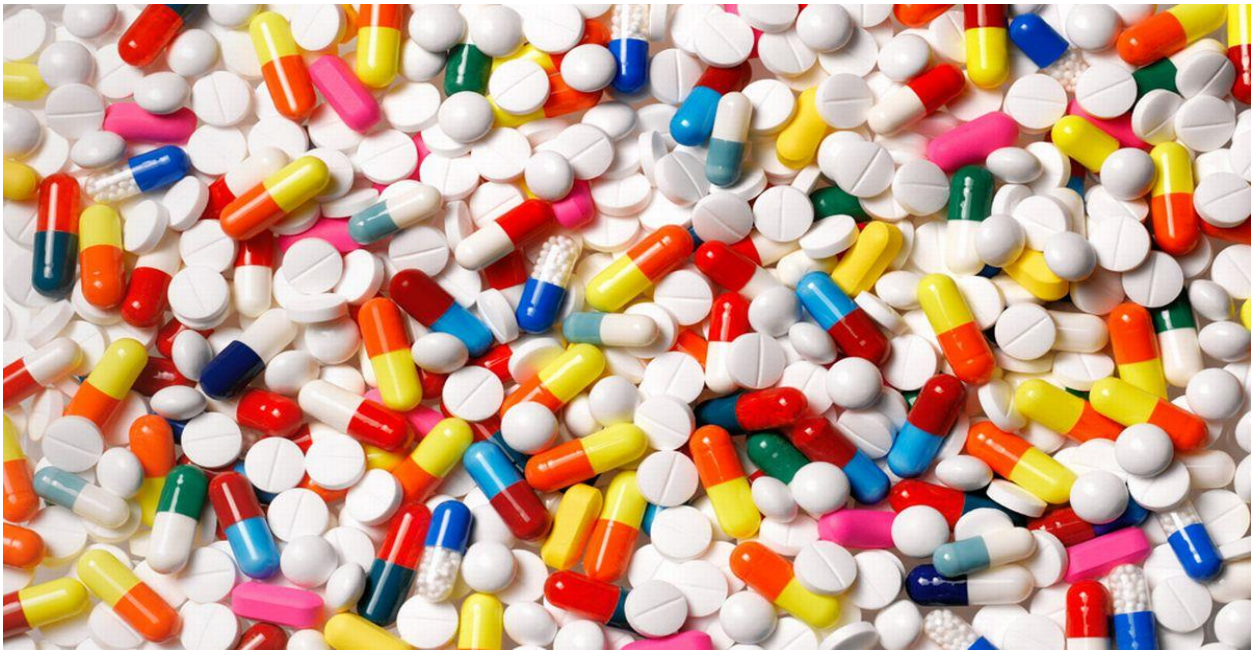

ScieGen Pharmaceuticals Stewardship Plan

To be Submitted by:
ScieGen Pharmaceuticals Inc.
89 Arkay Drive, Hauppauge NY 11788-3727

To be Submitted to:
Maine Department of Environmental Protection
17 State House Station
Augusta, ME 04333-0007

Rev: 03/2022

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Perjury Statement

ScieGen Pharmaceuticals Inc., is privileged to submit our stewardship plan to the State of Maine for review and approval. This stewardship plan has been organized, generated and developed with our highest level of integrity. As such, we affirm that this stewardship plan, including initial program budget, is complete and true to the best of our knowledge. We provide the following perjury statement to affirm this declaration.

Perjury Statement and Signature

I, Dr. Pailla Malla Reddy CEO and President of ScieGen Pharmaceuticals Inc., hereby declare, under penalty of perjury, that the information provided in this document is true and correct, to the best of my knowledge.

Dr. Pailla Malla REDDY

President and CEO

ScieGen Pharmaceuticals Inc.

Acknowledgements

ScieGen Pharmaceuticals Inc. wishes to thank the top management team and its employees for their contributions, feedback, and assistance during the development of the ScieGen Pharmaceuticals stewardship plan.

Dr. Pailla Malla Reddy	**Chief Executive Officer / President**
Mr. Siva Reddy PV	**Chief Operating Officer**
Dr. Raghu Ram Pannala	**Senior Vice President**
Mr. Brett Barczak	**Senior Vice President**
Mr. Saketh Pailla Reddy	**Director**
Mr. Balamurali Nagisetti	**Director**
Mr. Pashupathinath Siddamshetty	**Senior Manager**

Plan Submittal Executive Summary

State of Maine is missioned to solve complex issues surrounding the safe and secure management and disposal of unwanted pharmaceutical drugs within the state. Not only does the State aim solve inherent issues with the unwanted pharmaceutical drugs, it strives to perform mission endeavors at a high standard using effective and advanced means that build on an environmentally sound infrastructure. Vendors and manufacturers working in step with the State's mission must also meet the requirements by offering solutions that dovetail with current and in place requirements.

ScieGen Pharmaceuticals Inc. is an established manufacturer of pharmaceutical finished formulations (Capsules and Tablets) for the prescription retail market. In addition to being a manufacturer for over 12 years, the company is a longtime proponent of pharmaceutical waste disposal. From the beginning quality rejected raw material, In-process material, and finished formulations including controlled substances are disposed in a law abiding manner utilizing existing infrastructure. ScieGen Pharmaceuticals Inc. recognized early on that there was an unmet challenge with the disposal of unwanted pharmaceutical finished formulations that are left in home medicine cabinets due to patient non-compliance, product shelf-life or other reasons.

The organization and industry have progressed through education and legislation, and ScieGen Pharmaceuticals Inc. continues to educate its customers on the benefits it offers as the market leader in providing pharmaceutical finished product lifecycle management solutions.

More recently, increased legislative initiatives that support the company's long-standing leadership in pharmaceutical waste management have been enacted. These recent changes prompted ScieGen Pharmaceuticals Inc., to create a single, fully compliant mail back program that is comprehensive and yet a simple solution. Our stewardship plan comply with legislative directives.

As required, we have submitted our stewardship plan and developed a fully compliant all-in-one mail back solution that complies with every aspect of our responsibilities required by the law. Our stewardship plan provides a mail-back solution at no additional cost to the consumer. Our solution is not only effective but economical. In addition to our stewardship plan, we have put in place processes to manage the efficacy of the solution and outlined the oversight and management of the process.

We appreciate involved stakeholders efforts to include manufacturers, legislators, distributors, retailers and end user patients. We look forward to our pharmaceutical product lifecycle leadership in this area and anticipate a continued shift that will enable the industry to better manage the safe disposal of unwanted finished pharmaceutical formulations. ScieGen Pharmaceuticals Inc. will continue to be a leader in finished pharmaceutical formulations lifecycle management and hope that others will do their part in minimizing the negative impacts of improper disposal in the United States.

Best Regards,

Dr. Pailla Malla REDDY

President and CEO

ScieGen Pharmaceuticals Inc.

