#### REQUEST FOR APPROVAL

To: Rachel Machi Wagoner

Director

From: Zoe Heller

Deputy Director, Policy Development

Request Date: December 24, 2021

Decision Subject: Consideration of UltiMed's Product Stewardship Plan for Home-

Generated Sharps Waste

Action By: January 10, 2022

# **Summary of Request**

UltiMed, Inc. (UltiMed) submitted its stewardship plan for home-generated sharps waste, which includes its initial program budget, titled, *UltiMed Sharps Stewardship Plan* (Plan) to the Department of Resources Recycling and Recovery on October 11, 2021, pursuant to section 42032(a)(1) of the Public Resources Code. An addendum titled, *UltiMed Stewardship Plan – 1.4 Addendum 110421*, was submitted on November 4, 2021, as part of the Plan. This Request for Approval presents staff's analysis and compliance recommendation regarding UltiMed's Plan.

### **Staff Analysis**

## Background

Senate Bill 212 (Jackson, Chapter 1001, Statutes of 2018) established the statewide Pharmaceutical and Sharps Waste Stewardship Act (Act), requiring the first statewide stewardship program for both covered drugs and home-generated sharps waste in the country. Stewardship programs for home-generated sharps waste are primarily mailback programs where ultimate users are provided sharps waste containers and mailback materials at the point of sale. Under the Act, a program operator, which is either a covered entity or a stewardship organization established on behalf of a group of covered entities, must design and operate a statewide stewardship program for the proper collection and disposal of covered products at no cost to consumers. A covered entity can be a manufacturer, distributor, wholesaler, repackager, owner or licensee of a trademark or brand, or importer as defined in Public Resources Code (PRC) section 42030(f)(1), (see Attachment 1). Additional responsibilities of program operators include operating a comprehensive education and outreach program, submitting annual reports and annual budgets to the Department of Resources Recycling and Recovery (CalRecycle), and paying CalRecycle an administrative fee every three months that covers CalRecycle's, and any other state agency's, costs of implementation related to oversight and enforcement. Because other state agencies have authority over the covered products or the handling, transport, and/or disposal of covered products, those

state agencies, including, but not limited to the California State Board of Pharmacy and California Department of Public Health, are responsible for providing program operators compliance determinations with respect to the applicable laws and regulations they oversee prior to a program operator's submittal of its stewardship plan to CalRecycle. Additionally, annually on or before January 15, a covered entity, or a stewardship organization on behalf of a group of covered entities, must submit updated covered product lists to the California State Board of Pharmacy. For covered entities to be in compliance, a covered product sold or offered for sale in or into California must be subject to an approved stewardship plan within one year of the date of adoption of the implementing regulations (i.e., January 7, 2022). The covered entity can operate a stewardship program individually or be part of a stewardship organization with an approved stewardship plan. A program operator must fully implement the program described in that plan within 270 days of CalRecycle approval of its stewardship plan.

CalRecycle adopted regulations to approve, conditionally approve, or disapprove covered drugs and sharps stewardship plans, annual reports, and annual budgets, and provide oversight and enforcement of the Act. CalRecycle is also required to post a list of stewardship organizations and other entities that are in compliance with the Act and to coordinate with the California State Board of Pharmacy to obtain verified lists of covered products. Enforcement for non-compliance is addressed through administrative civil penalties, through revocation of an approved plan, and/or through other methods outlined in the implementing regulations.

PRC section 42032 requires that within six months of the adoption date of implementing regulations, a program operator shall submit to CalRecycle for approval a complete stewardship plan that meets the applicable requirements of PRC section 42030 *et seq.* and Title 14 of the California Code of Regulations (CCR) section 18972.1 *et seq.* (see Attachment 2), for the establishment and implementation of a stewardship program. CalRecycle's regulations became effective January 7, 2021. Therefore, stewardship plans were due to CalRecycle by July 7, 2021, unless the deadline was tolled by the California State Board of Pharmacy's review. CalRecycle has 90 days to review and approve, disapprove, or conditionally approve plans pursuant to PRC section 42032(d). CalRecycle's 90-day review period may be extended if CalRecycle needs to consult with another state agency.

