UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

AUG 2 4 2012

OFFICE OF
SOLID WASTE AND
EMERGENCY RESPONSE

MEMORANDUM

SUBJECT: EPA Office of Inspector General Report, *EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal* (Report No. 12-P-0508, May 25, 2012)

FROM: Mathy Stanislaus Lisa Feldt for
Assistant Administrator

TO: Arthur A. Elkins, Jr.
Inspector General

Thank you for the opportunity to respond to the Office of Inspector General (OIG) report, *EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal,* Report No. 12-P-0508, May 25, 2012. The Office of Solid Waste and Emergency Response (OSWER) concurs with the recommendations. Our response to these recommendations and our proposed milestone schedule for implementing corrective actions are found below.

OIG Recommendation 1: *Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.*

OSWER Response: OSWER agrees to identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste. OSWER agrees that pharmaceuticals are a category of chemicals that need attention and recently completed a limited research effort to identify and evaluate new and existing pharmaceuticals for potential addition to the lists of regulated hazardous wastes. OSWER is now reviewing the results of this project and deciding on next steps that could be completed within available resources to address identified potential risks from disposal of pharmaceuticals. Possible next steps include initiating rulemaking where data are available indicating that certain pharmaceuticals meet the regulatory standard for acutely hazardous waste or gathering additional existing data on certain pharmaceuticals, resources permitting. As we evaluate next steps, we will consider whether and how these limitations could be addressed with available resources. We expect to identify our next steps by December 31, 2012.

OIG Recommendation 2: *Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.*

OSWER Response: OSWER agrees that new pharmaceuticals should be reviewed to determine whether they qualify for regulation as a hazardous waste. OSWER agrees that due to the rapid development of new pharmaceuticals this category of chemicals should receive some

level of ongoing attention. As part of OSWER's decision on next steps as discussed in Response 1, we will also consider how to review new pharmaceuticals by December 31, 2012. We note that any work to review new pharmaceuticals will be conducted in the context of limited resources and competing priorities.

OIG Recommendation 3: *Develop a nationally consistent outreach and compliance assistance plan to help states address challenges that health care facilities, and others as needed, have in complying with RCRA regulations for managing HWPs.*

OSWER Response: OSWER agrees to develop nationally consistent outreach and compliance assistance to help in complying with the RCRA regulations for managing hazardous waste pharmaceuticals (HWPs). This will be done in three planned phases: 1) continue ongoing outreach and compliance assistance for the current regulations; 2) propose revisions to RCRA regulations to more effectively address hazardous waste pharmaceuticals in the health care sector; and 3) develop a communications plan detailing outreach efforts to implement the new regulations.

- Phase 1: Within available resources, we will continue appropriate outreach and compliance assistance efforts for the current regulations.

- Phase 2: Our current plans anticipate that in lieu of the previously proposed universal waste rule, we will propose a rule designed to facilitate proper management of hazardous waste pharmaceuticals in the health care industry. We anticipate proposing a rule in August 2013. This date is dependent on a number of factors and may change due to the results of the inter- and intra-agency reviews that must occur prior to signature and publication. Any changes to the publication date of the proposed rule will be included in the semi-annual Regulatory Agenda. A schedule for the final rule will be developed within two months of the close of the comment period for the proposed rule.

- Phase 3: The communication plan for the revised regulations will be developed as part of the final rule package. OSWER will develop a schedule for the final rule after assessing the complexity of the public comments received and how long it will take to develop the final rule.

OSWER welcomes the opportunity to continue working with the OIG to implement these recommendations and to ensure that hazardous waste pharmaceuticals are properly managed. If you have any questions, please contact Suzanne Rudzinski, in the Office of Resource Conservation and Recovery at (703)308-8635.

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