

REQUEST FOR APPROVAL

To: Rachel Machi Wagoner
Director

From: Zoe Heller
Acting Deputy Director, Materials Management and Local
Assistance Division
Deputy Director, Policy Development and Analysis Office

Request Date: June 14, 2022

Decision Subject: Consideration of UltiMed's Revised Home-Generated Sharps
Waste Stewardship Plan

Action By: June 27, 2022

Summary of Request

UltiMed, Inc. (UltiMed) submitted a revised stewardship plan for home-generated sharps waste, which includes its initial program budget, titled, *UltiMed Sharps Stewardship Plan (Revised Plan)* to the Department of Resources Recycling and Recovery (CalRecycle) on March 27, 2022, pursuant to the requirements in CalRecycle's December 27, 2021, Request for Approval, titled, *Consideration of UltiMed's Product Stewardship Plan for Home-Generated Sharps Waste*. This Request for Approval presents staff's analysis and compliance recommendation regarding UltiMed's *Revised Plan*.

Background

UltiMed is an individual sharps manufacturer. As a manufacturer, UltiMed submitted a home-generated sharps waste stewardship plan for 12 products that use UltiMed's "dispense and dispose" product, which combines the distribution of those sharps products with an FDA-cleared disposal container.

On October 11, 2021, UltiMed submitted its *UltiMed Sharps Stewardship Plan (Plan)* to CalRecycle, pursuant to Public Resources Code (PRC) section 42032, and on November 4, 2021, an addendum to the *Plan* titled *UltiMed Stewardship Plan – 1.4 Addendum 110421*. CalRecycle determined the *Plan* was complete and notified UltiMed on November 10, 2021, pursuant to PRC section 42032(c)(1) and Title 14 of the California Code of Regulations (CCR) section 18973.1(b).

On December 27, 2021, CalRecycle conditionally approved UltiMed's *Plan* pursuant to PRC section 42032(d)(1) and CCR sections 18973.1(e) and (g). CalRecycle provided UltiMed 90 days to submit a revised plan that addressed the conditions specified in the December 27, 2021, Request for Approval. The December 27, 2021, Request for Approval required UltiMed to submit (1) a letter, within 30 days of December 27, 2021, committing to revise and resubmit its plan to meet the conditions specified in the "Staff Analysis" section of the December 27, 2021 Request for Approval, and (2) a revised plan, within 90 days from December 27, 2021, that included the additional information to

meet the conditions specified in the “Staff Analysis” section of the December 27, 2021, Request for Approval.

UltiMed submitted the required letter on January 20, 2022. On March 27, 2022, UltiMed submitted a *Revised Plan*, which is the subject of this Request for Approval.

Staff Analysis

Each condition in the December 27, 2021, Request for Approval that CalRecycle required UltiMed to address is listed below, followed by a summary of staff’s analysis of UltiMed’s *Revised Plan* submitted on March 27, 2022.

1. CalRecycle Condition 1

Requirement: CalRecycle required the *Revised Plan* to meet the following conditions pursuant to PRC sections 42031.6, 42031.6(a)(1) through (3), and 42032.2(d)(1)(E) and CCR sections 18973.3(i)(1) through (4).

- a. Specify that materials will also be distributed to persons authorized to prescribe drugs and pharmacists, and that signage will be provided to hospitals, pharmacies, and other locations, as necessary.
- b. Describe how UltiMed's comprehensive education and outreach program will distribute materials in languages suited to local demographics. Explain the methodology UltiMed proposes to use to determine which languages are suited to various local demographics. Explain how non-English and non-Spanish language users will understand that live telephone support is available in other languages when the voice response system is only provided in English and Spanish.
- c. Specify that the website will be functional for mobile platforms and have language options suited to local demographics. Include a mechanism on the website to accept and fulfill requests from ultimate users for sharps waste containers and mail-back materials. Include a statement that instructions for safe handling and proper disposal and information on collection options will be available via the website.
- d. Verify all phone numbers are correct or remove the phone numbers to avoid confusion. Describe how the toll-free telephone number will provide services for hearing-impaired and speech-impaired individuals. Include a mechanism via the toll-free telephone number to accept and fulfill requests from ultimate users for sharps waste containers and mail-back materials. Include a statement that instructions for safe handling and proper disposal and information on collection options will be provided via the toll-free telephone number.

Result: Conditions 1(a) and (d) met. Conditions 1(b) and (c), above, partially met. Additional information from and additional actions by UltiMed are necessary.

UltiMed states in its *Revised Plan* that printed materials and signage will be distributed to hospitals and pharmacies, meeting condition 1(a). In the *Revised Plan*, UltiMed proposes that materials will be translated into English and Spanish when provided as a hard copy and that the website “and/or” call center will provide translations in other languages. However, the *Revised Plan* did not fully meet condition 1(b) because it does not describe how non-English and non-Spanish

language users will understand that education and outreach materials, including printed materials, are available in other languages or how materials are distributed to these users. UltiMed must describe how the comprehensive education and outreach program will distribute materials in languages suited to local demographics and explain how non-English and non-Spanish language users will understand that education and outreach materials are available in other languages suited to local demographics.

