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January 14, 2004

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MANAGEMENT OF PHARMACEUTICAL WASTES IN CALIFORNIA

Dear Ms. Smith:

Thank you for your February 10, 2003 letter and subsequent e-mails to the Department of Toxic Substances Control (DTSC). You stated in your letter that PharmEcology Associates, LLC, (PharmEcology): 1) assists health care organizations, pharmacies, drug distributors and manufacturers in determining if waste pharmaceuticals meet the criteria for hazardous waste based on the federal Resource Conservation and Recovery Act (RCRA), 2) provides information on whether the individual states have additional hazardous waste criteria, and 3) will launch a website that will aid a subscriber in determining whether a pharmaceutical is regulated as hazardous waste when discarded. In your letter, you asked DTSC a series of questions aimed at clarifying how waste pharmaceuticals are regulated in California. DTSC has taken the liberty of augmenting those questions in an attempt to better explain how pharmaceutical wastes are regulated in California. To minimize the length of this response, DTSC has structured the majority of this letter in question & response format.

California's hazardous waste control laws (statutes and regulations) are found in the California Health and Safety Code, division 20, chapter 6.5 (Hazardous Waste Control), and title 22, California Code of Regulations, Division 4.5 (Environmental Health Standards for the Management of Hazardous Waste), respectively. These laws classify wastes as either hazardous or non-hazardous and further categorize hazardous wastes as either RCRA hazardous waste as defined in Health and Safety Code section 25120.2, or as non-RCRA hazardous waste as defined in Health and Safety Code section 25117.9. Non-RCRA hazardous wastes are wastes that are not identified as hazardous waste pursuant to the federal hazardous waste regulations (40 Code of Federal Regulations) but are identified (and regulated) as hazardous waste in California. DTSC noticed that you used the term "California-only" hazardous waste throughout your letter. For purposes of this response to your letter and e-mails, DTSC

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has taken the term "California-only" to mean any waste pharmaceuticals that would not be federally regulated. Recognizing that some of these waste pharmaceuticals may also be regulated as hazardous waste in states other than California, for clarity, DTSC respectfully requests that you do not use the term "California-only" on your website or in printed guidance.

Question 1: Does California exempt pharmaceutical wastes from hazardous waste regulation, and, if so, where is that exemption found?

DTSC Response: California law, [Senate Bill 1966 (Wright, Chapter 536, Statutes of 1996)], effective January 1, 1997, transferred DTSC's authority to regulate wastes which are hazardous solely because they are/contain pharmaceuticals to the Department of Health Services (DHS). The bill amended the definition of biohazardous waste, a subcategory of medical waste, to include waste pharmaceuticals¹ that are not subject to federal regulation as hazardous waste and are not hazardous for any reason other than their pharmaceutical content. Therefore, pharmaceutical wastes meeting those definitions are not subject to DTSC regulation as hazardous waste. Instead, in California such wastes are regulated by DHS as medical waste. For general information about California's medical waste management program, please refer to: [Http://www.dhs.ca.gov/ps/ddwem/environmental/Med_Waste/medwasteindex.htm](http://www.dhs.ca.gov/ps/ddwem/environmental/Med_Waste/medwasteindex.htm). The "exemption" is located in two statutes, Health and Safety Code section, 25117.5 [division 20, chapter 6.5 (Hazardous Waste Control)] and Health and Safety Code section 117635 [division 104, part 14 (Medical Waste Management Act)].

Note: In California, "pharmaceutical wastes" that do not qualify for the above-mentioned exemption are subject to DTSC regulation as hazardous waste. Such wastes includes (1) RCRA-regulated waste pharmaceuticals as mentioned above, (2) hazardous waste mixtures containing pharmaceuticals, (3) wastes derived from pharmaceutical wastes that are not federally regulated but exhibit a California hazardous waste characteristic not exhibited by the pharmaceuticals themselves (non-RCRA hazardous waste), and (4) radioactive hazardous waste pharmaceuticals (including waste mixtures containing radioactive pharmaceuticals).

Question 2: How are waste pharmaceuticals which are identified as hazardous waste by 40 CFR regulated in California?