Section 1. Introduction

ScieGen Pharmaceuticals Inc. is a manufacturer of generic pharmaceutical finished formulations (Tablets/Capsules) authorized by Food and Drug Administration in the United States. The company maintains a growing and sustained market for its generic pharmaceutical finished formulations and has done so since established in manufacturing /operations facilities in Hauppauge, New York, ScieGen Pharmaceuticals Inc. has established itself as fulfilling requirements of current Good Manufacturing Practice requirements.

In our concerted effort to maintain our presence and footprint in the United States, the company proudly submits our stewardship plan details and our plan of operation for managing our mail-back program for the disposal of unwanted pharmaceutical drugs. This effort is coordinated and implemented in complete compliance with applicable regulations. Our stewardship plan details our full strategy for maintaining and adhering to the legal requirements wherever it affects our business practices and product distribution and mail back processes.

Section 2. Contact Information

Selecting a qualified and experienced professional to spearhead our stewardship program is key to plan objectives. As such, Dr. Pailla Malla Reddy, Chief Executive Officer and President of ScieGen Pharmaceuticals Inc., has been identified and selected as the company's primary contact and responsible party for submitting and overseeing the stewardship plan.

Dr. Pailla Malla Reddy is a successful pharmaceutical entrepreneur with over 30 years of experience in the industry. He began his career working in various positions in pharmaceutical companies in India, Nigeria, and the United States. Dr. Reddy is a graduate of Osmania University in India where he earned a BS degree in Chemistry with concentrations in genetics and botany. He later earned his Masters and Ph.D. in Organic Chemistry from Kanpur University.

Dr. Pailla Malla Reddy led and directed ScieGen Pharmaceuticals Inc. since 2009 as one of the key professionals. Dr. Pailla Malla Reddy is well versed in understanding the intricacies of our business. Furthermore, he maintains years of executive management, finance experience and has demonstrated over the years in his excellent capacity to consistently lead the pharmaceutical manufacturing company to deliver quality-finished formulations and to achieve excellent customer satisfaction.

Dr. Pailla Malla Reddy's contact information is listed below:

Dr. Pailla Malla Reddy
CEO / President
ScieGen Pharmaceuticals Inc.

Drug Take Back Program
ScieGen Pharmaceuticals Inc.
89 Arkay Drive, Hauppauge NY 11788-3727
631-434-2723
Contact Email: drugtakeback@sciegenpharm.com
Internet Address: https://sciegenpharm.com/drugtakeback

Section 3. Covered Entities

ScieGen Pharmaceuticals Inc. uniquely designates itself and its own subsidiary Radha Pharmaceuticals Inc., as covered entities. Radha Pharmaceuticals Inc. is the virtual manufacturer fully owned by ScieGen Pharmaceuticals Inc. ScieGen Pharmaceuticals Inc. is the only manufacturer for Radha Pharmaceuticals Inc. We have the capability to take back unwanted pharmaceutical formulations for our own covered entities without engaging third parties. Our mail back program provides patients and pharmacists an all-in-one solution for returning unwanted drugs to the manufacturer for the proper disposal.

The address details of covered entities are as follows:

ScieGen Pharmaceuticals Inc.
89 Arkay Drive,
Hauppauge, NY 11788-3727
Tel: 631 - 434 – 2723
Email: info@sciegenpharm.com

Radha Pharmaceuticals Inc.
330 Oser Avenue,
Hauppauge, NY 11788-3630
Tel: 631 – 434 -2723
E-mail: info@radhapharm.com

ScieGen Pharmaceuticals Inc.
330 Oser Avenue,
Hauppauge, NY 11788-3630

Dr. Pailla Malla Reddy is designated and will act as the covered entity's point of contact (POC). He can be reached at:

Dr. Pailla Malla Reddy

Chief Executive Officer & President

ScieGen Pharmaceuticals Inc.

89 Arkay Drive

Hauppauge, NY 11788-3727

631-434-2723

Contact Email: drugtakeback@sciegenpharm.com

Internet Address: https://sciegenpharm.com/drugtakeback

Section 4. List of Products Sold

The finished pharmaceutical formulations manufactured, sold and distributed for prescription use is approved by United States Food and Drug Administration. Though vast, the company maintains a high standard for manufacturing finished formulations both capsules, and tablets that are meticulously manufactured and quality controlled to one of the very best standard allowable. It should be noted that all our finished pharmaceutical formulations, including those products to be sold by ScieGen Pharmaceuticals Inc. as part of the stewardship plan, center around consumer needs:

- All products are packed in labeled HDPE Bottles, with appropriate CRC Cap on the top.
- Silica adsorbent packs are added to the bottles for increased protection from moisture.
- State of the art quality control laboratory with advanced analytical instruments and quality assurance team to ensure quality in processes and products.
- ScieGen manufactures only solid oral formulations (Capsules and Tablets) that are friendly to the mail back program.

As part of our stewardship plan, ScieGen Pharmaceuticals Inc., as the covered entity will take back the following products if it becomes unwanted.

Table 1. Product List of ScieGen Pharmaceuticals Inc.

NDC	Name of Prescription Drug	Pack Size
50228045110	Atorvastatin Calcium Tablets , USP 10 mg	1000
50228045190	Atorvastatin Calcium Tablets , USP 10 mg	90
50228045205	Atorvastatin Calcium Tablets , USP 20 mg	500
50228045290	Atorvastatin Calcium Tablets , USP 20 mg	90
50228045310	Atorvastatin Calcium Tablets , USP 40 mg	1000
50228045390	Atorvastatin Calcium Tablets , USP 40 mg	90
50228045405	Atorvastatin Calcium Tablets , USP 80 mg	500
50228045490	Atorvastatin Calcium Tablets , USP 80 mg	90
50228017401	Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 100 mg	100
50228017405	Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 100 mg	500
50228017460	Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 100 mg	60
50228017501	Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 150 mg	100
50228017505	Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 150 mg	500
50228017560	Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 150 mg	60