UltiMed's *Revised Plan* states that the website will be mobile optimized and have a submission form to accept requests for sharps waste containers and mail-back materials and included statements that the website will include information on safe handling and proper disposal. UltiMed's *Revised Plan* describes that "UltiMed will use Google Translate to provide translations in over 100 languages" and that the call center will have an interactive voice response directory in languages suited to local demographics with live translators. However, UltiMed also states that the website "and/or" call center will support other languages, which makes it unclear whether both the website and the toll-free telephone number will have language options suited to local demographics, as is required pursuant to CCR sections 18973.3(i)(3) and (4). Therefore, UltiMed did not fully meet condition 1(c) and must clarify that both the website and call center will offer language options suited to local demographics.

UltiMed removed conflicting phone numbers from the *Revised Plan* to prevent confusion. The *Revised Plan* includes a description that the toll-free telephone number will have an interactive voice response directory in languages suited to local demographics, include teletype services for hearing- and speech-impaired individuals, accept requests for sharps waste containers and mail-back materials, and include instructions for safe handling and proper disposal of sharps waste. The *Revised Plan* includes sufficient information to meet condition 1(d).

2. CalRecycle Conditions 2 and 4 through 8

Requirements: CalRecycle required the *Revised Plan* to meet the conditions specified in the "Staff Analysis" section of the December 27, 2021, Request for Approval.

Result: Conditions 2(a) and 4(a) through 8(a) met.

UltiMed's *Revised Plan* includes additional information, clarification, and descriptions to meet conditions 2(a) and 4(a) through 8(a) related to the following sections from the December 27, 2021, Request for Approval: "Local Agency Requests," "Coordination Efforts," "Handling, Transport, and Disposal System," "Metrics," "Records," and "Grants, Loans, and Sponsorships." Examples of these revisions include specifying a missing metric related to measuring the amount of sharps waste collected by household hazardous waste facilities requesting reimbursement, removing an undefined audit-related term, and providing clarifying descriptions of how UltiMed's records will be managed.

3. CalRecycle Condition 3

Requirement: CalRecycle required the *Revised Plan* to meet the following condition pursuant to PRC section 42032.2(e) and CCR section 18973.3(h).

- a. Remove the statement that ordinance repeals are “not applicable” and revise to explain how ultimate users will receive all required services in the stewardship program in the event of an ordinance repeal.

Result: Condition 3(a) partially met. Additional information from and additional actions by UltiMed are necessary.

UltiMed removed the statement that ordinance repeals are “not applicable,” and the *Revised Plan* includes some description of what will occur in the event a jurisdiction repeals its local stewardship program ordinance, partially meeting condition 3(a). However, the *Revised Plan* does not explain how the entirety of the stewardship program, including education and outreach, will be expanded. UltiMed must explain how ultimate users will receive all required services in the stewardship program in the event of an ordinance repeal.

The *Revised Plan* states that “should any jurisdiction (i.e., city or county) repeal their local sharps stewardship ordinance, UltiMed will work with the jurisdiction to include them in the state-wide program.” CalRecycle notes that UltiMed’s use of “i.e.,” creates an inclusive list and using “e.g.,” would be more appropriate. CCR section 18972.1(a)(6) provides a definition for “local jurisdiction” that is not limited to cities and counties.

4. CalRecycle Condition 9

Requirement: CalRecycle required the *Revised Plan* to meet the following condition pursuant to CCR section 18973(d).

- a. Use terminology defined in PRC and CCR or define and consistently utilize terminology within the Plan.

Result: Condition 9(a) partially met. Additional information from and additional actions by UltiMed are necessary.

Although UltiMed made revisions that use terminology defined in PRC and CCR and consistently utilize terminology throughout its *Revised Plan*, some issues remain. Therefore, condition 9(a) was partially met.

On page 27, UltiMed refers to itself as the “stewardship operator and participant,” neither of which are terms defined in the *Revised Plan*. On page 32 of the *Revised Plan*, UltiMed defines jurisdiction as “city or county.” CCR section 18972.1(a)(6) provides a definition for “local jurisdiction” that is not limited to cities and counties.

UltiMed provides two certification statements in the perjury statement section. The first certification statement in the *Revised Plan* uses the language “complete and correct” instead of “true and correct,” which is required. Additionally, the statement incorrectly references CCR section 18973(d). The correct citation is CCR section 18973(e). The second certification statement uses the word “collection” in place of the word “handling” as required in CCR section 18973.3(d)(2). UltiMed must revise the certification statements to match the language required in CCR sections

18973(e) and 18973.3(d)(2) and correct the citation within the first certification statement to 18973(e).