UltiMed is an individual sharps manufacturer. As a manufacturer, UltiMed submitted a sharps plan for twelve products that use UltiMed's "dispense and dispose" product, which combines the distribution of sharps with an FDA-cleared disposal container. Overall, staff found that UltiMed's Plan (see Attachments 3 and 4) is substantially compliant with all material requirements in CCR sections 18973, 18973.3, and 18973.6, but additional information from and additional actions by UltiMed are necessary (see CCR section 18973.1(e)). The components of UltiMed's Plan which are deficient, and the conditions UltiMed must meet for CalRecycle to approve the Plan, pursuant to CCR section 18973.1(g), are described below.

# **UltiMed Plan Areas of Identified Deficiencies**

#### 1. Education and Outreach

Requirements: Describe a comprehensive education and outreach program that includes activities to promote program awareness, including, but not limited to, provision of educational and outreach materials for persons authorized to prescribe drugs and pharmacists. These materials include signage for hospitals and pharmacies, and materials distributed in languages suited to local demographics, pursuant to PRC section 42031.6 and CCR sections 18973.3(i)(1) and (2). Establish a website and toll-free telephone number to provide information to promote the stewardship program and that includes a mechanism to accept requests for sharps waste containers and mail-back materials pursuant to PRC section 42032.2(d)(1)(E) and CCR sections 18973.3(i)(3) and (4). The telephone number is required to provide services for hearing-impaired and speech-impaired individuals.

Result: Additional information from and additional actions by UltiMed are necessary. UltiMed must meet the conditions outlined below under the section titled "CalRecycle Condition 1."

UltiMed proposes to conduct an education and outreach program that includes online and smartphone messaging platforms, television, radio, QR codes, and provision of "customary materials" to multiple levels of distribution channels that include wholesalers, retailers, pharmacies, consumers, and other stakeholders. UltiMed's Plan proposes using marketing tactics and states its intention to promote its products and educate users on how to properly use the products. The Plan does not state that materials will be provided to persons authorized to prescribe drugs and pharmacists or describe that the materials will include signage for hospitals and pharmacies, pursuant to CCR sections 18973.3(i)(1) and (2).

UltiMed identifies the primary languages spoken in the state of California to be English and Spanish and proposes to provide materials and translate the website into English and Spanish. UltiMed also identifies "Asian languages" as the third most spoken, and states that the phone number will be able to assist in all languages, including Chinese, Tagalog, and Vietnamese. The Plan does not include provision of materials or translation of the website into any "Asian languages" despite identifying these languages as the third most spoken. UltiMed does not provide sufficient description of how it will determine that the languages used in its education and outreach program will be suited to local demographics, as opposed to the state of California demographics, or how local demographics will be analyzed to provide outreach materials in suitable languages beyond English and Spanish. In addition, UltiMed proposes a telephone number with options to hear information in English and Spanish and live telephone support for "all languages" but does not specify how the caller would understand they could request telephone support in a language other than English or Spanish.

UltiMed proposes to establish a website and toll-free telephone number to assist ultimate users and pharmacists with obtaining "product use information" and "informal training" as described on page 34. The Plan states that UltiMed "intends to" establish an accessible website. UltiMed's website's digital content and navigability must be accessible to disabled individuals and maintained to ensure all information is up to date and accurate, as required. The Plan does not provide a description that the website and toll-free telephone number will include instructions for safe handling, proper disposal, and information on available collection options. Additionally, the Plan does not explain how pharmacists will be made aware of the "product use information" available to them through the toll-free telephone number. There are inconsistencies in the phone numbers proposed in the Plan. On page 22 the toll-free telephone number is listed as 1-844-8SHARPS (1-844-874-2777), but pages 24 and 33 refer to 1-844-877-2777. Furthermore, UltiMed's Plan states that telephone access will accommodate those that are hearing-impaired but does not describe how it will provide services for hearing-impaired and speech-impaired individuals.

The Plan does not state that the website or toll-free telephone number will include a mechanism to accept requests for sharps waste containers and mail-back materials from ultimate users. UltiMed notes that its product design limits the necessity for ultimate users to request sharps containers. Although this may be true, it is unclear if an ultimate user would be able to request a sharps waste container and mail-back materials in cases such as a defective container in the UltiMed product or lost mail-back materials.