DTSC Response: Pharmaceutical wastes which are federally identified as hazardous wastes are regulated by DTSC as RCRA-hazardous wastes in California. For general information about the regulation and management of RCRA hazardous waste(s) in

1 Pharmaceutical is defined in Health and Safety Code section 117747.

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California, please contact DTSC's Public and Business Liaisons (Duty Officers) at 1-800-728-6942 and/or view DTSC's website:
[Http://www.dtsc.ca.gov/ToxicQuestions/dofags.html](http://www.dtsc.ca.gov/ToxicQuestions/dofags.html).

Question 3: How are waste pharmaceuticals which are not identified as hazardous waste by 40 CFR, but which are identified as hazardous waste by California's expanded hazardous waste criteria, regulated in California?

DTSC Response: Pharmaceutical wastes which are not federally identified as hazardous wastes, but which are identified as hazardous waste by California's expanded hazardous waste criteria may or may not be regulated as hazardous waste in California. If the pharmaceutical waste is identified as hazardous waste only because it is comprised of or contains waste pharmaceuticals, the waste is exempt from DTSC regulation as hazardous waste (see response to question 1). On the other hand, if the pharmaceutical waste were identified as hazardous waste for any other reason, the waste would be regulated as a non-RCRA hazardous waste in California. For general information about the regulation and management of non-RCRA hazardous waste(s) in California, please contact DTSC's Public and Business Liaisons (Duty Officers) at 1-800-728-6942 and/or view DTSC's website:
[Http://www.dtsc.ca.gov/ToxicQuestions/dofags.html](http://www.dtsc.ca.gov/ToxicQuestions/dofags.html)

Question 4: Health and Safety Code section 118000 requires that a "registered hazardous waste transporter" transport all medical waste. Is this the same designation as that used for a person who transports RCRA hazardous waste?

DTSC Response: Yes. In California, only a registered hazardous waste transporter may transport medical waste to an off-site medical waste treatment facility. In California, persons who transport medical waste (medical waste transporters) and persons who transport hazardous waste (hazardous waste transporters) must comply with basically the same liability insurance and registration requirements. DTSC authorizes and registers these transporters. Additionally, a medical waste transporter must also register with DHS and comply with applicable medical waste tracking requirements. DHS registers a medical waste transporter with its DTSC issued registration number (not EPA identification number). Therefore, the terms medical waste transporter and hazardous waste transporter are often used interchangeably in California with regards to transporting medical waste.

Question 5: Can waste pharmaceuticals be shipped to a medical waste incinerator?

DTSC Response: Pharmaceutical wastes that are exempt from hazardous waste regulation can be shipped to a medical waste incinerator in accordance with the medical waste management act. California law requires that medical waste be transported offsite by a registered hazardous waste transporter² (see response to question 4).

2 There is an exemption to this requirement, see Health and Safety Code section 118030.

California currently does not have any authorized offsite hazardous waste or medical waste incinerator facilities. Therefore, generators of hazardous wastes (either RCRA hazardous wastes or non-RCRA hazardous wastes) comprised of pharmaceutical wastes cannot send those wastes to an incinerator in California at this time. If a pharmaceutical waste generator in California sends its hazardous waste comprised of pharmaceuticals to an out-of-state incinerator, the generator should ensure that the incinerator facility has all required permits or licenses that are required by the state in which the incinerator is located. California law requires the pharmaceutical waste be transported by a registered hazardous waste transporter and requires the completion of applicable documentation (DHS tracking documents and/or uniform hazardous waste manifest).

Question 6: Health and Safety Code section 118222(b) includes a reference to Section 117635, Pharmaceuticals, which refers back to Section 118215 (a) and (d). However, section 118215 does not appear to have a subsection (d). Has it been deleted?

DTSC Response: During the 1999-2000 Legislation Session, Health and Safety Code section 118215³ was amended. As part of the amendment, Health and Safety Code section 118215, subdivision (d) was incorporated into subdivision (a)(3), subsections (A) and (B). Please refer to that section for the pertinent information. Please note that each of the treatment options specified in Health and Safety Code section 118215 subdivisions (a)(1), (2), and (3) requires DHS's prior approval.

Question 7: Based on a Federal Register (FR) Notice published on May 16, 2001, (Hazardous Waste Identification Rule (HWIR): Revisions to the Mixture and Derived-From Rules) U.S. EPA excluded from regulation certain mixtures and derived-from wastes containing or resulting from hazardous wastes (i.e., mixtures containing P and U listed chemicals that were listed solely because of ignitability, reactivity or corrosivity.) Has California adopted, or will it consider adopting, U.S. EPA's recent revisions to the mixture and derived-from rules?

