

REQUEST FOR ACTION

To: Rachel Machi Wagoner
Director

From: Zoe Heller
Deputy Director, Division of Circular Economy

Mark de Bie
Deputy Director, Waste Permitting, Compliance, and Mitigation
Division

Request Date: January 2, 2024

Decision Subject: Consideration of The Drug Takeback Solutions Foundation's
Revised 2022 Annual Report for Covered Drugs

Action By: January 16, 2024

Summary of Request

The Drug Takeback Solutions Foundation (The Foundation) submitted its revised 2022 annual report, titled, *The Drug Takeback Solutions Foundation State of California Stewardship Plan for Covered Drugs 2022 Annual Report (Revised 2022 Annual Report)* on October 15, 2023. This Request for Action presents a summary of staff's analysis regarding The Foundation's *Revised 2022 Annual Report* and The Foundation's covered drugs stewardship program.

Background

The Foundation is a stewardship organization that, as reported in its *Revised 2022 Annual Report*, represents 85 covered entities under its approved stewardship plan for covered drugs, titled, *Stewardship Plan for Covered Drugs (Plan)*. On February 16, 2022, the Department of Resources Recycling and Recovery (CalRecycle) conditionally approved the *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). The Foundation's *Revised 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 period of one year. The Foundation submitted its 2022 annual report, titled, *The Drug Takeback Solutions Foundation State of California Stewardship Plan for Covered Drugs 2022 Annual Report (2022 Annual Report)* on March 31, 2023, which CalRecycle found incomplete on May 1, 2023, and required The Foundation to revise its 2022 annual report and resubmit to CalRecycle within 30 days. The Foundation resubmitted its *2022 Annual Report* on May 31, 2023. CalRecycle determined the *2022 Annual Report* was complete and notified The Foundation on June 22, 2023, pursuant to PRC section 42033.2(d)(1) and 14 CCR section 18973.1(b). On August 16, 2023, CalRecycle disapproved The Foundation's *2022 Annual Report* and referred The Foundation to CalRecycle's Waste Permitting,

Compliance, and Mitigation Division (WPCMD) for potential enforcement in the Request for Action (RFA), titled, *Consideration of The Drug Takeback Solutions Foundation's 2022 Annual Report for Covered Drugs (August 2023 RFA)*. On August 24, 2023, in response to the referral, WPCMD issued The Foundation a Notice of Violation (NOV). The NOV provided written notice of noncompliance and that CalRecycle may commence an enforcement action against The Foundation for continued noncompliance with the Pharmaceutical and Sharps Waste Stewardship Law. The Foundation was required to revise and resubmit its 2022 annual report to CalRecycle within 60 days 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 of the *August 2023 RFA*. On October 15, 2023, The Foundation submitted its *Revised 2022 Annual Report*, which is the subject of this RFA. CalRecycle has 90 days to approve, disapprove, or conditionally approve the *Revised 2022 Annual Report* pursuant to PRC section 42033.2(d)(4) and 14 CCR section 18973.1.

Staff Analysis

Staff evaluated The Foundation's *Revised 2022 Annual Report* to determine whether the requirements of statute, regulations, and The Foundation's *Plan* were met, as directed in "Summary 1 of Requirements Not Met" through "Summary 5 of Requirement Not Met" in the "Staff Analysis" section of the *August 2023 RFA*. The sections below present a summary of staff's analysis of The Foundation's *Revised 2022 Annual Report* and The Foundation's covered drugs stewardship program.

Additionally, this RFA provides a status of CalRecycle's enforcement action.

August 2023 RFA Summary 1 of Requirements Not Met

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to PRC section 42032.2(c) and 14 CCR section 18973.4(c)(3).