<u>CalRecycle Condition 1:</u> Pursuant to CCR section 18973.1(g), UltiMed must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- 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. (The requirements necessitating this condition appear in PRC section 42031.6(a)(1) and (2) and CCR section 18973.3(i)(1) and (2)).
- 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 (The requirements necessitating these conditions appear in CCR section 18973.3(i)(2)-(4)).
- 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 via the website; for instance, if an ultimate user misplaces or discards the mail-back materials. (The requirements necessitating this condition appear in PRC sections 42031.6(a)(3) and 42032.2(d)(1)(E) and CCR section 18973.3(i)(3)).
- 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. (The requirements necessitating this condition appear in PRC section 42032.2(d)(1)(E) and CCR section 18973.3(i)(4)).

# 2. Local Agency Requests

Requirements: Description of the process for coordinating with local agencies for the removal of home-generated sharps waste from local household hazardous waste (HHW) facilities, either by reimbursement for transportation and disposal costs or removal of the home-generated sharps waste pursuant to PRC section 42032.2(d)(1)(F)(ii) and CCR section 18973.3(g).

Result: Additional information from and additional actions by UltiMed are necessary. UltiMed must meet the conditions outlined below under the section titled "CalRecycle Condition 2."

UltiMed's Plan requires verification that an HHW facility is listed on California Department of Public Health (CDPH) and California Department of Toxic Substances Control (DTSC) websites as part of the registration process prior to the local agency receiving reimbursement. An HHW facility being listed on a website should not be a limiting factor for participation and eligibility to receive reimbursement from UltiMed or any program operator. Rather than relying on CDPH and DTSC websites, the Plan should state that UltiMed will provide reimbursement to any facility operated by a local agency that is properly authorized to accept and manage household hazardous waste.

The Plan states that UltiMed will coordinate with other sharps stewardship program operators to reimburse a local agency for disposal costs related to home-generated sharps waste and describes processes that UltiMed, and other program operators, will do in order to process local agency reimbursements. However, the Plan does not describe how UltiMed will ensure local agency requests are fulfilled if coordination does not occur. Program operators must mutually agree to specific coordination efforts; one program operator cannot dictate how coordination with others will occur. Therefore, UltiMed cannot dictate what other program operators must do in order for UltiMed to fulfill its statutory and regulatory requirements.

<u>CalRecycle Condition 2:</u> Pursuant to CCR section 18973.1(g), UltiMed must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- a. Remove reference to website listings as an eligibility criterion for HHW facilities to be eligible for reimbursement and provide reimbursement to any facility operated by a local agency that is properly authorized to accept and manage household hazardous waste. (The requirements necessitating this condition appear in PRC section 42032.2(d)(1)(F)(ii) and CCR section 18973.3(g)).
- b. Remove reliance on coordination with other program operators to fulfill local agency requests that UltiMed may receive. (The requirements necessitating this condition appear in PRC section 42032.2(d)(1)(F)(ii) and CCR section 18973.3(g)).

# 3. Ordinance Repeals

Requirements: Describe processes, logistics, and timing of implementation that will be necessary for the stewardship program to expand into jurisdictions not included in the stewardship plan in the event a jurisdiction repeals it local stewardship program ordinance pursuant to PRC section 42032.2(e) and CCR section 18973.3(h).

Result: Additional information from and additional actions by UltiMed are necessary. UltiMed must meet the condition outlined below under the section titled "CalRecycle Condition 3."

UltiMed indicates that ordinance repeals are not applicable to UltiMed's stewardship program initiatives because a mail-back solution is provided with every product, and the product will be sold throughout the state. However, regardless of whether the mail-back program is provided throughout the state with every product sold, the stewardship program encompasses more aspects than mail-back, such as local agency requests and education and outreach, that must be provided. The Plan does not explain how the requirements pursuant to PRC section 42032.2(e) and CCR section 18973.3(h) will be met.

<u>CalRecycle Condition 3:</u> Pursuant to CCR section 18973.1(g), UltiMed must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

a. Remove the statement on page 32 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. (The requirements necessitating this condition appear in PRC section 42032.2(e) and CCR section 18973.3(h)).