50228017601	Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 200 mg	100
50228017660	Bupropion Hydrochloride Extended-Release Tablets, USP (SR) 200 mg	60
50228014405	Bupropion Hydrochloride Extended-Release Tablets, USP (XL) 150 mg	500
50228014430	Bupropion Hydrochloride Extended-Release Tablets, USP (XL) 150 mg	30
50228014505	Bupropion Hydrochloride Extended-Release Tablets, USP (XL) 300 mg	500
50228014530	Bupropion Hydrochloride Extended-Release Tablets, USP (XL) 300 mg	30
50228010901	Carisoprodol Tablets, USP 350 mg	100
50228010905	Carisoprodol Tablets, USP 350 mg	500
50228010910	Carisoprodol Tablets, USP 350 mg	1000
50228015701	Celecoxib Capsules 100 mg	100
50228015705	Celecoxib Capsules 100 mg	500
50228015801	Celecoxib Capsules 200 mg	100
50228015805	Celecoxib Capsules 200 mg	500
50228015960	Celecoxib Capsules 400 mg	60
50228015660	Celecoxib Capsules 50 mg	60
50228046001	Carbidopa and Levodopa Extended-Release Tablets, USP 25 mg / 100 mg	100
50228046010	Carbidopa and Levodopa Extended-Release Tablets, USP 25 mg / 100 mg	1000
50228046101	Carbidopa and Levodopa Extended-Release Tablets, USP 50 mg / 200 mg	100
50228046110	Carbidopa and Levodopa Extended-Release Tablets, USP 50 mg / 200 mg	1000
50228045701	Carbidopa and Levodopa Immediate-Release Tablets, USP 10 mg / 100 mg	100
50228045705	Carbidopa and Levodopa Immediate-Release Tablets, USP 10 mg / 100 mg	500
50228045801	Carbidopa and Levodopa Immediate-Release Tablets, USP 25 mg / 100 mg	100
50228045805	Carbidopa and Levodopa Immediate-Release Tablets, USP 25 mg / 100 mg	500
50228045810	Carbidopa and Levodopa Immediate-Release Tablets, USP 25 mg / 100 mg	1000
50228045901	Carbidopa and Levodopa Immediate-Release Tablets, USP 25 mg / 250 mg	100
50228045905	Carbidopa and Levodopa Immediate-Release Tablets, USP 25 mg / 250 mg	500
50228012405	Clopidogrel Tablets USP 75 mg	500
50228012410	Clopidogrel Tablets USP 75 mg	1000
50228012430	Clopidogrel Tablets USP 75 mg	30
50228012490	Clopidogrel Tablets USP 75 mg	90
50228042990	Droxidopa Capsules 100 mg	90
50228043090	Droxidopa Capsules 200 mg	90
50228043190	Droxidopa Capsules 300 mg	90
50228033410	Ethacrynic Acid Tablets, USP 25 mg	100
50228037905	Ezetimibe Tablets, USP 10 mg	500
50228037930	Ezetimibe Tablets, USP 10 mg	30
50228037990	Ezetimibe Tablets, USP 10 mg	90
50228011301	Fluoxetine Capsules, USP 10 mg	100
50228011310	Fluoxetine Capsules, USP 10 mg	1000
50228011401	Fluoxetine Capsules, USP 20 mg	100
50228011410	Fluoxetine Capsules, USP 20 mg	1000

50228011501	Fluoxetine Capsules, USP 40 mg	100
50228011505	Fluoxetine Capsules, USP 40 mg	500
50228011530	Fluoxetine Capsules, USP 40 mg	30
50228042001	Fluoxetine Tablets, USP 10 mg	100
50228042030	Fluoxetine Tablets, USP 10 mg	30
50228042101	Fluoxetine Tablets, USP 20 mg	100
50228042130	Fluoxetine Tablets, USP 20 mg	30
50228042230	Fluoxetine Tablets, USP 60 mg	30
50228017901	Gabapentin Capsules, USP 100 mg	100
50228017905	Gabapentin Capsules, USP 100 mg	500
50228017910	Gabapentin Capsules, USP 100 mg	1000
50228018001	Gabapentin Capsules, USP 300 mg	100
50228018005	Gabapentin Capsules, USP 300 mg	500
50228018010	Gabapentin Capsules, USP 300 mg	1000
50228018101	Gabapentin Capsules, USP 400 mg	100
50228018105	Gabapentin Capsules, USP 400 mg	500
50228017701	Gabapentin Tablets, USP 600 mg	100
50228017705	Gabapentin Tablets, USP 600 mg	500
50228017801	Gabapentin Tablets, USP 800 mg	100
50228017805	Gabapentin Tablets, USP 800 mg	500
50228018201	Hydralazine Hydrochloride Tablets, USP 10 mg	100
50228018210	Hydralazine Hydrochloride Tablets, USP 10 mg	1000
50228018501	Hydralazine Hydrochloride Tablets, USP 100 mg	100
50228018301	Hydralazine Hydrochloride Tablets, USP 25 mg	100
50228018310	Hydralazine Hydrochloride Tablets, USP 25 mg	1000
50228018401	Hydralazine Hydrochloride Tablets, USP 50 mg	100
50228018410	Hydralazine Hydrochloride Tablets, USP 50 mg	1000
50228014601	Hydrochlorothiazide Capsules, USP 12.5 mg	100
50228014605	Hydrochlorothiazide Capsules, USP 12.5 mg	500
50228014610	Hydrochlorothiazide Capsules, USP 12.5 mg	1000
50228018960	Levetiracetam Extended-Release Tablets, USP 500 mg	60
50228019060	Levetiracetam Extended-Release Tablets, USP 750 mg	60
50228013630	Levocetirizine Dihydrochloride Tablets, USP 5 mg	30
50228013690	Levocetirizine Dihydrochloride Tablets, USP 5 mg	90
50228044690	Metformin Hydrochloride Extended-Release Tablets, USP 1000 mg	90
50228044501	Metformin Hydrochloride Extended-Release Tablets, USP 500 mg	100
50228010701	Metformin Hydrochloride Tablets, USP 1000 mg	100
50228010705	Metformin Hydrochloride Tablets, USP 1000 mg	500
50228010710	Metformin Hydrochloride Tablets, USP 1000 mg	1000
50228010501	Metformin Hydrochloride Tablets, USP 500 mg	100
50228010505	Metformin Hydrochloride Tablets, USP 500 mg	500

50228010510	Metformin Hydrochloride Tablets, USP 500 mg	1000
50228010601	Metformin Hydrochloride Tablets, USP 850 mg	100
50228010605	Metformin Hydrochloride Tablets, USP 850 mg	500
50228046501	Nabumetone Tablets, USP 500 mg	100
50228046505	Nabumetone Tablets, USP 500 mg	500
50228046601	Nabumetone Tablets, USP 750 mg	100
50228046605	Nabumetone Tablets, USP 750 mg	500
50228043201	Naproxen Sodium Tablets, USP 275 mg	100
50228043205	Naproxen Sodium Tablets, USP 275 mg	500
50228043301	Naproxen Sodium Tablets, USP 550 mg	100
50228043305	Naproxen Sodium Tablets, USP 550 mg	500
50228043401	Naproxen Tablets, USP 250 mg	100
50228043405	Naproxen Tablets, USP 250 mg	500
50228043501	Naproxen Tablets, USP 375 mg	100
50228043505	Naproxen Tablets, USP 375 mg	500
50228043601	Naproxen Tablets, USP 500 mg	100
50228043605	Naproxen Tablets, USP 500 mg	500
50228034010	Olmesartan Medoxomil Tablets, USP 20 mg	1000
50228034030	Olmesartan Medoxomil Tablets, USP 20 mg	30
50228034090	Olmesartan Medoxomil Tablets, USP 20 mg	90
50228034110	Olmesartan Medoxomil Tablets, USP 40 mg	1000
50228034130	Olmesartan Medoxomil Tablets, USP 40 mg	30
50228034190	Olmesartan Medoxomil Tablets, USP 40 mg	90
50228033910	Olmesartan Medoxomil Tablets, USP 5 mg	1000
50228033930	Olmesartan Medoxomil Tablets, USP 5 mg	30
50228033990	Olmesartan Medoxomil Tablets, USP 5 mg	90
50228012610	Pramipexole Dihydrochloride Tablets 0.125 mg	1000
50228012690	Pramipexole Dihydrochloride Tablets 0.125 mg	90
50228012710	Pramipexole Dihydrochloride Tablets 0.25 mg	1000
50228012790	Pramipexole Dihydrochloride Tablets 0.25 mg	90
50228012810	Pramipexole Dihydrochloride Tablets 0.5 mg	1000
50228012890	Pramipexole Dihydrochloride Tablets 0.5 mg	90
50228012910	Pramipexole Dihydrochloride Tablets 0.75 mg	1000
50228012990	Pramipexole Dihydrochloride Tablets 0.75 mg	90
50228013010	Pramipexole Dihydrochloride Tablets 1 mg	1000
50228013090	Pramipexole Dihydrochloride Tablets 1 mg	90
50228013110	Pramipexole Dihydrochloride Tablets 1.5 mg	1000
50228013190	Pramipexole Dihydrochloride Tablets 1.5 mg	90
50228035390	Pregabalin Capsules 100 mg	90
50228035490	Pregabalin Capsules 150 mg	90
50228035590	Pregabalin Capsules 200 mg	90

