

23



RECEIVED

6/18/2020

1772

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

\$500.00 Fee made payable to: Nevada State Board of Pharmacy

(non-refundable and not transferable money order or cashier's check only)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☒ New OUTSOURCING FACILITY

☐ Ownership Change (Provide current license number if making changes:) OUT _____

☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4

☒ Partnership - Pages 1-3 & 6 (LLC)

☐ Non Publicly Traded Corporation – Pages 1-3 & 5

☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: FARMAKEIO OUTSOURCING

Physical Address: 920 S. KIMBALL AVE STE. 100

City: SOUTH LAKE State: TX Zip Code: 76092

Telephone: 817-203-8216 Fax: 833-887-4969

Toll Free Number: 888-477-1567 (Required per NAC 639.708)

E-mail: JUSTIN.GRAVES@FKO-OUTSOURCING.COM Website: FKO-OUTSOURCING.COM

Supervising Pharmacist: JUSTIN GRAVES RPH. Nevada License #: PENDING APPROVAL

APPEARED
20536 OK

SERVICES PROVIDED

Yes/No

☐ ☒ Parenteral

☒ ☐ Sterile Compounding - PELLETS ONLY. WE DO NOT COMPOUND AQUEOUS STERILE INJECTABLES

☐ ☒ Non Sterile Compounding

☐ ☒ Mail Service Sterile Compounding

☒ ☐ Other Services: SOLID DOSAGE FORM PELLETS ONLY

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only

Date Processed: JUN 24 2020

Amount: 500.00

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY

Page 2

FEI Number (From FDA application): 3014982757

Please provide the name of the facility as registered with the FDA and the registration number:

FARMAKEIO OUTSOURCING 3014982757

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.

NONE

Please provide the name and Nevada license number of the supervising pharmacist:

Name: JUSTIN GRAVES RPh. Nevada License Number: Pending Approval
MPJE PASSEDA Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: NONEThis page must be submitted for all types of ownership.

Within the last five (5) years:

- 1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒
- 2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒
- 3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☒
- 4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒
- 5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3


I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.


Original Signature of Person Authorized to Submit Application, no copies or stamps

JUSTIN GRAVES
Print Name of Authorized Person

6-17-20
Date

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY

Page 6

OWNERSHIP IS A PARTNERSHIP

General _____

Limited ☒ (LLC)

LLC

Partnership Name: FAAMAKEIO OUTSOURCINGMailing Address: 920 S. KIMBALL AVE STE 100City: SOUTH LAKE State: TX Zip Code: 76092Telephone Number: 888-477-1567 Fax Number: 833-887-4969Contact Person: JUSTIN GRAVES

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
 Use separate sheet if necessary

Name	G or L	Percentage
SEE ATTACHED DOCUMENT		

List names of 4 largest partners and percentage of ownership:

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____



October 31, 2019

US FDA Dallas District Office (DAL-DO)
4040 North Central Expressway, Suite 300
Dallas, TX 75204
Phone: 214-253-5200
Fax: 214-253-5314

RE: Response to FDA Form 483 Observations

FEI: 3014982757 – FarmaKeio Outsourcing LLC
Inspection Dates: 10/22/2019 - 10/30/2019*

Greetings,

Please accept this letter as a formal response to observations listed in the FDA Form 483 issued to FarmaKeio Outsourcing LLC on 10/30/2019.

Observation 1

- The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the statement, "This is a compounded drug," is not on your drug product labels.

Response:

Section 503B(a)(10)(A)(i), states; "the statement 'This is a compounded drug.' or a reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug;"

Each product label produced by FarmaKeio Outsourcing LLC contains the phrase, "Compounded Drug" printed directly on the label. Given that the text allows for a "reasonable comparable alternative statement (as specified by the Secretary) that prominently identifies the drug as a compounded drug", FarmaKeio Outsourcing LLC believed the term "Compounded Drug" to be a reasonable alternative statement. FarmaKeio Outsourcing LLC product labels also contain the phrases, "Not for resale" and "Office Use Only" per Section 503B(a)(10)(A)(iii)(IX). This section explicitly states these terms are to be used verbatim and does not give an option for an alternative statement. FarmaKeio Outsourcing LLC will comply with FDA requests and add the phrase "This is a" to our product labels in front of the statement "Compounded Drug" which already exists on our product labels. We would respectfully request this item be moved from a 483 observation to a discussion item as the regulatory text causes confusion around whether the statement should be on the label verbatim.