#### 4. Coordination Efforts

<u>Requirement:</u> Description of coordination with other program operators to avoid confusion to the public and all program participants pursuant to CCR section 18973.3(j).

Result: Additional information from and additional actions by UltiMed are necessary. UltiMed must meet the condition outlined below under the section titled "CalRecycle Condition 4."

UltiMed proposes to coordinate by aligning with "CalRecycle initiatives" but does not describe how it will coordinate with other program operators, as required. UltiMed, in order to avoid confusion to the public and all program participants, must work with other program operators to mutually agree to specific coordination efforts.

<u>CalRecycle Condition 4:</u> Pursuant to CCR section 18973.1(g), UltiMed must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

a. Propose a process to coordinate with approved program operators to avoid confusion to the public and all program participants that is not dependent upon a CalRecycle approval process. (The requirement necessitating this condition appears in CCR section 18973.3(j)).

# 5. Handling, Transportation, and Disposal System

<u>Requirements:</u> Provide a handling, transport, and disposal system, at no cost to the ultimate user, that complies with applicable state and federal laws, pursuant to PRC section 42032.2(d)(1)(D) and CCR section 18973.3(f)(2). Containers and mail-back materials shall be provided at no cost to the ultimate user, pursuant to PRC section 42032.2(d)(1)(F)(i).

Result: Additional information from and additional actions by UltiMed are necessary. UltiMed must meet the condition outlined below under the section titled "CalRecycle Condition 5."

UltiMed proposes to provide all-in-one sharps waste containers at the point of sale by selling products that dispense new sharps and have a disposal compartment for used sharps. Mail-back materials will be included in the products' original packaging. On page 8, the Plan states, "our product provides a mail-back solution with all sharps dispensed in the State of California at no additional charge to the consumer." However, on page 21 the Plan states, "mail-back materials, combined with each box of sharps, is sold at the point of sale." It is unclear if the mail-back materials are included at no cost at the point of sale of the sharps, or if they are sold at an additional cost. This information is inconsistent with what is stated on page 8 and does not comply with the requirement for sharps waste containers and mail-back materials to be provided at no cost to the ultimate user.

<u>CalRecycle Condition 5:</u> Pursuant to CCR section 18973.1(g), UltiMed must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

a. Clarify throughout the Plan that the sharps waste container and mail-back materials are provided at no cost to the ultimate user. (The requirements

necessitating this condition appear in PRC section 42032.2(d)(1)(D), 42032.2(d)(1)(F)(i), and CCR section 18973.3(f)(2)).

### 6. Metrics

Requirements: Include metrics to measure the amount of sharps waste collected by HHW facilities operated by local agencies that request reimbursement or removal for disposal of sharps waste pursuant to CCR section 18973.3(f)(8).

<u>Result:</u> Additional information from and additional actions by UltiMed are necessary. UltiMed must meet the condition outlined below under the section titled "CalRecycle Condition 6."

UltiMed addresses this requirement in three different sections of its Plan in a manner that is confusing to the reader and does not clearly demonstrate that the Plan complies with the requirement to include metrics to measure the amount of sharps waste collected by HHW facilities. First, Section 7.7 of UltiMed's Plan titled "Metrics for Measuring Sharps Waste by Household Hazardous Waste Facilities Operated by Local Agencies" does not include metrics for measuring collection of sharps waste. Section 7.7 of UltiMed's Plan directs the reader to Section 7.4 titled "Alternative Sharps Waste Collection Methods" which does not include metrics to measure the amount of sharps waste collected by HHW facilities. Section 8 titled "Local Agency Reimbursement" includes the required metrics that local agencies shall "report on the amount, by weight, of home-generated sharps waste disposed." However, the contradictory information included in Section 7.4 as referenced in Section 7.7 creates ambiguity as to whether or not UltiMed has complied with the requirement to include metrics to measure the amount of sharps waste collected by HHW facilities.

<u>CalRecycle Condition 6:</u> Pursuant to CCR section 18973.1(g), UltiMed must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

a. Clarify information in the Plan regarding the metrics that will be used to measure the amount of sharps waste collected by HHW facilities operated by local agencies that request reimbursement or removal for disposal of sharps waste. (The requirement necessitating this condition appears in CCR section 18973.3(f)(8)).

