

EXELIXIS, INC. SAFE DRUG DISPOSAL PROGRAM PLAN (the "Program")

Provided in accordance with Alameda County Ordinance Number: O-2012-27

Submission Date of the Program: 30 January 2015

Producer: Exelixis, Inc. ("Exelixis")

Recipient: Scott Seery, Alameda County Department of Environmental Health

Submittal: Acceptable and approved by Exelixis for use as a public document

I. ACKNOWLEDGMENT

In order to comply with the Alameda County Safe Drug Disposal Ordinance and Regulations (the "Ordinance"), which requires Producers (as the term is defined in the Ordinance) to submit a plan outlining our Program for the safe collection and disposal of Unwanted Product(s) from residential prescription drug consumers within Alameda County, Exelixis respectfully submits the following Program to the Alameda County Department of Environmental Health for consideration and approval.

II. SPECIAL CONSIDERATIONS

Exelixis is a small biotech company located in South San Francisco, California, and in November 2012, Exelixis received Orphan drug approval from the FDA for its first commercial product, Cometriq[®], which is indicated for the treatment of patients with progressive, metastatic medullary thyroid cancer ("MTC"). Cometriq[®] represents the only commercial drug that Exelixis distributes in the United States, and due to the approved indication of Cometriq[®], Exelixis has very limited distribution of Cometriq[®] both within the entire United States, and more specifically, Alameda County for the following reasons:

- As stated above, Cometriq[®], is only indicated for the treatment of patients with MTC, which has a very small patient population of approximately 500 patients within the United States annually;
- As of the beginning of 2015, Exelixis has one (1) patient actively receiving Cometriq[®] within Alameda County;
- Cometriq[®] is not available for purchase through any distributor operating within Alameda County;
- Cometriq[®] is only available by shipment through our exclusive specialty pharmacy, Diplomat Specialty Pharmacy ("Diplomat"), and Diplomat does not operate any facilities or sites with a physical location within Alameda County;
- Cometriq[®] is a capsule formulation that is provided in cartons and dispensed by prescription only, and shipped directly to the patient, or to a physician after a physician sends a prescription directly to Diplomat; and
- Diplomat specializes in hands on support to patients, which will enable Exelixis to easily track and monitor Cometriq[®] use and provide direct disposal solutions to patients.

For the reasons above, Exelixis respectfully requests that we receive consideration under the Ordinance as a unique, low volume Producer, and that we are able to submit a Program that coincides with our limited volume. Specifically, we respectfully request that the review and oversight of our Program take into account that our current Alameda County patient population – currently one (1) – be considered in assessing any fees, setting goals, and allowing a mail-back process as our main destruction vehicle for patients seeking to dispose of Unwanted Product(s).

III. GENERAL INFORMATION

a. Contact Information

Table 1

Producer	Plan Owner	Plan Liaison
Exelixis, Inc. 210 East Grand Avenue South San Francisco, CA 94080 Main: 650-837-7000	Exelixis, Inc. Attn: Jeffrey Hessekiel & Donald Campodonico 210 East Grand Avenue South San Francisco, CA 94080 Jeffrey Hessekiel jhesseki@exelixis.com 650-837-8174 Donald Campodonico dcampodo@exelixis.com 650-837-8022	Exelixis, Inc. Attn: Jeffrey Hessekiel & Donald Campodonico 210 East Grand Avenue South San Francisco, CA 94080 Jeffrey Hessekiel jhesseki@exelixis.com 650-837-8174 Donald Campodonico dcampodo@exelixis.com 650-837-8022

Producer Website: <http://www.exelixis.com> & <http://www.cometriq.com>

b. Plan Liaison Stipulation

In accordance with Section 7(A)(i)(b) ("Plan Content"), Exelixis stipulates that the Plan Liaisons listed in Table 1 above, are familiar with the Program, our commercial drug, Cometriq®, and that the Plan Liaisons have the authority to make binding representations and determinations related to the Program.

IV. COLLECTION MEASUREMENT GOALS

a. 100% Collection Goal

Exelixis expects to be able to track and dispose of 100% of Unwanted Product that will be delivered to Alameda County patients.