50228035690	Pregabalin Capsules 225 mg	90
50228035090	Pregabalin Capsules 25 mg	90
50228035790	Pregabalin Capsules 300 mg	90
50228035190	Pregabalin Capsules 50 mg	90
50228035290	Pregabalin Capsules 75 mg	90
50228038160	Quetiapine Extended-Release Tablets, USP 150 mg	60
50228038260	Quetiapine Extended-Release Tablets, USP 200 mg	60
50228038360	Quetiapine Extended-Release Tablets, USP 300 mg	60
50228038460	Quetiapine Extended-Release Tablets, USP 400 mg	60
50228038060	Quetiapine Extended-Release Tablets, USP 50 mg	60
50228042460	Ranolazine Extended-Release Tablets 1000 mg	60
50228042360	Ranolazine Extended-Release Tablets 500 mg	60
50228042830	Solifenacin Succinate Tablets 10 mg	30
50228042890	Solifenacin Succinate Tablets 10 mg	90
50228042730	Solifenacin Succinate Tablets 5 mg	30
50228042790	Solifenacin Succinate Tablets 5 mg	90

Table 2. Product List of Radha Pharmaceuticals Inc.

NDC	Name of Prescription Drug	Pack Size
77771018201	Hydralazine Hydrochloride Tablets, USP 10 mg	100
77771018210	Hydralazine Hydrochloride Tablets, USP 10 mg	1000
77771018301	Hydralazine Hydrochloride Tablets, USP 25 mg	100
77771018310	Hydralazine Hydrochloride Tablets, USP 25 mg	1000
77771018401	Hydralazine Hydrochloride Tablets, USP 50 mg	100
77771018410	Hydralazine Hydrochloride Tablets, USP 50 mg	1000
77771018501	Hydralazine Hydrochloride Tablets, USP 100 mg	100
77771032301	Metaxalone Tablets, USP 800 mg	100
77771032305	Metaxalone Tablets, USP 800 mg	500
77771015660	Celecoxib Capsules 50 mg	60
77771015701	Celecoxib Capsules 100 mg	100
77771015705	Celecoxib Capsules 100 mg	500
77771015801	Celecoxib Capsules 200 mg	100
77771015805	Celecoxib Capsules 200 mg	500
77771015960	Celecoxib Capsules 400 mg	60
77771017460	Bupropion SR tablets 100 mg	60
77771017405	Bupropion SR tablets 100 mg	500

77771017560	Bupropion SR tablets 150 mg	60
77771017505	Bupropion SR tablets 150 mg	500
77771017660	Bupropion SR tablets 200 mg	60
77771045701	Carbidopa / Levodopa Tablets, USP 10 mg/100 mg	100
77771045705	Carbidopa / Levodopa Tablets, USP 10 mg/100 mg	500
77771045710	Carbidopa / Levodopa Tablets, USP 10 mg/100 mg	1000
77771045801	Carbidopa / Levodopa Tablets, USP 25 mg/100 mg	100
77771045805	Carbidopa / Levodopa Tablets, USP 25 mg/100 mg	500
77771045810	Carbidopa / Levodopa Tablets, USP 25 mg/100 mg	1000
77771045901	Carbidopa / Levodopa Tablets, USP 25 mg/250 mg	100
77771045905	Carbidopa / Levodopa Tablets, USP 25 mg/250 mg	500
77771045910	Carbidopa / Levodopa Tablets, USP 25 mg/250 mg	1000
77771043401	Naproxen Tablets 250 mg	100
77771043405	Naproxen Tablets 250 mg	500
77771043501	Naproxen Tablets 375 mg	100
77771043505	Naproxen Tablets 375 mg	500
77771043601	Naproxen Tablets 500 mg	100
77771043605	Naproxen Tablets 500 mg	500
77771047012	Levetiracetam Tablets 250 mg	120
77771047005	Levetiracetam Tablets 250 mg	500
77771047112	Levetiracetam Tablets 500 mg	120
77771047105	Levetiracetam Tablets 500 mg	500
77771047212	Levetiracetam Tablets 750 mg	120
77771047205	Levetiracetam Tablets 750 mg	500
77771047360	Levetiracetam Tablets 1000 mg	60

Section 5. State Agency Compliance Certifications

ScieGen Pharmaceuticals Inc. acknowledges that our pharmaceutical finished formulations, stipulated under this stewardship plan, must comply with local, state, and federal requirements.

Our Stewardship plan will be submitted to the relevant health regulatory authorities for approval if required.

Section 6. Program Budget and Funding

ScieGen Pharmaceuticals Inc. is a multi-million-dollar company, recording profits year over year since 2009 with the capacity to sustain its position as a future covered entity. With a strong financial history, ScieGen Pharmaceuticals Inc., is prepared financially to establish and maintain a sustainable and acceptable stewardship plan to be initiated in the United States. Specifically, the anticipated budget for our stewardship plan addresses all the pertinent needs required to promote the proper mail back and disposal of unwanted finished pharmaceutical formulations. The following table details how ScieGen Pharmaceuticals Inc., plans to budget and finance our stewardship plan. Our stewardship plan budget allocates funds towards consumer and pharmacy personnel education as it relates to the proper mail back and disposal of unwanted finished pharmaceutical formulation manufactured by ScieGen Pharmaceuticals Inc.

Estimated capital and annual costs to implement and operate the stewardship program are list separately and include the following items:

1. **Capital Costs:** Program setup includes the initial costs associated with the plan, resources required, program implementation and stewardship education.

2. **Collection, Transportation, and Disposal Costs:** Expenses associated with managing the mail-back program, USPS shipping fees, storage and fees associated to dispose the unwanted finished pharmaceutical formulations.

3. **Education & Outreach Costs:** Includes marketing to retail pharmacies and ultimate users to educate them on importance of compliance and the various methods available for the proper disposal of unwanted pharmaceutical finished formulations manufactured by ScieGen Pharmaceuticals Inc.