Observation 2

- You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, a) you compound a drug product that is identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Response:

FarmaKeio Outsourcing LLC compounds Testosterone Pellets without PVP (polyvinylpyrrolidone) as some clinicians may consider this inactive an irritant, and pellets are compounded in strengths requested by practitioners to allow for more precise dosing of their patients. Testopel 75mg dosing is limited, as a clinician may wish to dose up to 2400mg of Testosterone in males, requiring up to #32 Testopel 75mg pellets. This number of pellets would most likely cause extrusions as opposed to using #12-200mg compounded Testosterone pellets. Clinicians also treat female patients requiring doses smaller than 75mg or doses that cannot be met by a combination of Testopel 75mg pellets.

Because of the different inactive as well as dosing differences, FarmaKeio Outsourcing LLC believes this constitutes a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

Observation 3

- Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, you are not monitoring the environmental conditions for each batch of product you manufacture.

Response:

At this time, FarmaKeio Outsourcing LLC only compounds solid dosage forms (pellets) which are terminally sterilized using irradiation, specifically, electron-beaming. FarmaKeio Outsourcing LLC **does not** currently compound sterile aqueous solutions requiring aseptic processing.

Per FDA Guidance for Industry 2004 on Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice, Section II(B); *“There are basic differences between the production of sterile drug products using aseptic processing and production using terminal sterilization.*

Terminal sterilization usually involves filling and sealing product containers under high-quality environmental conditions. Products are filled and sealed in this type of environment to minimize the microbial and particulate content of the in-process product and to help ensure that the subsequent sterilization process is successful. In most cases, the product, container, and closure have low bioburden,



but they are not sterile. The product in its final container is then subjected to a sterilization process such as heat or irradiation. In an aseptic process, the drug product, container, and closure are first subjected to sterilization methods separately, as appropriate, and then brought together. Because there is no process to sterilize the product in its final container, it is critical that containers be filled and sealed in an extremely high-quality environment. Aseptic processing involves more variables than terminal sterilization. Before aseptic assembly into a final product, the individual parts of the final product are generally subjected to various sterilization processes. For example, glass containers are subjected to dry heat; rubber closures are subjected to moist heat; and liquid dosage forms are subjected to filtration. Each of these manufacturing processes requires validation and control. Each process could introduce an error that ultimately could lead to the distribution of a contaminated product. Any manual or mechanical manipulation of the sterilized drug, components, containers, or closures prior to or during aseptic assembly poses the risk of contamination and thus necessitates careful control. A terminally sterilized drug product, on the other hand, undergoes final sterilization in a sealed container, thus limiting the possibility of error."

The excerpt above from the Guidance acknowledges the difference between Aseptic Processing and Terminal Sterilization. Both methods may be employed to produce sterile drugs, however, in the case of FarmaKeio Outsourcing LLC, terminal sterilization is the only method used at this time.

Per Guidance for Industry 2018, Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities Under Section 503B of the FD&C Act, Section III.B (Line 231), "Terminally sterilized drugs should be produced in ISO 8 or better air quality as determined under dynamic conditions." FarmaKeio Outsourcing LLC has certified the processing rooms in its facility as ISO 7 under dynamic conditions. The guidance goes on to specify that the environmental monitoring program should "Include at least daily monitoring of the ISO 5 zone during operations." (Line 399), however, as our process uses terminal sterilization which requires ISO 8 or better air quality, we do not require ISO 5 areas and therefore do not meet the conditions for the daily ISO 5 monitoring. Line 365 states, "The frequency and methods of environmental and personnel control and monitoring should be commensurate with the risk to product quality." Terminal sterilization has a much lower risk of producing a non-sterile product compared to aseptic processing and therefore is justification for less frequent monitoring.

