

## REQUEST FOR ACTION

**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 2, 2023

**Decision Subject:** Consideration of UltiMed's 2022 Annual Report for Home-Generated Sharps Waste

**Action By:** November 16, 2023

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### **Summary of Request**

UltiMed, Inc. (UltiMed) submitted its 2022 annual report, titled, *Pharmaceutical and Sharps Waste Stewardship 2022 Annual Report (2022 Annual Report)* on August 18, 2023. This Request for Action presents a summary of staff's analysis regarding UltiMed's *2022 Annual Report* and UltiMed's home-generated sharps waste stewardship program.

### **Background**

UltiMed submitted a home-generated sharps waste stewardship plan, titled *UltiMed Sharps Stewardship Plan (Plan)*, as an individual sharps manufacturer for 11 of its products, which combine sharps products with a sharps waste container and mail-back materials. On December 27, 2021, the Department of Resources Recycling and Recovery (CalRecycle) conditionally approved UltiMed's *Plan* pursuant to Public Resources Code (PRC) section 42032(d)(1) and Title 14 of the California Code of Regulations (14 CCR) sections 18973.1(e) and (g). On November 15, 2022, UltiMed's *Plan* was approved. UltiMed's *2022 Annual Report* covers the entire 2022 calendar year (January 1, 2022, through December 31, 2022).

PRC section 42033.2(a)(1) states that, on or before March 31, 2022, and each year thereafter, a program operator shall submit to CalRecycle a report that describes the stewardship program activities during the previous reporting year. UltiMed submitted its *2022 Annual Report*, on June 21, 2023, which CalRecycle found incomplete on July 20, 2023, and was required to revise its 2022 annual report and resubmit to CalRecycle within 30 days. UltiMed resubmitted its *2022 Annual Report* on August 18, 2023. CalRecycle determined the *2022 Annual Report* was complete and notified UltiMed on September 15, 2023, pursuant to PRC section 42033.2(d)(1) and 14 CCR section 18973.1(b). CalRecycle has 90 days to approve, disapprove, or conditionally approve the *2022 Annual Report* pursuant to PRC section 42033.2(d)(4) and 14 CCR section 18973.1.

### **Staff Analysis**

UltiMed states in its *2022 Annual Report* that it conducted the following program activities:

- Focused on building awareness and providing education through multiple programs including customer meetings, conversations at tradeshow, and advertising
- Conducted outreach that included 26 advertisements with over 650,000 impressions

Staff analyzed and evaluated UltiMed’s *2022 Annual Report* to determine whether the requirements of statute, regulations, and UltiMed’s *Plan* were met. The sections below present a summary of staff’s analysis of UltiMed’s *2022 Annual Report* for those requirements where additional information from and/or additional actions by UltiMed may be necessary for CalRecycle to determine whether the requirements of statute, regulations, and UltiMed’s *Plan* were met.

### **Education and Outreach**

Requirements: A description and evaluation of the comprehensive education and outreach activities including, but not limited to, electronic examples of promotional marketing materials, numerical results of the education and outreach metrics outlined in the stewardship plan, and a discussion of what the metrics reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility pursuant to 14 CCR section 18973.5(i)(1)-(3). A stewardship plan for home-generated sharps waste must include materials to be utilized that are distributed in languages suited to local demographics, consistent with section 7295 of the Government Code. These materials shall include, but are not limited to, signage for hospitals, pharmacies, and other locations, as necessary, pursuant to 18973.3(i)(2).

### Analysis: Requirements Partially Met

UltiMed’s *2022 Annual Report* includes three examples of education and outreach materials: a distributor website display advertisement for a digital media campaign, a flyer, and a screenshot of the website home page. These examples do not demonstrate that UltiMed distributed education and outreach materials in both English and Spanish, as described in its *Plan*. UltiMed’s *Plan* also states that “printed materials will feature universally recognized translation icons.” Although the *2022 Annual Report* does not specify whether the flyer provided in the *2022 Annual Report* is an example of “printed materials,” the example materials should be representative of UltiMed’s comprehensive education and outreach program, which includes printed copies of English and Spanish materials and access to translated documents in languages suited to local demographics consistent with section 7295 of the Government Code.