## 7. Records

Requirement: Describe how and where the records generated during the collection, transportation, and disposal of collected home-generated sharps waste will be maintained, including all required records, pursuant to CCR section 18973.3(f)(3).

Result: Additional information from and additional actions by UltiMed are necessary. UltiMed must meet the conditions outlined below under the section titled "CalRecycle Condition 7."

UltiMed proposes that "all records and associated information are collected, stored, and managed by UltiMed's sharps disposal service provider and stewardship operator" and will be maintained in "an audit ready fashion." The Plan does not include a description of how and where these records will be maintained and does not define or describe the term "audit ready fashion."

Additionally, the Plan states that "collection manifests," "mailer origination," and "final disposal documentation" records will be managed. It is unclear if receipts of returned home-generated sharps waste return mailings will be maintained pursuant to CCR section 18973.3(f)(3).

<u>CalRecycle Condition 7:</u> Pursuant to CCR section 18973.1(g), UltiMed must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following conditions:

- a. Describe how, where, and which records generated during collection, transportation, and disposal of collected home-generated sharps waste will be maintained. Clarify that receipts of returned home-generated sharps waste return mailings will be maintained. (The requirement necessitating this condition appears in CCR section 18973.3(f)(3)).
- b. Define "audit ready fashion" or describe what it means to maintain records in an "audit ready fashion." Include all required records for audit purposes. (The requirement necessitating this condition appears in CCR section 18973.3(f)(3)).

# 8. Grants, Loans, and Sponsorships

<u>Requirement:</u> Description of the process for providing grants, loans, sponsorships, reimbursements, or other incentives pursuant to CCR section 18973.3(k).

Result: Additional information from and additional actions by UltiMed are necessary. UltiMed must meet the condition outlined below under the section titled "CalRecycle Condition 8."

UltiMed's proposed budget (Section 6) includes a line item and description that sponsorships to organizations such as the American Diabetes Association are anticipated, but Section 12 of the Plan states that sponsorships are not anticipated at this time.

<u>CalRecycle Condition 8:</u> Pursuant to CCR section 18973.1(g), UltiMed must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

a. Clarify information about sponsorships and refer to that information consistently throughout the Plan; specifically, Sections 6 and 12 contain inconsistencies that must be corrected. (The requirement necessitating this condition appears in CCR section 18973.3(k)).

#### 9. Document Submittals

Requirement: A stewardship plan shall be complete and correct pursuant to CCR section 18973(d).

Result: Additional actions by UltiMed are necessary. UltiMed must meet the condition outlined below under the section titled "CalRecycle Condition 9."

Throughout the Plan, UltiMed identified potentially impacted residents or nonbusiness entities using various terms such as "UltiMed end users", "end users", "ultimate users", and "users". It is unclear whether the use these terms equate to "ultimate user" as defined in PRC 42030(z). For example, it is unclear on page 34 if the "users" that access self-paced instruction on the website are intended to be ultimate users.

Additionally, UltiMed introduces the term "stewardship operator" which is undefined in the Plan, is inconsistent with the statutory term "program operator," and is used inconsistently throughout the Plan. On page 26, UltiMed's Plan states, "...managed by UltiMed's sharps disposal service provider and stewardship operator." It is unclear if UltiMed intends its service provider to act as the program operator, which is inconsistent with PRC section 42030(q) that defines a program operator as "a covered entity, or stewardship organization on behalf of a group of covered entities, that is responsible for operating a stewardship program in accordance with this chapter." On pages 28 and 30, UltiMed's Plan states, "UltiMed, as the stewardship operator and participant..." It is unclear whether UltiMed is referring to itself as the program operator or what it means by also being a "participant."

<u>CalRecycle Condition 9:</u> Pursuant to CCR section 18973.1(g), UltiMed must revise and resubmit its Plan to CalRecycle within 90 days of signature of this Request for Approval, and the resubmitted plan must meet the following condition:

a. Use terminology defined in PRC and CCR or define and consistently utilize terminology within the Plan. (The requirement necessitating this condition appears in CCR section 18973(d)).