- a. Clarify whether Department of Finance's most recent publicly available population data was used to calculate whether any changes to the required number of authorized collection sites was necessary, or whether it was used to determine geographic spread within each county pursuant to 14 CCR section 18973.4(c)(3).
- b. Describe the circumstances that were beyond The Foundation's control that necessitated the use of supplemental mail-back distribution locations in counties that did not have the minimum number of authorized collection sites pursuant to PRC section 42032.2(c).
- c. Describe the efforts that were undertaken to achieve compliance with the convenience standard, including reasonable geographic spread, for the counties that have been reported in Attachment B of the *2022 Annual Report* as not meeting the convenience standard requirement pursuant to 14 CCR section 18973.4(c)(3).
- d. For the 44 counties that do not meet the convenience standards pursuant to PRC section 42032.2(a)(1)(F)(i), provide a list of the potential authorized collection sites that were considered, The Foundation's efforts to secure those locations, and the reasons those locations were not feasible as an authorized collection site pursuant to 14 CCR section 18973.4(c)(3).

Analysis: Requirements (a) and (b) Met, Requirements (c) and (d) Not Met

The Foundation's *2022 Annual Report* did not mention reviewing and using the most recent publicly available population data from the State of California Department of Finance to determine whether any changes to the required number of authorized collection sites were necessary or whether it was used to determine geographic spread within each county. In its *Revised 2022 Annual Report*, The Foundation reports that it "utilized the Department of Finance's most recent publicly available population data to calculate convenience per county and to determine if any changes to Authorized Collection Sites were necessary." The Foundation met requirement (a).

PRC section 42032.2(c) states that after a stewardship plan for covered drugs has been approved, the program operator may supplement service, *if approved by the department* (emphasis added), for a county in which it operates that does not have the minimum number of authorized collection sites *due to circumstances beyond the program operator's control* (emphasis added), by means including establishing a mail-back program. In its *2022 Annual Report*, The Foundation reported supplementing 38 counties with mail-back distribution locations that did not have the minimum number of authorized collection sites established but did not describe the circumstances beyond its control that prevented it from meeting the convenience standard outlined in PRC section 42032.2(a)(F)(i). In its *Revised 2022 Annual Report*, The Foundation describes the circumstances that were beyond its control that necessitated the use of supplemental mail-back distribution locations in 38 counties where it did not establish the minimum number of authorized collection sites. The *Revised 2022 Annual Report* states "due to the other operator's contractual relationships with three of the five largest Retail Pharmacy chains, the Foundation is contractually prohibited from approaching these chains for expansion at a site-by-site level." Other reasons The Foundation provided are that pharmacies declined to participate due to "reasons of safety and diversion, space constraints, internal take-back programs, lack of interest or response, improper licensing, no public access, fear or preference against interactions with the California Board of Pharmacy, and pharmacist responsibilities." The Foundation met requirement (b).

The Foundation's *Revised 2022 Annual Report* provides a description of the efforts conducted to meet the convenience standard in the counties in which it did not establish the minimum number of authorized collection sites. These efforts include conducting internet research and utilizing sales tools to identify potential pharmacies and law enforcement agencies. For each county that did not have the minimum number of authorized collection sites, The Foundation expanded its search to skilled nursing facilities, doctor's offices, health clinics, hospitals, home health agencies, hospice facilities, care facilities, surgery centers, outpatient facilities, behavioral health facilities, addiction rehabilitation facilities, and dental and other specialty health offices to be established as mail-back distribution locations if the facilities did not have proper licensing to serve as an authorized collection site.

As described in the *August 2023 RFA*, The Foundation did not establish enough authorized collection sites to meet the convenience standard in 44 counties. Additionally, in seven of those counties, The Foundation did not establish any

authorized collection sites or mail-back distribution locations. CalRecycle expects The Foundation to demonstrate, in subsequent annual reports, progress in establishing additional authorized collection sites in these 44 counties and a corresponding reduction in the need to use supplemental mail-back distribution locations.

The Foundation did not achieve the geographic spread goal of 90 percent of ultimate users living within 15-miles of an authorized collection site in 25 counties, as described in the *August 2023 RFA*. Fifteen counties have a geographic spread between 0 percent and 30 percent of ultimate users living within 15-miles of an authorized collection site and 10 counties have a geographic spread between 60 percent and 86 percent of ultimate users living within 15-miles of an authorized collection site. This requirement must be met on a per county basis pursuant to PRC section 42032.2(a)(1)(F). The geographic spread requirement must be met by using authorized collection sites alone and does not include mail-back distribution locations. Therefore, requirement (c) is not met. CalRecycle expects that The Foundation will continue to establish authorized collection sites in the 25 counties to achieve the geographic spread requirement on a per county basis and report its efforts to establish authorized collection sites in subsequent annual reports, pursuant to 14 CCR section 18973.4(c)(3).