4. **Grants, Loans and Sponsorship Costs:** Although ScieGen Pharmaceuticals Inc., does not anticipate having any grants or loan expenses, sponsorships may be used when appropriate for market outreach.

5. **Independent Financial Audit Costs:** ScieGen Pharmaceuticals Inc., anticipates some level of expenses with an independent financial audit cost by any 3rd party audit provider when required.

6. **Departmental Administrative Fee:** ScieGen Pharmaceuticals Inc., anticipates applicable departmental administrative fees associated with the implementation of and the ongoing management of stewardship activities.

7. **Miscellaneous Costs:** ScieGen Pharmaceuticals Inc. anticipates negligible miscellaneous costs with the plan, implementation, and the ongoing management of stewardship activities.

ScieGen Pharmaceuticals Inc., proposes to operate the stewardship program on its own and through the general operation of the overall business. Therefore, the estimated recommended funding level is equal to the estimated annual budget set forth.

ScieGen Pharmaceuticals Inc. has recommended a reserve in the amount of 70% of the recommended annual funding level. This would equal approximately 7+ months of the annual estimated costs associated to operate the stewardship plan in the United States.

ScieGen Pharmaceuticals Inc., believes that this is more than sufficient to cover any stewardship plan obligations. This reserve capacity will be in the form of liquidity through cash reserves, debt revolver capacity, or assets.

Table 3. Annual Budget (COO to Review and Approve)

	2022	2023	2024	2025	2026
Recommended Funding Level	**$ 145,000**	**$ 122,000**	**$ 152,000**	**$ 154,000**	**$ 157,000**
Stewardship Program Costs					
Stewardship Capital Costs					
Total Capital Costs	$ 100,000	0	0	0	0
Program setup cost includes initial costs associated with plan, resources required, program implementation and stewardship education. Product setup costs include items related to developing the mail-back product line (i.e., packaging, labeling, education, website, and inventory.					
Stewardship Recurring Costs					
Collection, Transportation, and Disposal	0	70,000	100,000	102,000	105,000
Expenses associated with managing the mail-back program; is determined by quantity of product unwanted. (Based on expected volumes distributed and medication nonadherence 40% to 50%) ex: the distributed quantity in the past 12 months is around 39,000 bulk packs).					
Administrative Costs	20,000	20,000	20,000	20,000	20,000
Overall management of the programs to include compliance efforts, analytics and corrective actions. Overall management of the webpage and toll-free telephone number and associated activities.					
Education & Outreach	20,000	20,000	20,000	20,000	20,000
Includes marketing to wholesalers and retailers.					
Includes marketing materials used to educate the market on compliant products under the stewardship plan Continued development of marketing materials for the implementation of the outreach program (such as flyers, education, promotional materials informational, and diagrams					
Grants, Loans, Sponsorships	5,000	5,000	5,000	5,000	5,000
Independent Financial Audit Expense	0	7,000	7,000	7,000	7,000
Estimate of additional work that may be required by third party auditors					
Departmental Administrative Fee if any	As applicable	As applicable	As applicable	As applicable	As applicable

Total	$ 45,000	$ 122,000	$ 152,000	$ 154,000	$ 157,000
Total Annual Costs	$ 145,000	$ 122,000	$ 152,000	$ 154,000	$ 157,000

Recommended Reserve Level Amount

Reserve amount equals 70% of the annual estimated funding level.	**$ 101,500**	**$ 85,400**	**$ 106,400**	**$ 107,800**	**$ 109,900**

Section 7. Policies and Procedures for Collecting, Tracking and Managing Unwanted Pharmaceutical Finished Formulations

Having been in the manufacture of finished pharmaceutical formulations for more than a decade, ScieGen Pharmaceuticals Inc., has always been conscientious and cognizant of the importance of managing and tracking the collection, and disposal of unwanted pharmaceutical finished formulations. Policies, processes, and standard operating procedures (SOPs) that emphasize the safe disposal of our unwanted finished pharmaceutical formulations is vital to our continued progress. As a Food and Drug Administration (FDA) approved manufacturer, we continuously develop customer-centered processes that endorse quality, safety, efficacy and purity in the finished pharmaceutical formulations.

Any noncompliance issues or willful negligence in adhering to in adhering to established policies and procedures are expeditiously remediated. We employ systematic procedures for safely and securely collecting, and managing unwanted pharmaceutical formulations on multiple levels. From our quality management system that addresses product recall, handling of quality rejection, we make every effort to gather information and details regarding the lifecycle management of finished pharmaceutical formulations manufactured at ScieGen Pharmaceuticals Inc.

Licenses (or) permits will be obtained from relevant authorities if required. ScieGen Pharmaceuticals Inc., shall establish systems to monitor, measure and record necessary data for safely disposing unwanted pharmaceutical finished formulations is effective and proven.

Information provided in this section provides details on how we integrate standard operating procedures to ensure compliance to company and government agencies.

7.1 Mail-back Material Design, Distribution and Process

ScieGen Pharmaceuticals Inc., proposes a tamper-evident sealable, self-addressed, prepaid mailer as a mail-back material along with a pamphlet.

ScieGen propose to distribute these mail-back materials in the following ways:

In person / Retail Pharmacies:
ScieGen propose to make these mailers available at pharmacy retail units using our 3PL service provider.

By Phone:
Mailers can be obtained by calling the Toll Free Number 1-855-724-3436.

By Email:
Mailers can be requested by addressing an email to drugtakeback@sciegenpharm.com

Webpage:
ScieGen propose to develop a web page with mail-back instructions at
https://sciegenpharm.com/drugtakeback

The mail-back envelopes are easy to use. The end users have to place the unwanted finished pharmaceutical formulations within the envelope and seal prior to mailing it back to Covanta Hempstead Company (or) ScieGen Pharmaceuticals Inc.

Our stewardship plan allots budgetary funds for the free mail-back of unwanted finished pharmaceutical formulations using a prepaid, pre-addressed USPS mail label.

7.1.1 Patient Mail-back Material Distribution Amounts

Striving to comply with local and federal regulations, we employ a concerted effort to combine and emphasize efficiency, convenience, and simplicity as part of our mail-back plan. Our process for distributing mail back is simple and convenient as described in section 7.1 and the proposed material distribution amount will be in excess to meet the demand.

7.1.2 Consumer-provided Unwanted Medicines Disposal Information

ScieGen Pharmaceuticals Inc., knows that necessary information on unwanted medicines entails:

- Detailing complete and thorough instructions on how to use the mail-back envelope, that includes step-by-step instructions.
- Communicating the importance of adhering to local and federal laws relative to the disposal of unwanted finished pharmaceutical formulations.
- Stating in broad terms, the consequences for disregarding local and federal mandates for disposing unwanted finished pharmaceutical formulations.