As noted in Section II above, our drug is indicated for a very small market, and we anticipate that our sales volume in Alameda County will remain low (currently one (1) active patient, with the possibility that at any time, the County could have zero active patients receiving Cometriq®). Because of our specialty pharmacy distribution model through one distributor located outside Alameda County, Diplomat, we do not anticipate high level exposure or sales. Accordingly, we will be able to closely track usage, and ensure drugs can be returned and disposed of in accordance with the Ordinance as further described below.

In addition, and in accordance with the Ordinance, Exelixis stipulates that in the event, through our mail-back disposal program, other Unwanted Product(s) that were not produced by Exelixis, are sent for destruction by our patients, Exelixis will accept and properly dispose of those Unwanted Product(s).

V. IMPLEMENTATION DESCRIPTION

The Program will be implemented within sixty (60) days from the date of approval by the County. Due to the nature of our drug distribution (shipment only) and the limited volume of our drug currently reaching patients within Alameda County (currently one (1) patient), we will not need any individual physical Collection Points, as we will implement and develop a mail-back program and arrange for disposal and destruction of any Unwanted Product.

While our main and preferred method of handling and disposing of Unwanted Product will be through our mail-back program, Exelixis will also make available information advising patients of various locations of local drop-off sites that currently operate within Alameda County as identified via the Alameda County website:

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

VI. COLLECTION COMPONENTS

Our collection Program is made up of the following components:

- Due to the unique and limited nature of our distribution, we will be able to communicate directly with the patient, and/or the patient's physician regarding the specifics of our Program.
- We (in concert with Diplomat) will track each patient, and communicate with the patient, and if necessary, the patient's physician, each time Cometriq® is shipped to a patient within Alameda County.
- Exelixis (or Diplomat on Exelixis' behalf) will notify the prescribing physician to communicate to Diplomat if the patient is taken off of treatment prior to completing the shipped drug regimen.
- If the patient discontinues the therapy, the patient will be able to utilize our mail-back process to return any remaining Unwanted Product (i.e., Cometriq®).
- Exelixis (or Diplomat on Exelixis' behalf) will provide a pre-paid self-addressed package for returning the Unwanted Product (i.e., Cometriq®) directly to our third-party logistics provider, Integrated Commercialization Solutions, Inc. ("ICS") for destruction.
- ICS, a California corporation, operates a site in Kentucky, and upon receipt of the Unwanted Products at the ICS site in Kentucky, ICS will document the receipt in their systems in accordance with our quality agreement and ship the product to their preferred, fully licensed 3rd party subcontractor, for destruction.
- Destruction of the Unwanted Product will be performed by incineration and a certificate of destruction will be provided to Exelixis confirming the disposal of the Unwanted Product(s).

VII. TRANSPORTER INFORMATION

As mentioned above, our primary disposal process will be handled through a mail-back program. We will utilize a well-known service such as Federal Express, United Parcel Service, or the United States Postal Service to ensure maximum convenience for the patient.

VIII. AGENT(S) FOR ARRANGING DISPOSAL AND DESTRUCTION

Diplomat	ICS
Diplomat Specialty Pharmacy – Corporate HQ 4100 S. Saginaw Street Flint, MI 48507 http://www.diplomat.is	ICS Corporate Office 3101 Gaylord Parkway Frisco, TX 75034 http://www.icsconnect.com/ ICS Distribution Center 420 International Blvd - #500 Brooks, KY 40109

All destruction will take place at the following licensed 3rd party destruction facility through ICS, and take place outside of California:

3rd Party Destruction Site Used by ICS
Stericycle Environmental Solutions – Corporate HQ 28161 N. Keith Drive Lake Forest, IL 60045 Stericycle Environmental Solutions – Destruction Certificate Contact 2120 Southwest Blvd Tulsa, OK 74107

IX. OUTREACH AND EDUCATIONAL MATERIALS

Exelixis (by way of Diplomat as specifically instructed by Exelixis, and on Exelixis' behalf) will provide information on standard 8.5" x 11" paper (an example is attached hereto as Appendix A) with every shipment of drug that is sent to any patient located within Alameda County, and will include 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.

APPENDIX A*

Sample – 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.

* Revised Flyer – replaces Appendix A from the original Exelixis submission on 30-Jan-2015 per S. Seery’s email to Exelixis on 02 Feb 2015.