The Foundation submitted Attachment A, a list of 3,695 potential authorized collection sites that were considered in the counties where The Foundation did not establish the minimum number of authorized collection sites, with its *Revised 2022 Annual Report*. However, the list did not contain potential authorized collection sites that were considered in three of the 44 counties (Contra Costa – incorporated, Modoc, and Plumas) where The Foundation did not establish the minimum number of authorized collection sites. By failing to provide the required list of the potential authorized collection sites that were considered for all 44 counties, The Foundation failed to meet this requirement. The Foundation was required to provide this information pursuant to PRC section 42033.2(b)(9). The Foundation did not meet requirement (d).

Summary 1.1 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 The Foundation's *Revised 2022 Annual Report* and require resubmittal, as indicated in the "Action" section below.

- a) Describe the efforts that were undertaken to achieve compliance with the convenience standard, including reasonable geographic spread, for the counties that have been reported in Attachment B of the *Revised 2022 Annual Report* as not meeting the convenience standard requirement pursuant to 14 CCR section 18973.4(c)(3).
- b) For the 44 counties that do not meet the convenience standards pursuant to PRC section 42032.2(a)(1)(F)(i), provide a list of the potential authorized collection sites that were considered, The Foundation's efforts to secure those locations, and the reasons those locations were not feasible as an authorized collection site pursuant to 14 CCR section 18973.4(c)(3) and PRC section 42033.2(b)(9).

August 2023 RFA Summary 2 of Requirements Not Met

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to PRC section 42033.2(b)(3), and 14 CCR sections 18973.1(a), 18973.4(c)(4), and 18973.4(c)(5).

- a. Include the amount of covered drugs collected, number of instances that collected covered drugs were picked up for disposal, and the number of receptacle liners picked up for disposal for each participating authorized collection site, pursuant to 14 CCR section 18973.4(c)(4) and PRC section 42033.2(b)(3).
- b. Clarify any discrepancies between reported metrics and the number of participating authorized collection sites pursuant to 14 CCR section 18973.1(a).
- c. Include the amount of mail-back materials distributed through the toll-free telephone number and amount of mail-back materials returned (that were distributed through the toll-free telephone number, or clarify why mail-back material metrics for the toll-free telephone number were not reported pursuant to 14 CCR section 18973.4(c)(5).
- d. Provide metrics and a description of the methodology, consistent with the approved *Plan*, The Foundation used to determine the amount of mail-back materials that were distributed and returned pursuant to 14 CCR sections 18973.4(c)(5)(C), 18973.4(c)(5)(D), and 18973.2(g)(6)(E).

Analysis: Requirements (b) and (d) Not Met, Requirements (a) and (c) Met

The Foundation's *2022 Annual Report* reported having 409 participating authorized collection sites while its *Attachment B – 2022 Collection Information* reported 1,559 liners collected, totaling 50,973.81 pounds of covered drugs collected from 371 authorized collection sites. In the *Revised 2022 Annual Report*, The Foundation again reports having 409 participating authorized collection sites while in its revised *Attachment B – 2022 Collection Information*, The Foundation reports 1,554 liners collected, totaling 50,808.31 pounds of covered drugs collected from 463 authorized collection sites. The Foundation included required metrics for the 409 authorized collection sites reported in its annual report and notes that "Attachment B: 2022 Collection Information includes all active sites and sites that were closed within the reporting period," explaining the metrics for an additional 54 authorized collection sites. The Foundation met requirement (a). However, The Foundation does not explain the discrepancies between the total number of liners and total weight of covered drugs collected reported in the *2022 Annual Report* compared to the *Revised 2022 Annual Report*. Therefore, requirement (b) is not met as The Foundation did not explain or clarify the discrepancy between reported metrics and the number of participating authorized collection sites.