FarmaKeio Outsourcing LLC monitors the certified cleanroom environments where components are manipulated outside of their original container and where pellets are produced and packaged, by performing viable air and surface sampling as well as non-viable particulate monitoring at least monthly. FarmaKeio Outsourcing LLC also monitors personnel, monthly, by performing gloved fingertip tests and viable garb sampling to ensure personnel are able to don their sterile garb aseptically and, therefore, not add bioburden to the process. FarmaKeio Outsourcing LLC had planned to increase monitoring activities to weekly in an abundance of caution to ensure the facility maintains a state of control with regards to facility maintenance and to ensure bioburden is minimized prior to sterilization. We as a firm feel this to be compliant with regards to 21 CFR Part 211.42(c) since the regulations do not specify Environmental Monitoring with every batch when terminal sterilization is used to produce sterile product.



FarmaKeio Outsourcing LLC, will comply and monitor the environmental conditions for each batch of product we manufacture if that is indeed the FDA's expectation, however, we would like to respectfully bring to the attention of the Administration that this expectation is not reflected in the regulations with regards to processes utilizing terminal sterilization instead of aseptic processing. We would respectfully request this item be moved from a 483 observation to a discussion item if it is determined that FarmaKeio Outsourcing LLC's current environmental monitoring processes are compliant.

Regards,

Cody Boatman
Chief Operating Officer
FarmaKeio Outsourcing, LLC

DEPARTMENT OF HEALTH AND HUMAN SERVICES FDA AND DRUG ADMINISTRATION																																																																											
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314		DATE OF INSPECTION 10/22/2019-10/26/2019 FBI NUMBER 3014982757																																																																									
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Cody Boatman, COO																																																																											
FIRM NAME FARMACEUTICAL OUTSOURCING LLC		STREET ADDRESS 920 S Kimball Ave Ste 100																																																																									
CITY, STATE, ZIP CODE, COUNTRY Southlake, TX 76092-9019		TYPE ESTABLISHMENT INSPECTED Pharmaceutical Drug Manufacturer Outsourcing Facility																																																																									
<p>This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.</p>																																																																											
<p>DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1</p> <p>The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). Specifically, the statement, "This is a compounded drug," is not on your drug product labels.</p> <ul style="list-style-type: none"> • Labels for the following drug products do not contain this statement include: <table border="1" style="margin: 10px auto; border-collapse: collapse; text-align: center;"> <thead> <tr> <th>Drug Name</th> <th>Drug Form</th> <th>Drug Strength</th> </tr> </thead> <tbody> <tr><td>TESTOSTERONE / TRIAMCINOLONE</td><td>PELLET</td><td>100MG / 20MCG</td></tr> <tr><td>TESTOSTERONE / TRIAMCINOLONE</td><td>PELLET</td><td>200MG / 40MCG</td></tr> <tr><td>TESTOSTERONE / TRIAMCINOLONE</td><td>PELLET</td><td>87.5MG / 17.5MCG</td></tr> <tr><td>TESTOSTERONE / TRIAMCINOLONE</td><td>PELLET</td><td>62.5MG / 12.5MCG</td></tr> <tr><td>TESTOSTERONE / TRIAMCINOLONE</td><td>PELLET</td><td>50MG / 10MCG</td></tr> <tr><td>TESTOSTERONE / TRIAMCINOLONE</td><td>PELLET</td><td>37.5MG / 7.5MCG</td></tr> <tr><td>TESTOSTERONE / TRIAMCINOLONE</td><td>PELLET</td><td>25MG / 5MCG</td></tr> <tr><td>TESTOSTERONE / TRIAMCINOLONE</td><td>PELLET</td><td>12.5MG / 2.5MCG</td></tr> <tr><td>ESTRADIOL</td><td>PELLET</td><td>6 MG</td></tr> <tr><td>ESTRADIOL</td><td>PELLET</td><td>10MG</td></tr> <tr><td>ESTRADIOL</td><td>PELLET</td><td>12.5MG</td></tr> <tr><td>ESTRADIOL</td><td>PELLET</td><td>15MG</td></tr> <tr><td>ESTRADIOL</td><td>PELLET</td><td>18MG</td></tr> <tr><td>ESTRADIOL</td><td>PELLET</td><td>20MG</td></tr> <tr><td>ESTRADIOL</td><td>PELLET</td><td>25MG</td></tr> <tr><td>TESTOSTERONE</td><td>PELLET</td><td>12.5MG</td></tr> <tr><td>TESTOSTERONE</td><td>PELLET</td><td>25MG</td></tr> <tr><td>TESTOSTERONE</td><td>PELLET</td><td>37.5MG</td></tr> <tr><td>TESTOSTERONE</td><td>PELLET</td><td>50MG</td></tr> <tr><td>TESTOSTERONE</td><td>PELLET</td><td>62.5MG</td></tr> <tr><td>TESTOSTERONE</td><td>PELLET</td><td>87.5MG</td></tr> <tr><td>TESTOSTERONE</td><td>PELLET</td><td>100MG</td></tr> <tr><td>TESTOSTERONE</td><td>PELLET</td><td>200MG</td></tr> </tbody> </table>				Drug Name	Drug Form	Drug Strength	TESTOSTERONE / TRIAMCINOLONE	PELLET	100MG / 20MCG	TESTOSTERONE / TRIAMCINOLONE	PELLET	200MG / 40MCG	TESTOSTERONE / TRIAMCINOLONE	PELLET	87.5MG / 17.5MCG	TESTOSTERONE / TRIAMCINOLONE	PELLET	62.5MG / 12.5MCG	TESTOSTERONE / TRIAMCINOLONE	PELLET	50MG / 10MCG	TESTOSTERONE / TRIAMCINOLONE	PELLET	37.5MG / 7.5MCG	TESTOSTERONE / TRIAMCINOLONE	PELLET	25MG / 5MCG	TESTOSTERONE / TRIAMCINOLONE	PELLET	12.5MG / 2.5MCG	ESTRADIOL	PELLET	6 MG	ESTRADIOL	PELLET	10MG	ESTRADIOL	PELLET	12.5MG	ESTRADIOL	PELLET	15MG	ESTRADIOL	PELLET	18MG	ESTRADIOL	PELLET	20MG	ESTRADIOL	PELLET	25MG	TESTOSTERONE	PELLET	12.5MG	TESTOSTERONE	PELLET	25MG	TESTOSTERONE	PELLET	37.5MG	TESTOSTERONE	PELLET	50MG	TESTOSTERONE	PELLET	62.5MG	TESTOSTERONE	PELLET	87.5MG	TESTOSTERONE	PELLET	100MG	TESTOSTERONE	PELLET	200MG
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SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Francis A Guidry, Investigator (Biotechnology) 																																																																									
		DATE ISSUED 10/30/2019 <div style="text-align: right; font-size: small;"> Francis A Guidry Investigator (Biotechnology) Signed By: Francis A Guidry, 2 Date Signed: 10/30/2019 12:12 </div>																																																																									