ScieGen Pharmaceuticals Inc., provides end users with beneficial and timely information in English for the proper disposal of unwanted finished pharmaceutical formulations. The mail-back materials include:

- A prepaid and pre-addressed mail-back envelope
- Printed Instructions (Pamphlet+Questionnaire)

7.1.3 Unwanted Medicines Mail Back Pamphlet (Proposed Contents of the Pamphlet)

Instructions

Before you begin:
Gather the unused and/or expired medicine you wish to mail for disposal. Leave all medicine in its original container(s). If you wish, you may use a marker to black out **your name, NDC code, and personal information** on the medicine bottle. However, please **do not** black out the name and quantity of the medicine. This helps us to identify the medicine for disposal.

Please leave medicine in the original container(s). Do not black out the name of the medicine, NDC code or the number of pills.

Please place all medicine you wish to dispose of into the postage-paid envelope provided.

Do not put the following items into the envelope:

1. DO NOT place loose pills into the envelope. Leave all pills in their original bottles. This will help us to identify the drug for disposal. If you need more than one envelope, please request an additional envelope from a participating site or call the toll-free number 1-855-724-3436.
2. DO NOT put syringes or sharp objects into the envelope. No syringes, sharps, or needles or other items that may cause injury to the postal carrier or program staff are to be placed into the postage-paid envelope. Even if these items are packaged or wrapped, they are not to be placed in the envelope. If you would like more information about proper disposal of sharps, please contact your healthcare provider
3. No batteries, electronics, medical devices (hearing aids, blood sugar monitors), or thermometers should be placed into the envelope. No needles, liquids loose pills, pills in baggies, broken glass, sharp objects, medical devices, or thermometers are to go into the envelope.

Once all your medicine is placed in the postage-paid envelope, complete the questionnaire below. Place your completed questionnaire in the envelope and seal it. It is now ready to be mailed. Complete the questionnaire and place it in the envelope with your medicine. If you have questions about what to put into the envelope, please call the Toll Free Program Helpline 1-855-724-3436.

Questionnaire

Name and Address of Customer:

Product Details:

Reason for Return:

Mailing Your Envelope

Mail the envelope as you would any other letter or package through the U.S. Mail.
There are several choices available to you including:

- Hand the envelope directly to your mail carrier,
- Bring it directly to your local Post Office for mailing,
- Place the envelope into a blue United States Postal Service mailbox at your local Post Office or other locations in your area, or
- Place the envelope in your home mailbox.

Thank you for participating in this program! If you have any further questions or comments about the program please call the toll-free number 1-855-724-3436..

7.1.4 Prepaid Mail-back Envelope

Increasing the probability of the return of unwanted pharmaceutical finished formulations is ultimate requirement for the success if our solution for all unwanted finished pharmaceutical formulations. Coordinating mail-back prepaid postage with the US Postal Service (USPS) in advance provides patients with a no-hassle mail-back prepaid envelope. Implementing prepaid mail-back envelopes increases the probability of the mailing back of our envelopes.

7.2 Collection, Transportation, and Disposal System Records

The quality management system in place at ScieGen Pharmaceuticals Inc.' is designed for accountability and transparency. The quality team propose that the records are to be maintained, managed, and kept ready for any audits. ScieGen Pharmaceuticals Inc., plans to generate collection, transportation, and disposal records according to our mail-back programs. Records include:

- Mailer Origination (the US Postal Service is used)
- Final disposal documentation

All records and associated information are collected, stored, and managed by ScieGen Pharmaceuticals Inc.,'s pharmaceutical waste disposal service provider and stewardship operator.

7.3 Mail-back / Disposal Service Providers

ScieGen Pharmaceuticals Inc. employs reputable transportation services and uses highly qualified disposal service providers that have proven to be reliable and predictable. USPS is a stable establishment and has proven, even during current crises, to be reputable, transporting our materials and information in a timely manner. Covanta Hempstead Company as our disposal service provider, has been in business for several years. The company has partnered with ScieGen Pharmaceuticals Inc., successfully and remains a solid, long-term provider, supporting pharmaceutical waste disposal needs. Working with our disposal service provider, our team has identified and established disposal location (see Table below). Upon arriving at the disposal facility, mail-back packages are weighed and incinerated.

Table 4. Mail-back / Disposal Service Providers

Provider Name	United States Postal Service (USPS)	Covanta Hempstead Company
Provider Mailing and Physical Address	475 L'Enfant Plaza SW Washington, DC 20260-0004	600 Merchants Concourse Westbury, NY 11590

7.4 Alternate Collection Methods - Unwanted Medicines

ScieGen Pharmaceuticals Inc., proposes a complete solution, offering patients with expired medicines a printed, prepaid postage envelope for mailing back unwanted finished pharmaceutical formulations. As such, ScieGen Pharmaceuticals Inc., is not implementing a receptacle-based program. However, encourages customer to make use of DEA Drug Back Day and other similar initiatives. ScieGen Pharmaceuticals Inc., mail-back program is economical and convenient.

7.4.1 Secure Receptacle Collection Process

See Alternate Collection Methods (Section 7.4)

7.4.1.1 Name of Consolidation Point

See Alternate Collection Methods (Section 7.4)

7.4.1.2 Collection Receptacle Monitoring and Service Scheduling

See Alternate Collection Methods (Section 7.4)

7.4.1.3 Consolidation Point Funding

See Alternate Collection Methods (Section 7.4)

7.4.1.4 Standard Operating Procedures for Reporting Safety and Security Incidents

Policies, processes, and standard operating procedures (SOPs) that address proper product management and incident resolution is important to our continued success. As a Food and Drug Administration approved organization, we maintain quality centered processes and product

that promote and support established methods for reporting incidents that could or would impact the quality, safety, efficacy, and purity of the finished pharmaceutical formulations.

Our state-of-the-art facilities and processes comply with current Good Manufacturing Practice (cGMP) requirements. Specifically, dedicated, and professionally highly qualified, team members are well trained and organized to manage the Quality Management System (QMS) processes and procedures. Our Quality Management System (QMS) addresses deviations, incidents associated with finished pharmaceutical formulations, with a hierarchical structure for receiving and communicating all product issues externally and internally. Our Quality Management System (QMS) comprise of procedures integrate defined information gathering, root-cause analysis (RCA) and Corrective and Preventive Action (CAPA) to ensure full resolution, and excellent customer satisfaction for all products manufactured and dispensed for prescription use.

Internal audits are scheduled at a pre-determined interval to ensure quality, safety, efficacy and purity in our processes and products.

7.4.2 Managing Take-back Events

See Alternate Waste Collection Methods (Section 7.4)

7.5 Metrics for Measuring Distributed and Mailed Back Envelopes

ScieGen Pharmaceuticals Inc., uses its third party logistic service provider RxCrossroads 3PL to store and fulfill sales orders to its distributors and retail pharmacies. RxCrossroads uses SAGE 100 2016 for enterprise resource planning (ERP) and HighJump for warehouse management system (WMS).

From the information gathered during the aforementioned processes, ScieGen Pharmaceuticals Inc, will collect data to create measurable metrics. Specifically, we will track units of finished pharmaceutical formulations:

Product units distributed into the State.

Number of mail-back envelopes distributed annually.

Number of mail-back envelopes returned to the manufacturer (or) disposal location using United States Postal Service.