The Foundation did not report mail-back material metrics for its toll-free telephone number in the *2022 Annual Report*. The Foundation's *Revised 2022 Annual Report* includes the amount of mail-back materials distributed and returned for all mechanisms of distribution, including metrics for the toll-free telephone number. The Foundation met requirement (c).

In the *2022 Annual Report*, The Foundation reported metrics of the amount of mail-back materials “distributed and returned” but did not describe its methodology used to determine the reported metrics, as described in its *Plan*. In the *Revised 2022 Annual Report*, The Foundation describes the methodology it uses to determine the metrics, stating that it “measures the quantity of Mailers by Mail-Back Distribution Site against the quantity of Mailers returned via the Mailers unique serial number and distribution location identifier,” but that the number of “Mailers” (defined in The Foundation’s *Plan* as “a generic term that refers to all prepaid, pre-addressed Standard Mail-Back Envelopes, Inhaler Mail-Back Envelopes, and Combination Product Mail-Back Packages”) distributed to ultimate users at mail-back distribution locations is unknown. The Foundation receives this data when the “Mailers” are received at destruction and states it “does not have visibility into how many Mailers are distributed to Ultimate Users at Mail-Back Distribution Locations.” However, The Foundation’s *Plan* states that the “measurement includes the type of Mailers distributed and Mailers distributed **by** (emphasis added) Mail-back distribution Site.” Because The Foundation did not provide metrics for the amount of mail-back materials distributed by mail-back distribution locations, The Foundation did not meet requirement (d). CalRecycle expects that The Foundation will collect metrics for mail-back materials distributed by mail-back distribution locations, as described in its *Plan*, and report the metrics in subsequent annual reports, pursuant to 14 CCR 18973.4(c)(5)(C).

Summary 2.1 of Requirement Not Met: The following serves as written notice of the requirement that must be met should the Director choose to conditionally approve or disapprove The Foundation’s *Revised 2022 Annual Report* and require resubmittal, as indicated in the “Action” section below.

- a) Clarify any discrepancies between reported metrics and the number of participating authorized collection sites pursuant to 14 CCR section 18973.1(a).

August 2023 RFA Summary 3 of Requirements Not Met

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR sections 18973.4(d)(1), 18973.4(d)(3)(C), and 18973.4(e)(1).

- a. Include a description in the annual report about the methods used to transport and dispose of covered drugs, including a description of the mechanism(s) to track the collection, transportation, and disposal of covered drugs pursuant to 14 CCR section 18973.4(d)(1).
- b. Explain the discrepancy between the weight of material disposed at each disposal facility and the weight collected from each authorized collection site pursuant to 14 CCR section 18973.4(d)(3)(C).
- c. Provide a description of whether policies and procedures, including monitoring activities, as established in the *Plan*, were followed during the reporting period pursuant to 14 CCR section 18973.4(e)(1).

Analysis: Requirements (a), (b), and (c) Met

The *2022 Annual Report* lacked a description of The Foundation's tracking mechanisms for covered drugs collected through its program. The *Revised 2022 Annual Report* includes a description of how The Foundation tracks the collection of covered drugs at each authorized collection site using "Serialization Tracking Forms" for each "Container" and "Inner Liner." The Foundation also tracks "Mailers" containing covered drugs from initial shipment through destruction. Page 14 of The Foundation's *Revised 2022 Annual Report* provides a list of elements tracked for each "Collection Receptacle Collection Kit" and "Mailer." Therefore, The Foundation met requirement (a).

The Foundation reported a consistent total weight of 51,615.30 pounds in its *Revised 2022 Annual Report*, including *Attachment B – 2022 Collection Information* and *Attachment D – Weights by Disposal Facility*. Therefore, The Foundation met requirement (b). See the "Additional Requirements Not Met" section below for analysis of the weights provided in the *2022 Annual Report* and the *Revised 2022 Annual Report*.

The *Revised 2022 Annual Report* contains a description of the policies and procedures followed during the reporting period, including activities where The Foundation performed audits of authorized collection sites and reviewed tracking and reporting documentation. Therefore, The Foundation met requirement (c).