DTSC Response: California has not adopted the above-mentioned federal U.S. EPA rule. However, California's hazardous waste regulations already contain language similar to that promulgated in U.S. EPA's recent clarification. Please see title 22, California Code of Regulations, section 66261.3(a)(2)(E).

As you already know, the federal hazardous waste regulations identify as hazardous wastes specific "P" or "U" listed discarded commercial chemical products. However, a discarded pharmaceutical is not automatically RCRA identified as a hazardous waste if it contains one of the "P" or "U" listed chemicals. These listings apply only to unused materials that meet the listing description. Individual wastes must be evaluated on a case-by-case basis to determine if the hazardous waste listings apply to the

³ Senate Bill 407, Statutes of 1999; Chapter 139, Alpert

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pharmaceutical wastes. Please see (U.S. EPA RCRA Online Faxbacks #'s: 13622, 13718, and 13530 for more information).

Note: Even if it is determined that none of the RCRA hazardous waste listings are applicable to a specific pharmaceutical waste, the generator must still determine if their waste exhibits any RCRA characteristic of a hazardous waste. In California, a generator is also required to determine if the waste exhibits any California characteristic of a hazardous waste.

Question 8: Would a pharmaceutical waste consisting solely of nitroglycerin (P081), (an example which was specifically discussed in the above-mentioned FR), be regulated as hazardous waste in California?

DTSC Response: It depends on the actual circumstances. Discarded nitroglycerin in finished dosage form has the potential to be both a listed hazardous waste (P081) and a characteristic (i.e., reactive) hazardous waste in California.

Is the waste a listed hazardous waste in California?: If the nitroglycerin were the sole active ingredient in the waste, and the waste was unused material, the waste would be identified as a RCRA hazardous waste in California and would be assigned the waste code (P081). However, because nitroglycerin (P081) was listed by U.S. EPA solely for reactivity, if the pharmaceutical waste was a mixture of nitroglycerin and another waste (presumably the pills would be a mixture of nitroglycerin and other inert binders), then it would not carry the P081 listing if the mixture was not reactive [title 22, California Code of Regulations, section 66261.3(a)(2)(E)].

Is the waste a characteristic hazardous waste in California?: Waste nitroglycerin in a mixture that does not exhibit the characteristic of reactivity (i.e., does not carry the P081 listing), may be regulated as non-RCRA hazardous waste in California due to its toxicity. Specifically, the waste may exhibit the State hazardous waste characteristic of toxicity due to its acute oral toxicity [title 22, California Code of Regulations, section 66261.24(a)(3)], or due to its aquatic toxicity [title 22 California Code of Regulations, section 66261.24(a)(6)].

Pursuant to title 22, California Code of Regulations, section 66261.24(b), a generator can calculate the concentration (percentage) of nitroglycerin in a waste that would exceed the regulatory threshold for acute oral toxicity as follows:

$$\text{Calculated oral LD}_{50} = \frac{100}{\sum_{x=1}^n \frac{\%A_x}{TA_x}}$$

where:

$\%A_x$ is the weight percent of each component in the waste mixture
 T_{Ax} is the acute oral or dermal LD_{50} or the acute oral LD_{LO} of each component
 Σ is the sum of all the math divisions for $\frac{\%A_x}{T_{Ax}}$

$$2500^4 \text{ mg/kg} = \frac{100}{\frac{\% \text{ Nitroglycerin}}{105 \text{ mg/kg (published oral } LD_{50} \text{ (rat) for nitroglycerin)}}$$

Concentration (in percent) = 4.2

Therefore, a mixture of waste containing nitroglycerin in concentrations of 4.2% or greater, would exhibit the characteristic of toxicity (be regulated as hazardous waste) in California. The waste could be managed as medical waste if the above mixture of waste was hazardous solely due to this toxicity, (does not contain non-pharmaceutical hazardous waste constituent).

A generator would have to consult the published toxicological data or test the waste using the procedure specified in title 22, California Code of Regulations, section 66262.24(a)(6) to determine if it exhibited the characteristic of toxicity by being aquatically toxic.

Question 9: A list provided to me by DHS indicates that waste epinephrine may be managed as solid waste (i.e., it is not hazardous waste). However, epinephrine is listed in 40 CFR 261.33 (P042). Is pharmaceutical waste containing epinephrine regulated as hazardous waste in California?

