

Alameda County Safe Drug Disposal Regulation Annual Report

Plan Owner:	Exelixis, Inc.
Submitted By:	Donald Campodonico, Plan Liaison
Original Plan Approval Date:	25-February-2015
Annual Report Due Date:	On or Before 25-February 2016

Part I: Report Narrative

I. Executive Summary

Exelixis, Inc., (“Exelixis”), a low volume Producer of our lone commercial product, Cometriq®, within the county of Alameda, received approval of our Plan on February 25, 2015 (see “Notice of Determination After Public Hearing” attached as Appendix A). Exelixis’ Plan within Alameda County does not require formation of individual physical Collection Points, or other collection requirements under the Ordinance, other than our developed mail-back program for the arrangement and safe disposal of Unwanted Product. Additionally, Exelixis’ Plan does not require oversight or reporting on other metrics under the Ordinance, such as, goals, broader outreach activities, and other stated take-back measures that do not apply to our mail-back Plan under the Ordinance. Therefore, certain required Annual Report information or data will be marked as “not applicable” in Exelixis’ Annual Report.

As indicated in our Plan, Exelixis provides information on the safe disposal of Unwanted Products sold into Alameda County on our website, and any patients within Alameda County purchasing our Product receive a copy of our mail-back flyer that provides our patients with instructions related to Exelixis’ mail-back option, as well as free drop off locations available within Alameda County.

To date, Exelixis’ proposes no new collection efforts for our product sold into Alameda County and Exelixis also notes that we have not encountered any challenges or difficulties related to our mail-back program as of the submission date of our report.

II. Reporting on Goals

For the past year, the goals for Exelixis’ Plan were to implement the mail-back instructions on our product’s website, implement the specific changes to our flyer requested by Alameda County, include information on drop off locations within Alameda County on our website and on the flyer that Exelixis’ specialty pharmacy provides to its patients when Product is shipped to a patient living within Alameda County. For the past year, since the Plan was implemented, the stated goals were met and achieved.

III. Future Goals

Currently, Exelixis does not have any future goals for our Plan within Alameda County. Exelixis will continue to operate our mail-back program with the same oversight and requirements as in the past year. This aspect of the report is therefore deemed, not applicable.

IV. Collection Practices

Due to the low volume of product distributed within Alameda County, Exelixis’ Plan is strictly a mail-back program operated in concert with our specialty pharmacy and third party logistic company within our supply chain. Upon receipt of a prescription for a patient within Alameda

County, the patient receives our product, and a copy of Exelixis' mail-back flyer that provides the patient with an 800 phone number in the event the patient wishes to have any Unwanted Product safely reclaimed and disposed.

After calling the 800 number, the patient informs the representative that he or she would like to return the unused or expired product in his or her possession. The representative generates a pre-paid, self-addressed package that is sent to the patient, and the patient may then place the unused or expired product, inside the pre-paid self-addressed package, seal the package, and drop it off at the near mail carrier's site.

Additionally, the flyer provided to the patient, as well as the mail-back information located on our product's website, includes information instructing patients where they can obtain additional information on the safe disposal of their medicines, as well as information for drop-off locations operating in Alameda County.

V. Educational Efforts and Public Outreach Activities

Exelixis, by way of our website (and through our specialty pharmacy, as specifically instructed by Exelixis, and on Exelixis' behalf) provides information (an example is attached to this report as Appendix B) with every shipment of drug that is sent to any patient located within Alameda County, and includes the following information:

- A reference to the Ordinance
- Notice of Exelixis' intent to comply with the Ordinance
- Information regarding the safe disposal of Cometriq®
- An overview of the return process of Cometriq® and what to expect
- A toll free number for questions concerning Cometriq® disposal
- Links to websites where patients can obtain additional information
- Information for drop-off locations operating in Alameda County

The educational materials will be in English, but Exelixis has consultants available to provide translated versions of the educational materials to patients in their native language as needed, including the toll free number provided.

VI. Safety and Security Report

In accordance with Section 15(C)(vi), please see Appendix C attached to this report.

