



April 18, 2024

Certified Tracking Number
7021 0950 0000 2875 6819Jim Erickson, President & CEO
UltiMed, Inc.
350 Highway 7, Suite 100
Excelsior, MN 55331**Re: CalRecycle's Compliance Determination for UltiMed's January 19, 2024
Revised 2022 Annual Report for Home-Generated Sharps Waste**

Dear Mr. Erickson:

The Department of Resources Recycling and Recovery (CalRecycle) reviewed UltiMed's January 19, 2024 *Revised 2022 Annual Report* covering calendar year January 1, 2022 through December 31, 2022, to determine whether UltiMed met the annual reporting requirements in the Pharmaceutical and Sharps Waste Stewardship statute and regulations (the Law), the August 19, 2022 *UltiMed Sharps Stewardship Plan (Plan)*, and CalRecycle's November 20, 2023 disapproval notice. **Based on this review, CalRecycle disapproves UltiMed's January 19, 2024 Revised 2022 Annual Report.**

Background and History

As an individual sharps manufacturer, UltiMed elected to comply with the Law by submitting its *Plan* for twelve of its UltiGuard Safe Pack products. CalRecycle conditionally approved UltiMed's *Plan* on December 27, 2021, issuing a final approval on November 15, 2022.

On June 21, 2023, UltiMed submitted its *2022 Annual Report* to CalRecycle, as program operators are required to submit reports annually describing the stewardship program activities that occurred during the previous reporting year (Public Resources Code (PRC) section 42033.2(a)(1)). CalRecycle determined the *2022 Annual Report* was incomplete on July 20, 2023 and UltiMed resubmitted its *2022 Annual Report* on August 18, 2023. CalRecycle determined on September 15, 2023, that the *2022 Annual Report* was complete, as part of the required completeness review. On November 20, 2023, CalRecycle disapproved UltiMed's *2022 Annual Report* and referred UltiMed to CalRecycle's Waste Permitting, Compliance, and Mitigation Division (WPCMD) for potential enforcement. On December 22, 2023, WPCMD issued UltiMed a Notice to Cure. The Notice to Cure provided UltiMed an opportunity to submit a revised annual report pursuant to PRC section 42033.2. On January 19, 2024, UltiMed submitted its second *Revised 2022 Annual Report*. CalRecycle determined that the

January 19, 2024 *Revised 2022 Annual Report* was complete on February 15, 2024, as part of the required completeness review.

January 19, 2024 Revised 2022 Annual Report

CalRecycle's November 20, 2023 disapproval notice noted seven annual reporting requirements that were partially met. Due to changes in the January 19, 2024 *Revised 2022 Annual Report*, five of the seven reporting requirements were met: (1) Education and Outreach sub-requirement to discuss metrics; (2) Coordination Efforts; (3) Mailing and Physical Address for the corporate officer or designee; (4) Mailing and Physical Address for the covered entity; and (5) Document Submittal to include all required topics in the Executive Summary. The remaining two are discussed below:

Education & Outreach

The Law requires program operators to have a comprehensive education and outreach program and provide a description of the program and electronic examples in its annual reports including examples of educational materials "distributed in languages suited to local demographics" pursuant to Title 14 California Code of Regulation (14 CCR) sections 18973.3(i) and 18973.5(i). UltiMed's *Plan* states that UltiMed's education and outreach printed materials will be translated into English and Spanish, and those printed materials will feature universally recognized translation icons.

UltiMed's January 19, 2024 *Revised 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*. Although the January 19, 2024 *Revised 2022 Annual Report* does not specify whether the flyer provided in the January 19, 2024 *Revised 2022 Annual Report* was an example of "printed materials," the examples did not include any materials translated into Spanish or languages suited to local demographics consistent with 14 CCR section 18973.3(i). This requirement remains unmet.

Disposal Facilities List

The Law requires program operators to provide descriptions of the methods used to transport and dispose of consolidated home-generated sharps waste, including information for each disposal facility pursuant to 14 CCR sections 18973.1(a) and 18973.5(d)(3). UltiMed's *Plan* listed disposal facilities and treatment facilities as separate entities.

UltiMed's January 19, 2024 *Revised 2022 Annual Report* lists Daniels Health, MedSharps, HWM, and Curtis Bay as disposal facilities while UltiMed's *Plan* lists these as treatment facilities. An explanation is not provided to describe why these facilities are listed differently in UltiMed's *Plan* and its January 19, 2024 *Revised 2022 Annual Report*.

The January 19, 2024 *Revised 2022 Annual Report* states that UltiMed only collected one mail back container in 2022, which was sent to MedSharps. This

facility is listed as a treatment facility in UltiMed's *Plan*, not as a disposal facility. However, CalRecycle staff reviewed MedSharps' website which states that they are a "... fully-licensed biohazard autoclave treatment facility ... that dispose[s] of the biohazardous waste in the proper manner according to regulations." [website: medsharps.com/about-us]. Given that the only collected container went to a treatment facility that reportedly disposes of autoclaved wastes according to regulations, we consider this requirement met.

Determination

Taking into account the foregoing, CalRecycle disapproves UltiMed's January 19, 2024 Revised 2022 Annual Report.

With regard to the unmet requirement referenced above (i.e., regarding examples of Spanish educational materials), CalRecycle will not be taking an enforcement action. CalRecycle expects that, should UltiMed become a Program Operator in the future, its education and outreach materials will comply with the requirements pursuant to PRC section 42031.6 and 14 CCR sections 18973.3(i) and 18973.5(i).

If you have questions regarding this determination, please contact Eric Yee at eric.yee@calrecycle.ca.gov or (916) 323-1934.

Regards,

Signed by: Krystal Acierto, Acting Director

Dated: April 18, 2024