In two separate sentences, the *Revised Plan* states that UltiMed will reimburse local agencies for the “cost of destruction” and for the “removal” of home-generated sharps waste from household hazardous waste facilities. PRC section 42032.2(d)(1)(F)(ii)(II) and CCR section 18973.3(g) require a program operator to reimburse local agencies for “transportation and disposal costs,” not just the costs of destruction and removal. UltiMed must clarify that it will provide reimbursement for costs associated with “transportation and disposal” of home-generated sharps waste to any facility operated by a local agency that is properly authorized to accept and manage household hazardous waste.

Stakeholder Feedback

CalRecycle solicited public input on UltiMed's *Revised Plan* from March 28, 2022, through April 11, 2022, and received comment letters from MED-Project USA and the Pharmaceutical Product Stewardship Work Group. CalRecycle considered all comment letters received when reviewing UltiMed's *Revised Plan* for compliance.

Summary of Staff Analysis

CalRecycle staff analyzed UltiMed's *Revised Plan* to determine whether it met all the conditions from CalRecycle's December 27, 2021, Request for Approval. Additional information is still required from UltiMed regarding conditions 1(b), 1(c), 3(a), and 9(a), discussed in the “Staff Analysis” section above, for CalRecycle to determine if UltiMed's plan shall be approved pursuant to CCR section 18973.1(d).

Condition 1(b): The plan must describe how UltiMed's comprehensive education and outreach program will distribute materials in languages suited to local demographics and explain how non-English and non-Spanish language users will understand that education and outreach materials are available in other languages suited to local demographics.

Condition 1(c): The plan must specify that the website and call center will both independently meet the requirements to have language options suited to local demographics.

Condition 3(a): The plan must explain how ultimate users will receive all required services in the stewardship program in the event of an ordinance repeal.

Condition 9(a): Use terminology defined in PRC and CCR or define and consistently utilize terminology within the Plan. The plan must include certification statements that match the language required in CCR sections 18973(e) and 18973.3(d)(2) and correct the citation within the first certification statement to 18973(e). The plan must clarify that UltiMed will provide reimbursement for costs associated with “transportation and disposal” of home-generated sharps waste to any facility operated by a local agency that is properly authorized to accept and manage household hazardous waste.

Options

1. Find UltiMed did not meet the conditions, as specified in CalRecycle's December 27, 2021, Request for Approval. UltiMed's proposed stewardship plan for home-generated sharps waste remains "conditionally approved." Require UltiMed to revise and resubmit to resolve the issues identified in the "Staff Analysis" section above within 60 days of signature of this Request for Approval.
2. Find UltiMed did not meet the conditions for approval and (1) disapprove UltiMed's proposed stewardship plan for home-generated sharps waste, and (2) refer UltiMed to the Waste Permitting, Compliance and Mitigation Division for potential enforcement pursuant to Title 14, California Code of Regulations section 18973.1(h).

Action

Based on the analysis contained within this Request for Approval, I hereby find UltiMed did not meet all conditions, as specified in CalRecycle's December 27, 2021, Request for Approval. UltiMed's proposed stewardship plan for home-generated sharps waste remains "conditionally approved." UltiMed must revise and resubmit to resolve the issues identified in the "Staff Analysis" section above within 60 days of signature of this Request for Approval. UltiMed must fully implement its plan, revised to comply with the conditions outlined in the "Summary of Staff Analysis," within 270 days from the date of conditional approval on December 27, 2021. Failure to comply with all conditions and resubmit the plan within 60 days may result in disapproval of UltiMed's proposed stewardship plan for home-generated sharps waste.

Dated: June 23, 2022

Signed by: Rachel Machi Wagoner, Director

Attachments:

Documents listed below are posted to CalRecycle's website. To request documents that are referenced in this report but are not listed below, please submit a Public Records Act request (<https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/>).

1. [UltiMed Sharps Stewardship Plan](https://www2.calrecycle.ca.gov/Docs/Web/119760) (October 11, 2021)
<https://www2.calrecycle.ca.gov/Docs/Web/119760>
 - a. [UltiMed Sharps Stewardship Plan - Addendum](https://www2.calrecycle.ca.gov/Docs/Web/119877) (November 4, 2021)
<https://www2.calrecycle.ca.gov/Docs/Web/119877>
2. [Consideration of UltiMed's Product Stewardship Plan for Home-Generated Sharps Waste](https://www2.calrecycle.ca.gov/Docs/Web/120252)
<https://www2.calrecycle.ca.gov/Docs/Web/120252>
3. [UltiMed Sharps Stewardship Plan](https://www2.calrecycle.ca.gov/Docs/Web/121095) (March 27, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/121095>