Part II: Report Data

I. Producers Participating in the Plan

Exelixis, Inc.
210 East Grand Avenue
South San Francisco, CA 94080

II. Collection Point Information

Under our approved Plan, Exelixis is not required, and does not operate any Collection Point locations. The data requested under this section of the Annual Report is not applicable.

III. Mail-Back Program Information

In the past year, under our Plan, Exelixis provided zero (0) mail-back containers to our patients within Alameda County under our approved Plan. Since no patients within Alameda County utilized the mail-back disposal option under our approved Plan, our third party logistics company and the third party destruction facility our third party logistics company utilizes, processed zero (0) mail-back containers for destruction. The Collected Unwanted Products by weight for the past year totaled 0.0lbs or 0.0kgs.

IV. Disposal Facility Information

Our third party logistics vendor utilizes the services of Stericycle for its destruction of materials. Stericycle's destruction and certificate site is located at:

Stericycle Environmental Solutions – Destruction Certificate Contact
2120 Southwest Blvd
Tulsa, OK 74107

Total weight of Collected Product disposed of at ICS/Stericycle under our Plan: 0.0lbs or 0.0kgs.

Appendix A

Copy of Exelixis' Notice of Determination After Public Hearing



Arlu Levi, Director of Environmental Health
Phone: 510.567.6777 Fax: 510.337.9135

NOTICE OF DETERMINATION AFTER PUBLIC HEARING

**Product Stewardship Plan Review
Alameda County Safe Drug Disposal Ordinance**

PLAN OWNER: Exelixis, Inc.
210 East Grand Avenue
South San Francisco, CA 94080

PLAN LIAISON: Jeffrey Hessekiel & Donald Campodonico

PLAN DESCRIPTION: A Product Stewardship Plan proposed and operated individually by Exelixis for the collection and disposal of their one Covered Drug, *Cometriq*.

HEARING DATE: February 23, 2015

DETERMINATION:

The Exelixis, Inc. revised Stewardship Plan dated 1-30-2015, as updated 2-2-2015, is approved.

The Plan approval date is February 25, 2015.

The first Annual Report is due on or before: February 25, 2016

Signed: 
Arlu Levi, Director
Alameda County, Department of Environmental Health
Health Care Services Agency

Date: FEB 25, 2015

Appendix B

Exelixis' Safe Drug Disposal Program Flyer

The Alameda County Board of Supervisors unanimously passed an ordinance in July 2012 requiring pharmaceutical producers that sell, offer for sale, or distribute certain prescription drugs covered by the ordinance to patients who reside in Alameda County to develop and implement a process for the safe collection and disposal of any "Unwanted Products" from such residential prescription drug patients within Alameda County.

As the producer of Cometriq®, if you are in possession of Cometriq® that is either expired, or will not be used, please follow the following steps:

1. Call our specialty pharmacy, Diplomat, at the following toll free number:

1-855-253-EASE (1-855-253-3273)

2. Inform the representative that you would like to return your unused or expired Cometriq®
3. The representative will send you a pre-paid self-addressed package
4. Simply place the unused or expired Cometriq® in its original packaging inside the pre-paid self-addressed package, seal the package, and drop it off at the near mail carrier's site

Call: 1-855-253-EASE (1-855-253-3273) for Safe Disposal

Additional information on safe disposal of Cometriq® is also available at:

www.cometriq.com

There are also fixed locations currently operating in Alameda County where residents can drop-off their unwanted prescription drugs. You can find a local drop off location within Alameda County by visiting the following websites:

http://www.acgov.org/aceh/safedisposal/documents/Rx_drop-off_site_map.pdf
http://www.acgov.org/aceh/safedisposal/documents/Rx_drop-off_site_list.pdf

At Exelixis, we recognize the importance of safe drug disposal, and our responsibility to do our part in providing a way of disposing of unused or expired medications in an environmentally sound way.

Appendix C

Safety and Security Report

Exelixis had no known security or safety incidents during the past year of the collection of our product and no known legal proceedings arising from any such incident.