DTSC Response: The list DHS provided to you may be misleading. DTSC obtained a copy of that list. The list indicates that a solution of Epinephrine was tested for aquatic toxicity and a result of 1 mg/10 ml was obtained. The list also indicates that at this concentration, it does not fail the aquatically toxicity test. If the units of that test result are converted to the equivalent units of California's regulatory threshold of 500 mg/L, a value of 100 mg/L is obtained. A value of 100 mg/L is less than 500 mg/L and indicates that the substance is aquatically toxic. DTSC recommends that a generator fully evaluate the merits of any documentation it uses for a hazardous waste determination.

Pursuant to title 22, California Code of Regulations, section 66262.11, it is a generator's responsibility to determine whether its waste is a hazardous waste including determining if only hazardous waste listing would apply to a particular waste. In performing that determination, the generator must determine if any exemption (i.e., as described in question one) is applicable to its waste and whether or not the waste is a

4 See Health and Safety Code section 25141.5, threshold for acute oral toxicity (LD_{50}) = 2500 mg/kg.

hazardous waste. Even if it were aquatically toxic, an epinephrine containing pharmaceutical waste may qualify for the medical waste exemption (see DTSC response to question 1) provided that characteristic of the waste resulted solely from the presence of pharmaceuticals in the waste. Generators whose pharmaceutical wastes do not qualify for the medical waste exemption would utilize the process exemplified in DTSC's response to the previous question, to evaluate wastes toxicity. (one step of the hazardous waste determination process).

Question 10: The Florida Department of Environmental Protection has indicated it will not require hazardous disposal of partially used chemotherapy IVs, but the State of Minnesota does require such disposal. How does California differentiate between a totally unused IV of solution containing a "P" or "U" listed waste and one that had been hung and partially used?

DTSC Response: DTSC would not distinguish between the two solutions if they both were unused materials. However, if the partially empty container held used material (i.e., if material had been added to solution, for example by injection), then DTSC would classify that solution as used material. As used material, for purposes of hazardous waste classification, the solution would be either a "spent material" or a "by-product", but would not be a "commercial chemical product".

Question 11: What is the generator accumulation time requirement for extremely hazardous waste, as defined in title 22, California Code of Regulations, section 66261.110?

DTSC Response: Generator accumulation time requirements can be found in title 22, California Code of Regulations, section 66262.34. DTSC has made available a fact sheet addressing the accumulation of hazardous waste. You may obtain a copy via DTSC's website at:
http://www.dtsc.ca.gov/PublicationsForms/HWM_FS_Accumulating_HazWaste_Generators.pdf.

Question 12: How does DTSC deal with drugs such as colchicines which meets the criteria of an extremely hazardous waste but is not federally regulated? Is colchicine regulated by DTSC as a hazardous waste or DHS as a medical waste?

DTSC Response: If a waste pharmaceutical such as waste colchicine is an extremely hazardous waste and not a RCRA hazardous waste, as defined in Health and Safety Code section 25120.2, the waste pharmaceutical would be regulated by DHS as medical waste. You should contact DHS's Medical Waste Management Program for information on managing waste pharmaceuticals such as waste colchicine. The internet weblink is:
http://www.dhs.ca.gov/ps/ddwem/environmental/Med_Waste/medwasteindex.htm.

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Question 13: If a waste pharmaceutical is regulated under RCRA, does California recognize the federal Conditionally Exempt Small Quantity Generator (CESQG) status and what are the generator requirements?

DTSC Response: California's hazardous waste regulations do not exempt CESQG wastes. Generators of RCRA or non-RCRA hazardous waste, with few exceptions, are required to have federal or State ID numbers, manifest their wastes, etc., as specified in title 22, California Code of Regulations, division 4.5, chapter 12 (Standards Applicable to Generators of Hazardous Waste). These requirements (except transportation) are not applicable to generators of medical waste. DTSC has made available a fact sheet addressing generator requirements available at the following website:
http://www.dtsc.ca.gov/PublicationsForms/HWM_FS_Generator_Requirements.pdf.

As you are aware, DTSC has referred a copy of your letter and this response to DHS. If you have further questions about medical waste management in California, please contact Mr. Ron Pilorin at:

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If you have questions regarding this letter, please call Ms. Valetti Lang, of my staff, at (916) 445-4413.

Sincerely,



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