August 2023 RFA Summary 4 of Requirements Not Met

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR sections 18973.4(j)(1), 18973.4(j)(3), and 18973.4(d)(3):

- a. Include all mailing and physical addresses associated with each covered entity pursuant to 14 CCR section 18973.4(j)(1).
- b. Include all mailing and physical addresses associated with each authorized collector pursuant to 14 CCR section 18973.4(j)(3).
- c. Include all mailing and physical addresses associated with each disposal facility pursuant to 14 CCR section 18973.4(d)(3).

Analysis: Requirements (a), (b), and (c) Met

The Foundation's *Revised 2022 Annual Report* includes *Attachment E – Covered Entities and Product List*, *Attachment B – 2022 Collection Information*, and *Attachment D – Weights by Disposal Facility (3)*, which specify that mailing and physical addresses for covered entities, authorized collectors, and disposal facilities are the same, unless otherwise indicated. Therefore, The Foundation met requirements (a) through (c).

August 2023 RFA Summary 5 of Requirements Not Met

Requirements: CalRecycle required the *Revised 2022 Annual Report* to meet the following requirements pursuant to 14 CCR sections 18973(d) and 18973.4(b):

- a. Utilize correct and consistent terminology, dates, and formatting within the annual report pursuant to 14 CCR section 18973(d).

- b. Include a concise summary of the information included in the report, including challenges, ways in which challenges are being addressed, and education and outreach efforts pursuant to 14 CCR section 18973.4(b).

Analysis: Requirement (a) Not Met, Requirement (b) Met

The Foundation's *Revised 2022 Annual Report* includes a reporting period for the entire 2022 calendar year (January 1, 2022, through December 31, 2022). The reporting period is consistent with statute and regulations.

The *Revised 2022 Annual Report* includes correct page numbers.

The Foundation's *2022 Annual Report* discussed the process for conducting good faith negotiations with potential authorized collectors and stated The Foundation "proceeds with an agreement to establish the Pharmacy as an Authorized Collector." The *August 2023 RFA* noted that a pharmacy is not the only type of location that may serve as an authorized collector. The Foundation's *Revised 2022 Annual Report* replaced "Pharmacy" with "Authorized Collector" to correct this error.

However, page 4 of the *Revised 2022 Annual Report* states that the "Plan became fully operational on November 13, 2023," making it unclear when The Foundation's program was fully implemented. Therefore, The Foundation did not meet requirement (a).

The Foundation's *2022 Annual Report* did not include a summary of the challenges, ways in which challenges are being addressed, or education and outreach efforts, as required. The Foundation's *Revised 2022 Annual Report* includes additional information regarding its lack of ability to place collection receptacles and how it is addressing the challenge by supplementing with mail-back distribution locations. The *Revised 2022 Annual Report* also describes The Foundation's education and outreach efforts to authorized collection sites and mail-back distribution locations by providing education and outreach materials and initiating social media posts. Therefore, The Foundation met requirement (b).

Summary 3.1 of Requirement Not Met: The following serves as written notice of the requirement that must be met should the Director choose to conditionally approve or disapprove The Foundation's *Revised 2022 Annual Report* and require resubmittal, as indicated in the "Action" section below.

- a) Utilize correct and consistent terminology, dates, and formatting within the annual report pursuant to 14 CCR section 18973(d).

Additional Requirements Not Met

In addition to the above analysis and evaluation of the "Summary 1 of Requirements Not Met" through "Summary 5 of Requirements Not Met" in the "Staff Analysis" section of the *August 2023 RFA*, staff identified new instances of requirements not met that were not present in The Foundation's *2022 Annual Report*.

Requirements: Include a list of distribution locations for each type of mail-back service utilized pursuant to 18973.4(c)(5)(A).

The annual report shall be complete and correct pursuant to 14 CCR section 18973(d). Implement a comprehensive education and outreach program pursuant to PRC section 42031.6 and 14 CCR section 18973.2(j). A program operator shall not promote the disposal of a covered product in a manner inconsistent with the services offered to ultimate users by the stewardship program pursuant to PRC section 42031.6(b) and 14 CCR section 18973.2(j)(7).

Analysis: Requirements Not Met

A list of mail-back distribution locations was included in The Foundation's *2022 Annual Report* in *Attachment B – Collection Information*. However, The Foundation's *Revised 2022 Annual Report* does not include the required list of mail-back distribution locations.

