

Yana Garcia
Secretary for Environmental Protection
Rachel Machi Wagoner
CalRecycle Director

September 15, 2023

Jim Erickson President and CEO UltiMed, Inc 350 Highway 7, Suite 100 Excelsior, MN 55331

Sent via e-mail

Re: CalRecycle's Completeness Determinations for UltiMed's 2022 Annual Report and 2024 Annual Program Budget for Home-Generated Sharps Waste

Dear Mr. Erickson:

The Department of Resources Recycling and Recovery (CalRecycle) received UltiMed, Inc's (UltiMed) 2022 annual report and 2024 annual program budget for homegenerated sharps waste on August 18, 2023, titled, *Pharmaceutical and Sharps Waste Stewardship 2022 Annual Report*. Public Resources Code (PRC) section 42033.2(d)(1) and Title 14 of the California Code of Regulations (14 CCR) section 18973.1(b) require CalRecycle to determine if the annual report and annual program budget are complete and notify UltiMed of its determination within 30 days of receipt (i.e., by September 18, 2023).

Staff reviewed UltiMed's 2022 annual report and 2024 annual program budget for home-generated sharps waste for completeness pursuant to the requirements in PRC sections 42033.2(a) through (c) and 14 CCR sections 18973, 18973.1(b), 18973.5, and 18973.6 and found the annual report complete and the annual program budget incomplete due to a missing independent financial audit.

Pursuant to 14 CCR section 18973.1(b)(2), Attachment 1 identifies the additional information required in the annual program budget in accordance with statutory, regulatory, and approved plan requirements. UltiMed's rationale for not providing an independent financial audit as part of its annual program budget was that it "does not have stand-alone financial statements for independent audit" because it is "operating the Program on its own through the general operation of the overall business." PRC sections 42033.4(b)(1) and (2) and 14 CCR section 18973.6(f) require a program operator, who can be a covered entity operating its own program, to provide an independent financial audit as part of its annual program budget.

The annual report completeness determination is separate from the compliance determination CalRecycle will now conduct pursuant to 14 CCR sections 18973.1(d) through (f). CalRecycle has 90 days from the date of the annual report submittal to review for compliance with all statutory and regulatory requirements and approve, conditionally approve, or disapprove the annual report (i.e., by November 16, 2023).

The annual program budget completeness determination is separate from the compliance determination that CalRecycle will conduct once it receives the resubmitted annual program budget pursuant to 14 CCR sections 18973.1(d) through (f). UltiMed must resubmit its 2024 annual program budget for home-generated sharps waste to CalRecycle within 30 days of this notification that its annual program budget is incomplete. If UltiMed does not submit a complete annual program budget, which includes an independent financial audit, within 30 days of this notification of incompleteness, CalRecycle will find the annual program budget incomplete and will proceed with the compliance review. Upon resubmittal, CalRecycle has 90 days from the date of receipt of the resubmitted 2024 annual program budget to review for compliance with all statutory and regulatory requirements and approve, conditionally approve, or disapprove the annual program budget.

Questions regarding this letter may be directed to pharmasharps@calrecycle.ca.gov. Regards,

Signed by: Rachel Machi Wagoner, Director **Dated:** September 15, 2023

Attachment 1. Additional Information Required in UltiMed's 2024 Annual Program Budget for Home-Generated Sharps Waste

Cc: Jason Smyth, Supervisor, Pharmaceutical and Sharps Unit Becky Haworth, Environmental Scientist, Pharmaceutical and Sharps Unit

Attachment 1. Additional Information Required in UltiMed's 2024 Annual Program Budget for Home-Generated Sharps Waste

Number	Statute, Regulation, and/or Plan Requirement	Comment
	14 CCR 18973.6(f) PRC 42033.2(c)(1) and 42033.4(b)(1)-(2)	The annual program budget must be submitted along with an independent financial audit of the stewardship program funded by the member covered entities participating in the stewardship program or by a covered entity, if it operates its own stewardship program. The audit shall be performed at least once each calendar year. The audit shall be conducted in accordance with generally accepted auditing standards in the United States of America by a Certified Public Accountant. The Certified Public Accountant shall not perform the non-audit services for the program operator or engage in any activities that would impair independence. The independent financial audit shall include, but not be limited to:
1		 Minutes, books, and records that clearly reflect the activities and transactions of the program operator's stewardship program. Stewardship program financial statements, as required by Generally Accepted Accounting Principles. An opinion on the stewardship organization's compliance with the aspects of section 42034 of the Public Resources Code and this Article. Findings and recommendations as they relate to the financial aspects of the stewardship program. Management Letter, if issued, by the stewardship organization's Certified Public Accountant.