#### Stakeholder Feedback

CalRecycle solicited public input on UltiMed's Plan from October 11, 2021, through October 25, 2021, and received three stakeholder comment letters. CalRecycle considered all comment letters received when reviewing UltiMed's Plan for compliance. The three letters were submitted by MED-Project USA, AdvaMed and California Life Sciences, and the Los Angeles County Solid Waste Management Committee/Integrated Waste Management Task Force. Each letter poses questions and concerns about UltiMed's Plan that generally align with CalRecycle's findings regarding education and outreach, ordinance repeals, and local agency requests.

# **California Environmental Quality Act**

Staff recommend that CalRecycle file a Notice of Exemption for UltiMed's Plan with the State Clearinghouse as provided under the California Environmental Quality Act.

# **Summary of Staff Analysis**

CalRecycle staff reviewed UltiMed's Plan to determine whether all statutory and regulatory requirements were met and found the Plan to be substantially compliant. Several components of UltiMed's Plan require additional information from and additional actions by UltiMed for CalRecycle to determine if the Plan is compliant.

# **Options**

- 1. Conditionally approve UltiMed's Plan, contingent upon UltiMed providing the following to CalRecycle:
  - A letter, within 30 days of signature on this Request for Approval, committing to revise and resubmit its Plan, to meet the conditions specified in the Staff Analysis section of this Request for Approval; and
  - b. A revised plan, within 90 days of signature on this Request for Approval, that includes the additional information to meet the conditions specified in the Staff Analysis section of this Request for Approval. The revised plan shall incorporate the information provided in the addendum, submitted November 4, 2021 (see Attachment 4).
- 2. Disapprove UltiMed's Plan. UltiMed shall resubmit its revised plan within 60 days of signature on this Request for Approval and CalRecycle will review the revised plan within 90 days of resubmittal.

# **Action**

Based on UltiMed's Plan and analysis within this Request for Approval, I hereby conditionally approve UltiMed's Plan, contingent upon UltiMed (1) providing a letter, within 30 days of signature on this Request for Approval, committing to revise and resubmit its Plan to meet the conditions specified in the Staff Analysis section of this Request for Approval, and (2) revising and resubmitting its Plan within 90 days as described in the Recommendation and Staff Analysis sections above. Failure to comply with all the conditions and resubmit within 90 days may result in disapproval of UltiMed's Plan. This Request for Approval shall serve as the written notice of the conditions that CalRecycle must identify pursuant to the first sentence in CCR section 18973.1(g). CalRecycle's conditional approval constitutes an approval for purposes of PRC section 42032(g). UltiMed must fully implement its Plan, revised to comply with the conditions outlined in the Staff Analysis, within 270 days from signature of this Request for Approval, titled, Consideration of UltiMed's Product Stewardship Plan for Home-Generated Sharps Waste. Additionally, I hereby direct staff to file a Notice of Exemption with the State Clearinghouse for UltiMed's Plan as provided under the California Environmental Quality Act.

Dated: December 27, 2021

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 (<a href="https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/">https://www2.calrecycle.ca.gov/Forms/ContactUs/PublicRecordsRequest/</a>).

- Pharmaceutical and Sharps Waste Stewardship Act (Public Resources Code sections 42030 et seq) https://leginfo.legislature.ca.gov/faces/codes\_displayexpandedbranch.xhtml?toc Code=PRC&division=30.&title=&part=3.&chapter=2.&article=
- 2. Pharmaceutical and Sharps Waste Stewardship Program Regulations (California Code of Regulations sections 18972.1 et seq)
  https://govt.westlaw.com/calregs/Browse/Home/California/CaliforniaCodeofRegulations?guid=I3A11525A8CDD4A6E87920BBB389851C4&originationContext=documenttoc&transitionType=Default&contextData=(sc.Default)&bhcp=1
- UltiMed Sharps Stewardship Plan https://www2.calrecycle.ca.gov/Docs/Web/119760
- 4. <u>UltiMed Stewardship Plan 1.4 Addendum 110421</u> https://www2.calrecycle.ca.gov/Docs/Web/119877