



Department of Toxic Substances Control



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Arnold Schwarzenegger
Governor

November 30, 2004

Ms. Kelly D. Moran, Ph.D.
TDC Environmental, LLC
4020 Bayview Avenue
San Mateo, California 94403

MANAGEMENT OF HOUSEHOLD PHARMACEUTICAL WASTES

Dear Ms. Moran:

Thank you for giving the Department of Toxic Substances Control (DTSC) an opportunity to review "Household Pharmaceutical Waste: Regulatory and Management Issues." The importance of appropriately managing household pharmaceutical wastes is becoming widely recognized. As discussed in your report, numerous studies have indicated the presence of both prescription and non-prescription drugs in surface waters. While the total effect of these waste pharmaceuticals is unclear, there is emerging evidence that waste pharmaceuticals found in surface waters have subtle effects on aquatic life.

Because surface water often serves as a source for domestic water supply, direct affect on human health is also a concern. However, DTSC's authority to regulate hazardous wastes is limited to that granted by the Legislature and documented in the Health and Safety Code (HSC). A legal review of applicable statute was completed in order to determine the extent that DTSC may regulate household generated pharmaceuticals. The results of that review found that the controlling statutes are HSC §117635(g) which states,

"Waste that is hazardous only because it is comprised of pharmaceuticals, as defined in Section 117747. Notwithstanding subdivision (a) of Section 117690, medical waste includes biohazardous waste that meets the conditions of this subdivision. Biohazardous waste that meets the conditions of this subdivision is not subject to Chapter 6.5 (commencing with Section 25100) of Division 20."

and HSC §25117.5(a) which states,

"Waste that is hazardous only because it is medical waste, as defined in the Medical Waste Management Act (Part 14(commencing with Section 117600) of

Division 104) shall not be governed by, subject to fees assessed by, or otherwise subject to, the requirements of this chapter or regulations adopted pursuant to this chapter."

Pharmaceutical waste meets the definition of both "medical waste" and "biohazardous waste", as defined in the Medical Waste Management Act (MWMA). (See, sections 117690 & 117635, respectively.) HSC sections 25117.5 and 117635, subd. (g) both state, respectively, that medical waste and biohazardous waste is not subject to the requirements of Chapter 6.5. Even though section 117670 defines "household waste", for purposes of the MWMA, to include "medical waste", the statutory framework indicates that pharmaceutical wastes are not intended to be regulated under Chapter 6.5.

Therefore, the management requirements for hazardous waste found in HSC, Division 20, Chapter 6.5, do not apply to household pharmaceutical waste. With regards to household pharmaceutical collection, HSC §117635(g) declares that the transporting, manifesting, and permitting requirements for hazardous waste do not apply. DTSC permits or other grants of authorization are not required for collection, and hazardous waste disposal requirements are not required.

The term "pharmaceutical" is defined in HSC §117747(a) and (b)(1) which states,

"Pharmaceutical" means a prescription or over-the-counter human or veterinary drug, including, but not limited to, a drug as defined in Section 109925 or the Federal Food, Drug, and Cosmetic Act, as amended, (21 U.S.C.A. Sec. 321(g)(1)).

(b) For purposes of this part, "pharmaceutical" does not include any pharmaceutical that is regulated pursuant to either of the following:

(1) The federal Resource Conservation and Recovery Act of 1976, as amended (42 U.S.C.A. Sec. 6901 et seq.).

However, because household generated wastes are defined as solid wastes, even listed RCRA pharmaceutical wastes generated by households would qualify for the exclusion found in HSC §117635(g).

This letter does not attempt to discuss all aspects of pharmaceutical waste management. It should, however, provide useful information relevant to your current report on household pharmaceutical waste management requirements. In some ways this determination will facilitate the collection of household pharmaceutical wastes by eliminating the authorization requirements typically required for household hazardous waste collection programs. It may also aggravate the subject issue by clarifying that household pharmaceutical waste need not be managed as a hazardous waste – disposal of household pharmaceutical wastes to solid waste landfill or publicly owned

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treatment works would not violate California hazardous waste law. Of course, other federal, state, and local laws may apply.

If you have any questions concerning this letter, please contact Mr. William Beckman of my staff at (916) 324-8293.

Sincerely,

A handwritten signature in black ink, appearing to read 'Karl Palmer', with a long horizontal flourish extending to the right.

Karl Palmer, Chief
Regulatory and Program Development Branch

cc: California CUPA Forum Board
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