The *2022 Annual Report* includes the three metrics UltiMed describes in its *Plan* that it will use to assess the program. However, UltiMed does not discuss what these metrics reveal about the performance of the education and outreach program related to ultimate user awareness, program usage, and accessibility. For example, the program usage metric (defined in the *Plan* as “Units returned through the USPS,

divided by units distributed”) appears to be very low (0.0005 percent), but UltiMed does not discuss reasons this may have occurred or opportunities for improvement.

Summary 1 of Requirements Not Met: The following serves as written notice of the requirements that must be met should the Director choose to conditionally approve or disapprove UltiMed’s *2022 Annual Report* as indicated in the “Action” section below.

- a. Provide electronic examples of promotional marketing materials that are representative of UltiMed’s comprehensive education and outreach program pursuant to 14 CCR sections 18973.5(i)(1) and 18973.3(i)(2).
- b. Discuss what the education and outreach metrics reveal about the performance of the comprehensive education and outreach program, including, but not limited to, ultimate user awareness, program usage, and accessibility pursuant to 14 CCR section 18973.5(i)(3).

### **Transportation and Disposal**

Requirements: For each disposal facility provide the name of facility, the mailing and physical address, and the total weight of material disposed pursuant to 14 CCR sections 18973.5(d)(2) and (d)(3). A program operator submitting an annual report shall provide to the department, upon request and by the requested deadline, clarifying information that is necessary to assist the department in its consideration of approval, pursuant to 14 CCR section 18973.1(a).

Analysis: Requirements Partially Met

UltiMed’s *2022 Annual Report* lists Daniels Health, Medsharps, HWM, and Curtis Bay as disposal facilities. However, UltiMed’s *Plan* lists Medsharps, HWM, Curtis Bay, and Healthwise Services as treatment facilities. An explanation is not provided to describe why these facilities are listed differently in UltiMed’s *Plan* and its *2022 Annual Report*.

Summary 2 of Requirements Not Met: The following serves as written notice of the requirements that must be met should the Director choose to conditionally approve or disapprove UltiMed’s *2022 Annual Report* as indicated in the “Action” section below.

- a. Clarify the list of disposal facilities provided in the annual report pursuant to 14 CCR sections 18973.1(a) and 18973.5(d)(3).

### **Coordination Efforts**

Requirements: Describe how the program operator coordinated with other program operators to avoid confusion to the public and all program participants in the event that multiple stewardship programs for home-generated sharps waste are in operation concurrently or new stewardship programs begin operating pursuant to 14 CCR section 18973.5(o).

Analysis: Requirement Partially Met

UltiMed’s *2022 Annual Report* states that “During this reporting period, there were coordination efforts with other program operators to discuss a shared logo opportunity.” No other information is provided. UltiMed must include more detail on

how it coordinated with the other program operators, including timelines and outcomes.

Summary 3 of Requirements Not Met: The following serves as written notice of the requirement that must be met should the Director choose to conditionally approve or disapprove UltiMed's *2022 Annual Report* as indicated in the "Action" section below.

- a. Describe how UltiMed coordinated with other program operators pursuant to 14 CCR section 18973.5(o).

### **Mailing and Physical Addresses**

Requirements: Provide contact information of the corporate officer, or designee, responsible for submitting and overseeing the stewardship plan, including, but not limited to, mailing and physical address pursuant to 14 CCR section 18973.5(a). Provide a list of participating covered entities covered by the stewardship plan and their contact information, including, but not limited to, mailing and physical address pursuant to PRC section 42033.2(b)(1) and 14 CCR section 18973.5(j)(2).

Analysis: Requirements Partially Met

UltiMed provides one address for itself, as the sole participating covered entity and Jim Erickson as the point of contact, in its *2022 Annual Report*. It is unclear if this is the mailing and/or physical address when both are required.