Weight of unwanted pharmaceutical formulations disposed.

With this information, ScieGen Pharmaceuticals Inc., will measure the metrics of unwanted medicines disposed annually.

7.6 Management and Handling of Stewardship Plan Noncompliance Issues

ScieGen Pharmaceuticals Inc., is a Food and Drug Administration (FDA) approved, and current Good Manufacturing Practice (cGMP) compliant finished pharmaceutical formulations manufacturer.

Our manufacturing facility and products are audited by Food and Drug Administration (FDA) and third party auditors.

Our Quality Management System (QMS) integrates quality by design into processes and products. Corrective and Preventive Actions (CAPA) are handled by our quality team on a case by case basis.

The stewardship plan will be added to our internal audit program. In the case of noncompliance, ScieGen Pharmaceuticals Inc., will initiate a Corrective and Preventive Action (CAPA) process to determine the root-cause of the noncompliant event. ScieGen Pharmaceuticals Inc., as the stewardship operator and participant will investigate for root-cause; modify procedures and protocols, as needed; and audit for effectiveness to mitigate any future noncompliance issues relative to the stewardship plan.

Section 8. Local Agency Reimbursement

Upon request and in coordination with other stewardship program operators, ScieGen Pharmaceuticals Inc., reimburses local agencies for transportation and disposal costs related to home-generated unwanted finished pharmaceutical formulations manufactured at ScieGen Pharmaceuticals Inc. A local agency may request reimbursement by registering with coordinating program operators or ScieGen Pharmaceuticals Inc. To register, the local agency provides:

- The facility name
- The name of point of contact, and
- A completed U.S. Department of the Treasury Internal Revenue Service Form W-9 for the facility to receive reimbursement.

ScieGen Pharmaceuticals Inc., or any other stewardship program operator, then verifies the credentials of such facility

After registering, the local agency may submit a request for reimbursement to coordinating program operators or ScieGen Pharmaceuticals Inc. The request:

- Is limited to the actual costs of transportation and disposal incurred in 270 days or more after the plan approval.
- Includes an invoice for the costs to be reimbursed.
- Is submitted with a declaration under penalty of perjury that the local agency has not knowingly requested reimbursement for expenses prohibited by the law.
- Requires the local agency to report on the finished pharmaceutical formulations disposed: National Drug Code (NDC), Product Description, Strength and Quantity (Total Units, Weight) etc.

ScieGen Pharmaceuticals Inc., or any other stewardship program operator, responds to local agency requests within 28 days and issues payment within 120 days of receipt of the local agency's invoice. Reimbursements from ScieGen Pharmaceuticals Inc., is issued with a statement that the local agency attest under penalty of perjury that by settling the statement, they are eligible for reimbursement and all reimbursed expenses are allowed under federal and state regulations.

ScieGen Pharmaceuticals Inc., will request from the local agency any additional information if required.

Section 9. Ordinance Repeals

Ordinance repeals are not applicable to ScieGen Pharmaceuticals Inc.'s stewardship program initiatives. Our stewardship plan provides a self-addressed, pre-paid mail back envelope as part of our program. Any local stewardship program in existence and /or repealed at any time has minimal impact on the mail-back program.

Section 10. Education and Outreach

10.1 Activities to Promote Awareness and Maximize User Participation

According to the Pew Research Organization, most Americans retrieve information through four main resources: Smartphone (Webpages) (86%), television (40%), radio (16%), and print material (10%). With these statistics as a basis and under the leadership of our stewardship program initiatives, ScieGen Pharmaceuticals Inc., intends to promote and increase user participation in our stewardship program through these mediums, especially online and smartphone messaging platforms, including the use of QR codes to access online information. Promoting awareness and education, we plan to create and provide customary materials to multiple levels of distribution channels, including third partly logistic service providers, wholesalers, retailers, pharmacies, pharmacists, patients and other stakeholders.

ScieGen Pharmaceuticals Inc.'s education and outreach in the unwanted finished pharmaceutical formulations disposal ecosystem are focused on:

- Increasing awareness
- Adopting desired practices, and
- Implementing effective communication

The program verifies the effectiveness of outreach efforts. The mail-back program is designed to be simple, and user friendly leading to increased safe disposal. It is evident that outreach success will contribute to operational success. ScieGen Pharmaceuticals Inc., plans to provide information to both target audiences identified in the stewardship plan and the legislation, to encourage the behavior change necessary to meeting the program's goals. For example, as the program informs more pharmacists and patients about the mail back program available for finished pharmaceutical products manufactured by ScieGen Pharmaceuticals Inc., we forecast that significant unwanted finished pharmaceutical formulations will be diverted from landfills.

10.2 Material Localization

Identifying with primary ethnic groups within the United States and having English as our primary official language, ScieGen Pharmaceuticals Inc. intends to provide marketing materials, flyers, brochures, mail-back materials, and so forth initially in English. ScieGen Pharmaceuticals Inc.'s dedicated customer service phone number Toll Free Number 1-855-724-3436 will be available to further assist, advantageously, and will make use of Quality Translations LLC

located at 252 W 37th Street, Suite 1201 - New York, NY 10018 for the translation of our promotional materials only if needed.

See section 10.3 Webpage localization for more information.

10.3 Webpage Localization

Our ability to standup a user-friendly Webpage that is accessible to around 330 million United States citizens of diverse ethnicities is important to developing multi-level communication channels for our patients, physicians, pharmacies, distributors and third party logistic service providers.

Identifying with primary ethnic groups within the United States and having English as our primary official language, ScieGen Pharmaceuticals Inc. intends to provide our website and webpages initially in English.

Furthermore, ScieGen Pharmaceuticals Inc.'s dedicated Toll Free Number 1-855-724-3436 will be available to further assist, advantageously, and will make use of Quality Translations LLC located at 252 W 37th Street, Suite 1201 - New York, NY 10018 for the translation of our pamphlet (instructions) if needed.

10.4 Toll-free Telephone Number and Customer Support

Easy accessibility to our teams for all our clients is our intent and goal. ScieGen Pharmaceuticals Inc., has proposed a self-addressed, postage paid, prepaid mailers with tamper-evident seal. Mail-back envelopes can be obtained by calling Toll Free Number. If customer requests to receive a mail-back envelope the same will be processed and handled appropriately.

In person / Retail Pharmacies:
ScieGen propose to make these mail-back envelopes available at pharmacy retail units using our 3PL service provider.

By Email:
Mail-back envelopes can be requested by addressing an email to
drugtakeback@sciegenpharm.com

Webpage:
ScieGen propose to develop a web page at https://sciegenpharm.com/drugtakeback
Mail-back envelopes can be requested by filling a form in the webpage.

ScieGen Pharmaceuticals Inc., does provide a toll-free telephone number to all patients and participants, professional and non-professional. Such telephone access will field questions and concerns and accommodate pharmacovigilance information if required to enhance compliance.

