

## REQUEST FOR APPROVAL

**To:** Rachel Machi Wagoner  
Director

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

**Request Date:** November 7, 2022

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

**Action By:** November 17, 2022

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### **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 (August 2022 Revised Plan)* to the Department of Resources Recycling and Recovery (CalRecycle) on August 19, 2022, pursuant to the requirements in CalRecycle's June 2022 Request for Approval, titled, *Consideration of UltiMed's Revised Home-Generated Sharps Waste Stewardship Plan*. This Request for Approval presents a summary of staff's analysis and compliance recommendation regarding UltiMed's *August 2022 Revised Plan*.

### **Background**

UltiMed submitted a home-generated sharps waste stewardship plan as an individual sharps manufacturer for 12 of its products, which combines sharps products with a sharps waste container and mail-back materials. On October 11, 2021, UltiMed submitted *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 (14 CCR) section 18973.1(b).

On December 27, 2021, CalRecycle conditionally approved UltiMed's *Plan* pursuant to PRC section 42032(d)(1) and 14 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 2021 Request for Approval.

On March 27, 2022, UltiMed submitted *UltiMed Sharps Stewardship Plan (March 2022 Revised Plan)* to meet conditions specified in the "Staff Analysis" section of the December 2021 Request for Approval. On June 23, 2022, CalRecycle maintained the conditional approval of UltiMed's *March 2022 Revised Plan* and provided UltiMed 60 days to submit a revised plan that addressed the remaining conditions specified in the June 2022 Request for Approval.

On August 19, 2022, UltiMed submitted its *August 2022 Revised Plan*, which is the subject of this Request for Approval.

### **Staff Analysis**

Each condition in the June 2022 Request for Approval that CalRecycle required UltiMed to address is listed below, followed by a summary of staff's analysis of UltiMed's *August 2022 Revised Plan*.

#### **1. CalRecycle Condition 1**

Requirement: CalRecycle required the *August 2022 Revised Plan* to meet the following conditions 1(b) and 1(c) pursuant to PRC sections 42031.6, 42031.6(a)(1) through (3), and 42032.2(d)(1)(E) and 14 CCR sections 18973.3(i)(1) through (4).

- 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.
- 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.

Result: Conditions 1(b) and (c) met.

In its *August 2022 Revised Plan*, UltiMed states that materials will be translated into English and Spanish when provided as a hard copy and will include a "universally recognized translation icon" directing ultimate users to its website to view or print translated documents. UltiMed's call center will have a live interpreter to assist non-English speaking ultimate users. UltiMed's *August 2022 Revised Plan* meets condition 1(b).

UltiMed's August 2022 Revised Plan describes that both the website and call center will independently support language options suited to local demographics consistent with Section 7295 of the Government Code. Therefore, UltiMed's *August 2022 Revised Plan* meets condition 1(c).

#### **2. CalRecycle Condition 3**

Requirement: CalRecycle required the *August 2022 Revised Plan* to meet the following condition 3(a) pursuant to PRC section 42032.2(e) and 14 CCR section 18973.3(h).

- a. The plan must explain how ultimate users will receive all required services in the stewardship program in the event of an ordinance repeal.

Result: Condition 3(a) met.

UltiMed commits to expanding its home-generated sharps waste stewardship program, inclusive of education and outreach, into any local jurisdiction that repeals its local stewardship program ordinance. UltiMed's *August 2022 Revised Plan* meets condition 3(a).

### 3. CalRecycle Condition 9

Requirement: CalRecycle required the *August 2022 Revised Plan* to meet the following condition 9(a) pursuant to 14 CCR section 18973(d).

- b. Use terminology defined in PRC and 14 CCR or define and consistently utilize terminology within the Plan. The plan must include certification statements that match the language required in 14 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.

Result: Condition 9(a) met.

UltiMed consistently utilizes terminology throughout its *August 2022 Revised Plan*. UltiMed provides a corrected certification statement and commits to providing reimbursement for costs associated with transportation and disposal of home-generated sharps waste to local household hazardous waste facilities. UltiMed’s *August 2022 Revised Plan* meets condition 9(a).

### **Stakeholder Feedback**

CalRecycle solicited public input on UltiMed’s *August 2022 Revised Plan* from August 22, 2022, through September 6, 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 *August 2022 Revised Plan* for compliance.

### **Summary of Staff Analysis**

CalRecycle staff analyzed UltiMed’s *August 2022 Revised Plan* and determined it meets all conditions from CalRecycle’s June 2022 Request for Approval.

### **Action**

Based on the analysis within this Request for Approval, I hereby approve UltiMed’s *August 2022 Revised Plan* that is designed to manage UltiMed’s covered sharps that combine the sharps products with a sharps waste container and mail-back materials.

**Signed by:** Rachel Machi Wagoner, Director

**Dated:** November 15, 2022

### **Attachments:**

Documents listed below are posted to CalRecycle’s website.

1. [UltiMed Sharps Stewardship Plan](https://www2.calrecycle.ca.gov/Docs/Web/122103) (August 19, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/122103>
2. [Consideration of UltiMed’s Revised Home-Generated Sharps Waste Stewardship Plan](https://www2.calrecycle.ca.gov/Docs/Web/121689) (June 23, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/121689>
3. [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 – 1.4 Addendum 110421](#) (November 4, 2021)

<https://www2.calrecycle.ca.gov/Docs/Web/119877>

4. [Consideration of UltiMed's Product Stewardship Plan for Home-Generated Sharps Waste](https://www2.calrecycle.ca.gov/Docs/Web/120252) (December 27, 2021)  
<https://www2.calrecycle.ca.gov/Docs/Web/120252>
5. [UltiMed Sharps Stewardship Plan](https://www2.calrecycle.ca.gov/Docs/Web/121095) (March 27, 2022)  
<https://www2.calrecycle.ca.gov/Docs/Web/121095>