Summary 4 of Requirements Not Met: The following serves as written notice of the requirements that must be met should the Director choose to conditionally approve or disapprove UltiMed's *2022 Annual Report* as indicated in the "Action" section below.

- a. Include mailing and physical addresses associated with the corporate officer, or designee, responsible for submitting and overseeing the stewardship plan pursuant to 14 CCR section 18973.5(a).
- b. Include mailing and physical addresses associated with the covered entity pursuant to 14 CCR section 18973.5(j)(2).

### **Document Submittals**

Requirements: Submit a written report describing the stewardship program activities during the previous reporting period of one year pursuant to PRC section 42033.2(a)(1) and 14 CCR section 18973.5. A concise summary of the information contained in the report that includes, but is not limited to, the highlights, outcomes and challenges, achievement of the convenience standards, education and outreach efforts, and ways in which challenges are being addressed, pursuant to 14 CCR section 18973.5(b).

Analysis: Requirement Partially Met

UltiMed's *2022 Annual Report* includes an executive summary that describes its mail-back program and states that its activities in 2022 "mainly focused on building awareness and providing education." The executive summary does not summarize these education and outreach efforts or discuss the highlights and challenges and ways in which challenges are being addressed, as required. For example, UltiMed

reports a 0.0005 percent program usage metric but does not include this as a challenge or discuss ways in which this is being addressed.

Summary 5 of Requirements Not Met: The following serves as written notice of the requirement that must be met should the Director choose to conditionally approve or disapprove UltiMed's *2022 Annual Report* as indicated in the "Action" section below.

- a. Include a concise summary of the information included in the report, including highlights and challenges, ways in which challenges are being addressed, and education and outreach efforts pursuant to 14 CCR section 18973.5(b).

### **Feedback from Interested Parties**

CalRecycle solicited public input on UltiMed's *2022 Annual Report* from August 23, 2023, through September 6, 2023, and did not receive any public comments.

### **Additional Information**

Effective February 17, 2023, UltiMed is no longer an active program operator. UltiMed asserts that, effective January 1, 2023, UltiMed's covered products are included in The Drug Takeback Solutions Foundation's home-generated sharps waste stewardship plan.

### **Action**

Pursuant to PRC section 42033.2(e) and 14 CCR section 18973.1, I hereby:

Approve UltiMed's *2022 Annual Report*.

Conditionally approve UltiMed's *2022 Annual Report*. Pursuant to 14 CCR section 18973.1(j), UltiMed must revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date this Request for Action notice is issued that includes the additional information specified in "Summary 1 of Requirements Not Met" through "Summary 5 of Requirements Not Met" in the "Staff Analysis" section above.

Disapprove UltiMed's *2022 Annual Report* and:

Refer UltiMed to CalRecycle's Waste Permitting, Compliance, and Mitigation Division for potential enforcement.

Require UltiMed to revise and resubmit its 2022 annual report to CalRecycle within 60 days of the date this Request for Action notice is issued that includes the additional information specified in "Summary 1 of Requirements Not Met" through "Summary 5 of Requirements Not Met" in the "Staff Analysis" section above.

Do not require UltiMed to revise and resubmit a 2022 annual report. Because (1) UltiMed is no longer an active program operator and the purpose of revising and resubmitting annual reports is to ensure ongoing program compliance, (2) UltiMed's *2022 Annual Report* demonstrated that it met or partially met all statutory, regulatory, and plan requirements, and (3) UltiMed asserts that its covered products are managed under another approved home-generated sharps waste stewardship plan.

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

**Dated:** November 20, 2023

**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 (<https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/>).

1. [Pharmaceutical and Sharps Waste Stewardship 2022 Annual Report](https://www2.calrecycle.ca.gov/Docs/Web/125277) (August 18, 2023) <https://www2.calrecycle.ca.gov/Docs/Web/125277>
2. [UltiMed Sharps Stewardship Plan](https://www2.calrecycle.ca.gov/Docs/Web/122103) (August 19, 2022) <https://www2.calrecycle.ca.gov/Docs/Web/122103>