Additionally, The Foundation included certification statements signed by Chris Smith in its *2022 Annual Report* and *Revised 2022 Annual Report* that declare the information provided in each document is "true and correct." However, there are several instances where CalRecycle identified unmet requirements and The Foundation adjusted the narrative and information in its *Revised 2022 Annual Report* from what was initially provided in its *2022 Annual Report*. The two annual report submissions contradict one another and make it impossible for all information in both annual reports to be true and correct. Thus, The Foundation's annual reports were not correct, and The Foundation failed to meet the requirement in 14 CCR section 18973(d). Moreover, The Foundation has falsely certified, in at least one of the annual reports, that all information provided in each annual report was true and correct, per 14 CCR section 18973(e). Examples include the following:

- The Foundation's *2022 Annual Report* included four disposal facilities with a total weight of 21,788.25 pounds of covered drugs. However, *Attachment D – Weights by Disposal Facility (3)* in the *Revised 2022 Annual Report* includes two disposal facilities with a combined total weight of 51,615.30 pounds of covered drugs disposed.
- The Foundation's *2022 Annual Report* included a list of 78 covered entities. However, its *Revised 2022 Annual Report* includes a list of 85 covered entities. It is unclear how many covered entities were participating in The Foundation's *Plan* during the 2022 calendar year.
- The Foundation's *2022 Annual Report* included example education and outreach materials (PDF pages 17 to 18) that appeared to promote "local take-back events" as a disposal option for covered drugs. The Foundation did not report hosting any collection events and The Foundation's *Plan* does not identify any proposed alternative forms of collection pursuant to 14 CCR section 18973.2(g)(6). Therefore, it appears The Foundation promoted the disposal of covered products inconsistent with the services offered to ultimate users by the stewardship program. The Foundation edited its educational brochure (pages 24 to 25) to remove reference to "local take-back events" in its *Revised 2022 Annual Report*. One of the annual reports is not "true and

correct.” It is unclear which version of the educational brochure was utilized and if “local take-back events” were advertised to ultimate users in 2022.

- Education and outreach materials in the *2022 Annual Report* (PDF pages 17 to 18) included the disclaimer, “This material has been provided for the purpose of compliance with legislation and does not necessarily reflect the views of Inmar Intelligence or the Producers participating in the Inmar Intelligence (Source: U.S. Food and Drug Administration) Product Stewardship Plan.” CalRecycle noted in the *August 2023 RFA* that education and outreach materials must provide information about the program that is consistent with statute and regulations and with the services offered to ultimate users by the stewardship program and that The Foundation does not describe what “views” it intends to communicate nor why the disclaimer is necessary. This disclaimer was removed from the example education and outreach materials in The Foundation’s *Revised 2022 Annual Report* submission (pages 24 to 25). One of the annual reports is not “true and correct,” and it is unclear if the disclaimer was included in The Foundation’s 2022 education and outreach materials.

As noted in the *August 2023 RFA*, education and outreach materials must be consistent with requirements in statute, regulations, and The Foundation’s *Plan*.

CalRecycle may conduct its own audit of The Foundation, including a review of the independent certified public accountant audit for compliance with statute and regulations and consistency with the program operator’s stewardship plan, annual report, and annual program budget pursuant to PRC section 42033.4(b)(3).

Summary 4.1 of Requirement Not Met: The following serves as written notice of the requirement that must be met should the Director choose to conditionally approve or disapprove The Foundation’s *Revised 2022 Annual Report* and require resubmittal, as indicated in the “Action” section below.

- a) Include the required list of mail-back distribution locations pursuant to 14 CCR section 18973.4(c)(5)(A).

