



July 20, 2023

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

Sent via e-mail

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

Dear Jim Erickson:

The Department of Resources Recycling and Recovery (CalRecycle) received UltiMed, Inc's (UltiMed) 2022 annual report and 2024 annual program budget for home-generated sharps waste on June 21, 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 July 21, 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 and annual program budget incomplete. Pursuant to 14 CCR section 18973.1(b)(2), Attachment 1 identifies the additional information required in the annual report and annual program budget in accordance with statutory, regulatory, and approved plan requirements.

These completeness determinations are separate from the compliance determinations that CalRecycle will conduct once it receives an annual report and annual program budget it determines are complete pursuant to 14 CCR sections 18973.1(d) through (f). UltiMed must resubmit its 2022 annual report for home-generated sharps waste and its 2024 annual program budget for home-generated sharps waste to CalRecycle within 30 days of CalRecycle's notification that its annual report and annual program budget are incomplete. If CalRecycle determines, upon resubmittal, that UltiMed's annual report and annual program budget are complete, CalRecycle has 90 days from the date of receipt of the resubmitted 2022 annual report and 2024 annual program budget to review for compliance with all statutory and regulatory requirements and approve, conditionally approve, or disapprove the annual report and annual program budget.

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

Regards,

Signed by: Rachel Machi Wagoner, Director

Dated: July 20, 2023

Attachment 1. Additional Information Required in UltiMed's 2022 Annual Report and 2024 Annual Program Budget for Home-Generated Sharps Waste

Cc: Jason Smyth, Supervisor, Pharmaceutical and Sharps Unit

Julia Dandar, Environmental Scientist, Pharmaceutical and Sharps Unit

Attachment 1. Additional Information Required in UltiMed’s 2022 Annual Report for Home-Generated Sharps Waste

Number	Statute, Regulation, and/or Plan Requirement	Comment
1	PRC 42033.2(b)(5)	The annual report must include information on the mail-back program.
2	14 CCR 18973.5(c)(1)	The annual report must include a description of how ultimate users had an opportunity to dispose of their home-generated sharps waste as described in the approved stewardship plan.
3	14 CCR 18973.5(c)(2) Plan Page 28	<p>The annual report must include the amount of sharps waste containers and mail-back materials distributed per county pursuant to section 18973.3(f)(6), through each of the following methods:</p> <ul style="list-style-type: none"> (A) Provided at point of sale (B) Initiated at point of sale (C) Website requests (D) Toll-free telephone number requests <p>The annual report must include all required metrics, even if they are zero. Additionally, UltiMed’s approved plan commits to providing the “units of covered product distributed into the State of California.”</p>
4	14 CCR 18973.5(c)(3) Plan Page 28	<p>The annual report must include the amount of home-generated sharps waste returned through the mail-back program, as required in the stewardship plan pursuant to section 18973.3(f)(6).</p> <p>UltiMed’s approved plan commits to providing the number of units and the weight of covered product returned through USPS to disposal facilities. The annual report does not include the weight of covered product returned.</p>
5	14 CCR 18973.5(d)(3)	<p>The annual report must include descriptions of the methods used to transport and dispose of consolidated home-generated sharps waste, including the following:</p> <p>For each disposal facility, include the total weight of material disposed.</p>

6	14 CCR 18973.5(i)(1)	The annual report must include a description and evaluation of the comprehensive education and outreach activities pursuant to 18973.3(i), including but not limited to electronic examples of promotional marketing materials.
7	14 CCR 18973.5(i)(2) Plan Page 35	<p>The annual report must include a description and evaluation of the comprehensive education and outreach activities pursuant to 18973.3(i), including but not limited to, numerical results of the education and outreach metrics outlined in the stewardship plan, pursuant to section 18973.3(i)(5).</p> <p>UltiMed’s approved plan commits to providing metrics for the units of covered product distributed into California, the weight of covered product returned, and the pharmacy locations that stock the product.</p>
8	14 CCR 18973.5(i)(3) Plan Page 35	<p>The annual report must include a description and evaluation of the comprehensive education and outreach activities pursuant to 18973.3(i), including but not limited to, a discussion of what the education and outreach metrics outlined in the stewardship plan reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility.</p> <p>UltiMed’s approved plan commits to using the education and outreach metrics to assess the program with the following metrics:</p> <ul style="list-style-type: none"> • Program Usage Metric: Units returned through the USPS, divided by units distributed • Accessibility Metric: Number of pharmacy locations that have access to the approved product, divided by the total number of pharmacy locations in the State of California • Penetration Metric: Number of pharmacy locations that distribute the approved product, divided by the total pharmacy locations that have access to it
9	PRC 42033.2(b)(8)	The annual report must include how the program operator complied with all elements in its stewardship plan.

Additional Information Required in UltiMed’s 2024 Annual Program Budget for Home-Generated Sharps Waste

Number	Statute, Regulation, and/or Plan Requirement	Comment
1	14 CCR 18973.6(f)	<p>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:</p> <ul style="list-style-type: none"> (1) Minutes, books, and records that clearly reflect the activities and transactions of the program operator’s stewardship program. (2) Stewardship program financial statements, as required by Generally Accepted Accounting Principles. (3) An opinion on the stewardship organization's compliance with the aspects of section 42034 of the Public Resources Code and this Article. (4) Findings and recommendations as they relate to the financial aspects of the stewardship program. (5) Management Letter, if issued, by the stewardship organization's Certified Public Accountant.