Access to a human representative will be made available to all callers upon request. Lastly, patients will be having the option of hearing information in English and the option to speak with a English speaking representative. Please refer section 10.2 Material Localization and section 10.3 Webpage Localization. With these options in place ScieGen Pharmaceuticals Inc. will achieve its accessibility goal.

10.5 Education and Outreach Metrics

Metrics will be established to evaluate the performance of the education provided to the patients using pharmacists and other promotional materials. Customer education is to be offered formally and informally. Formal training is provided at a pharmacy level, where pharmacist work with patients educating them the importance of compliance and patients to dispose the unwanted finished pharmaceutical formulations appropriately including mail-back envelopes. However, customers and pharmacists will also receive a level of education by contacting our customer service representatives through the toll-free telephone number. On this level, ScieGen Pharmaceuticals Inc., tracks the level and type of services provided to the various patient types categorically. Outside of toll-free telephone assistance, ScieGen Pharmaceuticals Inc., provides informal training through its web page where users can access applicable pages for additional instruction. It is our goal to ensure that all mediums for administering customer education is easily obtainable and second to that, is to make sure that the ScieGen Pharmaceuticals Inc., as a company, is identifying and properly handling frequent customer trends and product questions.

From the information gathered during the aforementioned activities, ScieGen Pharmaceuticals Inc., will collect the following data to create measurable metrics:

- Track units of compliant product distributed into the state
- Track number of mail-back envelopes distributed

- Track number of mail-back envelopes returned to USPS
- Track pharmacy locations that stock the product
- Track pharmacy re-stocking activities
- Track Webpage traffic and usage
- Track the efforts of program marketing and advertising

With this information, ScieGen Pharmaceuticals Inc., will use the following metric to assess the stewardship program:

- Program Usage Metric: Number of mail-back envelopes returned through the USPS, divided by number of mail-back envelopes distributed
- Accessibility Metric: Number of pharmacy locations that sell the finished pharmaceutical formulations with NDCs beginning 50228 and 77771 manufactured by ScieGen Pharmaceuticals Inc., divided by the total number of pharmacy locations.
- Penetration Metric: Number of pharmacy locations that distribute the finished pharmaceutical formulations with NDCs beginning 50228 and 77771, divided by the total pharmacy locations that have access to it.

10.6 Distinguishing Covered and Non-Covered Products

Mail-back envelopes and instructions are developed for use is available to pharmacists and patients alike.

Users will use the mail-back envelopes provided to return the unwanted pharmaceutical formulations with NDCs beginning 50228 and 77771.

10.7 Federal and State Legal Requirements and Compliance

Understandably so, the stewardship program operators are to comply with all applicable Federal and State legal requirements. The program operators are not to promote, under its educational and outreach programs the disposal of a covered product in an inconsistent manner with the services offered to the ultimate user under a stewardship program. ScieGen Pharmaceuticals Inc., program operator will make all efforts to ensure that only those products under our program are distributed in the United States of America. This includes working with the major pharmacy retailers and wholesalers to only promote the sale of approved products within the United States. In addition to promotion of approved

product sales, all marketing education and outreach will only promote the approved / compliant product and address the importance of mail-back solution for unwanted finished pharmaceutical formulations.

Section 11. Coordination Efforts

Constant communication, coordination, and collaboration are keys to promoting relative business, end user strategies, initiatives and plans coexisting among multiple program operators in effort to align with the state and federal requirements. Under the leadership of our Chief Executive Officer / President and our stewardship program point of contact, where appropriate, ScieGen Pharmaceuticals Inc., intends to engage and align ourselves with the product stewardship initiatives. Such coordination could conceptually be offered through patient counseling by pharmacists, coordinated and strategic engagements, dialogue, and d pamphlets, as applicable. Other coordinated efforts may be included. However, our intention is to maintain alignments with applicable state and federal requirements, submitting our annual report consistently and hosting educational programs, if needed, internally and externally to our organizations. The regular and concerted collaboration and communication effort is dependent on business stakeholders across the board. Our goal is to be current and in harmony with the legal requirements, as much possible.

Section 12. Loans, Sponsorships, Reimbursements, and Other Incentive Processes

No grants, loans, sponsorships, reimbursements, or other incentives are anticipated at present for the stewardship program.

Section 13. Service Provider Selection Processes

ScieGen Pharmaceuticals Inc. fully evaluates all service providers for integrity, stability, value, and quality of service. Specifically, service providers maintain the customary arm's length status to prevent biased arrangements and promote integrity. Furthermore, the negotiation of terms and pricing among possible and applicable service providers helps us to select only those entities that operate in the best value of our finished pharmaceutical formulations. ScieGen Pharmaceuticals Inc., strives to add value while acting in the best interest of the company and our end users.

Appendix C – AGREEMENT (Terms and Conditions with Covanta)

Covanta
4Recovery

SPECIAL WASTE APPROVAL
ENVIRONMENTAL, HEALTH AND SAFETY, AND OPERATIONS
TERMS AND CONDITIONS

All waste delivered under this approval must meet all of the conditions listed below. No variance from these conditions is allowed without written authorization from the Covanta 4Recovery Environmental Health and Safety Group. In addition, any change to the nature of this waste stream will invalidate this approval and require the generator to submit a new waste profile for (including all new Material Characterization Forms) approval.

Date of Approval:	**October 22, 2012**
Approval Number:	**10251 0**
Bill-To Company:	**D. Malone Enterprises Inc**
Ship-From Company:	**ScieGen Pharmaceuticals, Inc**

Facility Approved for Delivery:

Covanta Hempstead Company
600 Merchants Concourse
Westbury, NY 11590
Contact: **Scott Wheeler**
Phone: **+1 (516) 683-5438**
Fax: **+1 (516) 683-5438**

Waste Description: Mixed Pharmaceutical Waste

Shipping Requirements:

Direct Hopper Feed material is limited to no more 1000 Lbs per pallet

Waste must be labeled as to the contents and Non-Hazardous status.

D.O.T. regulated waste that requires placards on a truck are not acceptable.

An accurate and completed manifest of the materials must accompany each delivery.

A Preshipment Notification is required before each delivery.

All materials must be palletized and shrink-wrapped.

An executed non-hazardous certification must accompany each delivery.

Pharmaceutical Finished Products & Raw Ingredients, as profiled, are approved for disposal at Covanta Hempstead. This waste stream is acceptable under New York State Department of Environmental Conservation (NYSDEC) approval #CH-30-12N, expires 10/19/13. No other waste stream is acceptable for disposal under this approval, unless reviewed and approved by Covanta 4Recovery (C4R). Refer to the Special Waste Tracking Document (SWTD) for a detailed list of approved/rejected items, packaging/labeling requirements, and special comments. NYSDEC and Covanta approval numbers must be included in all labels for the waste. In addition, all labels must include the name of generator and a description of the waste. The facility will strictly enforce the terms and conditions for this approval. In the case a load delivered under this approval causes any handling, processing or compliance issues, the facility reserves the right to reject the load and suspend further shipments.

Signed:

Environmental Health and Safety Representitive

Jaime Salazar, 18623455283

Find out more about our services @

REV. 11/02

www.covanta4recovery.com