain, and greater complexity, than may have been contemplated by the agency during the drafting phase. Moreover, we believe that this request to extend the public comment period for 60 days is consistent with the agency's desire for a well-crafted final rule that facilitates the appropriate disposal of such wastes without undue burden on the public.

We trust that you will consider this request in light of the reasons provided and the importance of obtaining well-considered input from the affected public. If you have any questions, HDMA remains ready to discuss this request further. I can be reached at 703-885-0240 or at aducca@hdmanet.org.

Respectfully submitted,



Anita T. Ducca
Senior Director, Regulatory Affairs

cc: RCRA Docket
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