Status of CalRecycle Enforcement

An August 24, 2023, NOV was issued to The Foundation for violating the requirements of the Pharmaceutical and Sharps Waste Stewardship Law because The Foundation submitted a non-compliant *2022 Annual Report* for Covered Drugs pursuant to PRC section 42033.2(b) and 14 CCR section 18973.4. The NOV identified violations resulting from failure to comply with the following requirements:

1. Providing a collection system that complies with the convenience standards for authorized collection sites in each county in which the plan is implemented (PRC section 42032.2(a)(1)(F) and 14 CCR sections 18973.2(g)(2) and 18973.4(c)(3)).
2. Implementing a comprehensive education and outreach program (PRC section 42031.6 and 14 CCR section 18973.2(i)).
3. Fully implementing operation of an approved stewardship program no later than 270 days after approval by CalRecycle of the stewardship plan that establishes

the stewardship program (PRC section 42032(g) and 14 CCR section 18973.1(m)).

The *Revised 2022 Annual Report* did not provide information or supporting documentation correcting the violations outlined in CalRecycle's August 24, 2023, NOV by the required date of October 15, 2023. CalRecycle's enforcement staff are assessing next steps to address the compliance issues.

Feedback from Interested Parties

CalRecycle solicited public input on The Foundation's *2022 Annual Report* from October 17, 2023, through October 30, 2023, and received a comment letter from MED-Project USA. CalRecycle considered this comment letter when reviewing The Foundation's *Revised 2022 Annual Report*.

Action

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

- Approve The Foundation's *Revised 2022 Annual Report*.
- Conditionally approve The Foundation's *Revised 2022 Annual Report*. Pursuant to 14 CCR section 18973.1(j), The Foundation 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 1.1 of Requirements Not Met" through "Summary 4.1 of Requirement Not Met" in the "Staff Analysis" section above.
- Disapprove The Foundation's *Revised 2022 Annual Report* and:
 - Refer The Foundation to CalRecycle's Waste Permitting, Compliance, and Mitigation Division for potential enforcement.
 - Require The Foundation 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 1.1 of Requirements Not Met" through "Summary 4.1 of Requirement Not Met" in the "Staff Analysis" section above, pursuant to 14 CCR section 18973.1(k).
 - Do not require The Foundation to revise and resubmit a 2022 annual report because (1) The Foundation has not demonstrated consistent forward progress toward meeting annual reporting requirements and (2) The Foundation was referred to CalRecycle's Waste Permitting, Compliance, and Mitigation Division for potential enforcement on August 16, 2023.

Signed by: Rachel Machi Wagoner, Director

Dated: January 8, 2024

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

1. [*The Drug Takeback Solutions Foundation State of California Covered Drugs 2022 Annual Report*](#) (October 15, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125826>
 - a. [*Attachment A – Potential Authorized Collectors Notified*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/125829>
 - b. [*Attachment C – Service Providers*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/125832>
 - c. [*Attachment D – Weights by Disposal Facility \(3\)*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/125835>
 - d. [*Attachment E – Covered Entities and Product List*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/125838>
2. [*The Drug Takeback Solutions Foundation State of California Covered Drugs 2022 Annual Report*](#) (May 31, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/123732>
 - a. [*Attachment A – Potential Authorized Collectors Notified*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/123717>
 - b. [*Attachment B – 2022 Collector Information*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/123720>
 - c. [*Attachment C – Service Providers*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/123723>
 - d. [*Attachment D – Weights by Disposal Facility*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/123726>
 - e. [*Attachment E – Covered Entities and Product List*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/123729>
3. [*Stewardship Plan for Covered Drugs*](#) (October 15, 2022)
<https://www2.calrecycle.ca.gov/Docs/Web/122409>
 - a. [*Appendix A – Program Budget*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122424>
 - b. [*Appendix B – Participating Covered Entities*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122427>
 - c. [*Appendix C – Participating Authorized Collectors*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122430>
 - d. [*Appendix D – Service Providers*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122433>
 - e. [*Appendix E – Drugs Sold or Offered for Sale in California by Participating Covered Entities*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122436>
 - f. [*Appendix F – Contacted Potential Authorized Collectors*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122439>
 - g. [*Appendix G – Participating Mail-Back Distribution Locations*](#)
<https://www2.calrecycle.ca.gov/Docs/Web/122442>
4. [*Consideration of The Drug Takeback Solutions Foundation’s 2022 Annual Report for Covered Drugs*](#) (August 16, 2023)
<https://www2.calrecycle.ca.gov/Docs/Web/125109>