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION		
DISTRICT ADDRESS AND PHONE NUMBER 4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax: (214) 253-5314	DATE OF INSPECTION 10/21/2019-10/30/2019 ESTABLISHMENT 3014982757	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS MADE Cody Boatman, COO		
*FIRM NAME FARMAKIO OUTSOURCING LLC	STREET ADDRESS 920 S Kimball Ave Ste 100	
CITY, STATE AND CODE, COUNTRY Southlake, TX 76092-9019	TYPE OF ESTABLISHMENT OR OPERATION Prescription Drug Manufacturer	
<p>OBSERVATION 2</p> <p>You compound drugs that are essentially a copy of one or more approved drugs within the meaning of sections 503B(a)(5) and 503B(d)(2). Specifically, a) you compound a drug product that is identical or nearly identical to an approved drug that is not on the drug shortage list in effect under section 506F at the time of compounding, distribution, and dispensing; or b) are not identical or nearly identical to an approved drug, but contain a bulk drug substance that is also a component of an approved drug, and for which there is no change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.</p> <p>Examples of compounded drug products that are essentially a copy of one or more approved drugs include:</p> <ul style="list-style-type: none"> Testosterone Pellets in 12.5 mg, 25 mg, 37.5 mg, 50 mg, 62.5 mg, 87.5 mg, 100 mg, and 200 mg strengths. <p>OBSERVATION 3</p> <p>Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, you are not monitoring the environmental conditions for each batch of product you manufacture.</p> <p>Examples of compounded drug products lots that were ^{NOT} ^{AC} environmentally monitored during production:</p> <ul style="list-style-type: none"> BR, Lot 176, and BR, Lot 178 		
<p>*DATES OF INSPECTION</p> <p>10/22/2019(Tue), 10/23/2019(Wed), 10/24/2019(Thu), 10/25/2019(Fri), 10/28/2019(Mon), 10/29/2019(Tue), 10/30/2019(Wed)</p>		
SEE REVERSE OF THIS PAGE	EMPLOYER'S SIGNATURE Francis A Guidry, (Investigator) (Biotechnology) <div style="text-align: center; margin-top: 10px;"> </div>	DATE ISSUED 10/30/2019

