

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 2021 Annual Report for Home-
Generated Sharps Waste

Action By: June 29, 2022

Summary of Request

UltiMed, Inc. (UltiMed) submitted its 2021 annual report, titled, *Pharmaceutical and Sharps Waste Stewardship 2021 Annual Report (2021 Annual Report)* on March 31, 2022, as required by statute. This Request for Approval presents staff's analysis and compliance recommendation regarding UltiMed's *2021 Annual Report*.

Background

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

On December 27, 2021, the Department of Resources Recycling and Recovery (CalRecycle) conditionally approved UltiMed's *UltiMed Sharps Stewardship Plan (Plan)* pursuant to Public Resources Code (PRC) section 42032(d)(1) and Title 14, California Code of Regulations (14 CCR) sections 18973.1(e) and (g). UltiMed's *2021 Annual Report* covers the period of time its *Plan* was conditionally approved in calendar year 2021 (December 27, 2021, through December 31, 2021).

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 *2021 Annual Report*, on March 31, 2022. CalRecycle determined the *2021 Annual Report* was complete and notified UltiMed on May 2, 2022, 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 *2021 Annual Report* pursuant to PRC section 42033.2(d)(2) and 14 CCR section 18973.1. The sections below summarize staff's analysis of UltiMed's *2021 Annual Report*.

Staff Analysis

1. Program Activities

Requirement: A written report describing the stewardship program activities during the previous reporting period of one year pursuant to PRC sections 42033.2(a)(1) and 42033.2(b) and 14 CCR section 18973.5.

Result: Compliant

UltiMed's *2021 Annual Report* addresses all annual report requirements pursuant to PRC sections 42033.2(a)(1) and 42033.2(b) and 14 CCR section 18973.5. The *2021 Annual Report* states that, due to the short reporting period for calendar year 2021 (December 27 through December 31), UltiMed did not conduct any program activities and, therefore, did not have any information to report.

2. Actual Expenses from Reporting Period

Requirement: A list of all actual expenses incurred during the previous reporting period, pursuant to CCR section 18973.5(q), summarized in accordance with the budget categories specified in 14 CCR section 18973.6(b).

Result: Compliant

UltiMed's *2021 Annual Report* includes a list of actual expenses for the required budget categories. UltiMed did not implement its stewardship plan during this time period and, as a result, did not incur expenses and reported \$0 in actual expenses for the reporting period.

3. Accessibility

Requirement: The document is required to comply with section 7405 of the Government Code, and the Web Content Accessibility Guidelines 2.0 published in 2008 by the Web Accessibility Initiative of the World Wide Web Consortium at a minimum Level AA success criteria, pursuant to 14 CCR section 18973(a).

Result: Additional actions by UltiMed are necessary. UltiMed must meet the condition outlined below under the section titled "CalRecycle Condition 1."

UltiMed's *2021 Annual Report* contains multiple accessibility errors that must be remediated for its *2021 Annual Report* to be found compliant.

CalRecycle Condition 1: Pursuant to 14 CCR section 18973.1(j), UltiMed must revise and resubmit its 2021 annual report to CalRecycle within 60 days of signature of this Request for Approval, and the resubmitted annual report must meet the following condition:

- a) Correct accessibility errors in the *2021 Annual Report* to make it compliant with section 7405 of the Government Code and with the Web Content Accessibility Guidelines 2.0. (The requirement necessitating this condition appears in 14 CCR section 18973(a)).

Summary of Staff Analysis

CalRecycle staff reviewed UltiMed's *2021 Annual Report*, which describes UltiMed's program activities in its 2021 reporting period (December 27, 2021, through December 31, 2021), and found the *2021 Annual Report* substantially compliant with all material requirements in PRC section 42033.2(b), 14 CCR sections 18973 and 18973.5, and

UltiMed's conditionally approved *Plan*. However, additional actions by UltiMed are necessary for CalRecycle to determine that the *2021 Annual Report* is compliant.

Options

1. Conditionally approve UltiMed's *2021 Annual Report*, contingent upon UltiMed providing to CalRecycle a revised 2021 annual report, within 60 days of signature on this Request for Approval, that includes the additional information to meet the condition specified in the "Staff Analysis" section of this Request for Approval.
2. Disapprove UltiMed's *2021 Annual Report*. UltiMed shall resubmit its revised 2021 annual report within 60 days of signature on this Request for Approval and CalRecycle will review the revised 2021 annual report within 90 days of resubmittal.

Action

Based on the information and analysis in this Request for Approval, I hereby conditionally approve UltiMed's *2021 Annual Report*, contingent upon UltiMed revising and resubmitting its 2021 annual report, within 60 days as described in the "Options" section above. Failure to comply with the condition and resubmit within 60 days may result in disapproval of UltiMed's *2021 Annual Report*. This Request for Approval shall serve as the written notice of the condition that CalRecycle must identify pursuant to the first sentence in CCR section 18973.1(j).

Dated: June 23, 2022

Signed by: Rachel Machi Wagoner, Director

Attachments:

Documents listed below are posted to CalRecycle's website. To request the *2021 Annual Report*, 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>