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

- * Please contact this office immediately if any information on this license is incorrect.
- * This license must be displayed at the address licensed.
- * The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a \$100.00 delinquency fee for each location and must be remitted before the license will be issued.
- * A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at www.dshs.state.tx.us/fdlicense.
- * If you have any questions or desire additional information concerning the application process or this license, please contact the Food and Drug Licensing Group at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: <https://reglicensing.questionpro.com>. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

FARMAKEIO OUTSOURCING
920 S KIMBALL AVE STE 100
SOUTHLAKE TX 76092

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

FARMAKEIO OUTSOURCING LLC DBA
FARMAKEIO OUTSOURCING
920 S KIMBALL AVE STE 100
SOUTHLAKE, TX 76092

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

PRESCRIPTION DRUG MANUFACTURER

License # 1002630
Expires: October 17, 2020

NON-TRANSFERABLE


Commissioner

511290

FarmaKeio Outsourcing LLC.
Manager Information

Name:

Address:

Ownership %:

Managing Member
Dan DeNeui-CEO

Bowman Dr, Colleyville, TX 76034 (60%)

DOB:

Phot

DL

Managing Member
Michael Cole-CFO

Southview Trail, Southlake, TX 76092 (25%)

994

Member
Cody Boatman-COO

Cl Greenville, TX 75401 (5%)

Member
Robert Harris-Partner

Serenity Ave, Wylie, TX 75098 (5%)

86

66

Member
Justin Graves-Quality Director

4 Rabbit Ridge Road Heath, TX 75032 (5%)

7

Business address and phone number for all members above:

J. Kimball Ave.
Suite 100
Southlake, TX 76092
817-203-8216
Fax 833-887-4969



TEXAS
Health and Human
Services

Texas Department of State Health Services

John Hellerstedt, M.D.
Commissioner

April 28, 2020

Justin Graves
Farmakeio Outsourcing
920 S. Kimball Ave., Suite 100
Southlake, TX 76092

CFN: 2079625
Lic.: 1002630
Type: 2501
File: 5676

Re: License Verification NV

Dear Mr. Graves:

Enclosed is the license information you requested for Farmakeio Outsourcing, LLC located at 920 South Kimball Avenue, Suite 100, Southlake, Texas, 76092. The firm currently holds license number 1002630 as a prescription drug manufacturer (outsourcing facility) in Texas and is in good standing.

If you have questions or need additional information, please contact me or Mr. Justin Arnold at 512-834-6755, via fax at (512) 834-6759, or email me at Karen.Tannert@dshs.texas.gov.

Sincerely,

Karen Tannert For!

Karen Tannert, R.Ph., M.P.H.
Drugs and Medical Devices Unit
Consumer Protection Division

Mailing address:

Karen Tannert
Drugs and Medical Devices Unit MC 1987
PO Box 149347
Austin, TX 78714-9347

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: FARMAKEIO Outsourcing

Address: 920 S. KIMBALL AVE. STE. 100

City: SOUTH LAKE State: TX Zip: 76092

I hereby authorize the TEXAS DEPARTMENT OF STATE ^{HEALTH} SERVICES to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [Signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO NOT WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
1002630	Current	04/17/2020	01/09/2022

Has this license been encumbered in any way? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Type of Encumbrance: (if any) <input type="checkbox"/> Revoked <input type="checkbox"/> Surrendered <input type="checkbox"/> Limited <input type="checkbox"/> Suspended <input type="checkbox"/> Restricted <input type="checkbox"/> Probation Please attach copies of any pertinent legal documents
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USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
Has applicant met all licensing requirements of your state? (If no, please explain)	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No

Signature of State Official	Title	State	Date	State Seal
<u>Justin Arnold for Karen Tannert</u>	<u>Compliance Officer Chief Pharmacist</u>	<u>TX</u>	<u>04/28/2020</u>	