



IN THE MATTER OF:

**CASE NOS. A-2022-0406
A-2023-0435**

Jungle Jim's Pharmacy
c/o Ronald Ferguson, RPh
5484 Dixie Highway
Fairfield, OH 45041

License No. 02-1513150

SETTLEMENT AGREEMENT WITH THE OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the Ohio Board of Pharmacy (Board) and Jungle Jim's Pharmacy for the purpose of resolving all issues between the parties relating to the Board investigation of following compounding guidelines, failure to verify licenses, and positive identification compliance. Together, the Board and Jungle Jim's Pharmacy are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. Jungle Jim's Pharmacy is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1513150.

FACTS

1. The Board initiated an investigation of Jungle Jim's Pharmacy, Terminal Distributor of Dangerous Drugs license number 02-1513150, related to following compounding guidelines, failure to verify licenses, and positive identification compliance.
2. On or about December 11, 2023, the Board sent a Notice of Opportunity for Hearing to Jungle Jim's Pharmacy, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.
3. On or about December 28, 2023, Jungle Jim's Pharmacy, through counsel Elizabeth Collis and Greg Tapoci, timely requested an administrative hearing, which was subsequently scheduled for August 6, 2024.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative proceedings.

TERMS

NOW THEREFORE, in consideration of the mutual promises herein expressed, the parties knowingly and voluntarily agree as follows:

1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.
2. Jungle Jim's Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated December 11, 2023; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
3. Jungle Jim's Pharmacy agrees to pay to the Board a monetary penalty the amount of \$2,500. This fine will be attached to your license record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine you must login to www.elicense.ohio.gov and process the items in your cart.
4. The Board hereby imposes a written reprimand on Jungle Jim's Pharmacy's TDDD license, number 02-1513150.
5. Jungle Jim's Pharmacy agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.
6. Jungle Jim's Pharmacy agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Jungle Jim's Pharmacy of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Jungle Jim's Pharmacy by the Board and will NOT discharge Jungle Jim's Pharmacy from any obligation under the terms of this Agreement.
7. Jungle Jim's Pharmacy agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
8. Jungle Jim's Pharmacy understands that it has the right to be represented by counsel for review and execution of this agreement.

9. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Jungle Jim's Pharmacy will operate.
10. Jungle Jim's Pharmacy explicitly withdraws its request for a hearing, waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code, and waives any right to an appeal.
11. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.
12. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.
13. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.
14. If any of the provisions, terms, or clauses of this Agreement are declared illegal, unenforceable, or ineffective by an authority of competent jurisdiction, those provisions, terms, and clauses shall be deemed severable, such that all other provisions, terms, and clauses of this Agreement shall remain valid and binding upon both Parties.
15. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

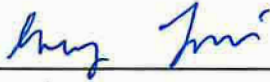
Approved by:



Ronald Ferguson, on behalf of,
Jungle Jim's Pharmacy, Respondent

7/26/24

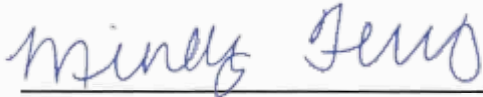
Date of Signature



Greg Tapoci
Attorney for Respondent

7-26-24

Date of Signature



Mindy Ferris, RPh, President,
Ohio Board of Pharmacy

07.29.2024

Date of Signature



**NOTICE OF OPPORTUNITY FOR HEARING
FOR TERMINAL DISTRIBUTOR OF DANGEROUS DRUGS LICENSE**

IN THE MATTER OF:

**CASE No. A-2022-0406
A-2023-0435**

Jungle Jim's Pharmacy
c/o Ronald Ferguson, RPh
5484 Dixie Highway
Fairfield, OH 45041

License No. 02-1513150

December 11, 2023

Dear Ronald Ferguson, RPh and Jungle Jim's Pharmacy:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code, the State of Ohio Board of Pharmacy (Board) proposes to take disciplinary action against your license as a Terminal Distributor of Dangerous Drugs (TDDD) under authority of Section 4729.57.

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code (ORC) and the rules adopted thereunder, the Board has the authority to suspend, revoke, restrict, limit, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or \$1,000 if the acts committed have not been classified as an offense by the ORC.
2. Jungle Jim's Pharmacy is a Licensed TDDD under License No. 02-1513150, which lists the Responsible Person as Ronald Ferguson, RPh.

ALLEGATIONS

1. On or about March 11, 2019, a Board inspection revealed significant sterile compounding violations, which resulted in Jungle Jim's Pharmacy entering into an agreement with the Board to dispense all sterile compounded products with a beyond-use date (BUD) of one-hour, until the pharmacy was found by the Board to be compliant with United States Pharmacopeia Chapter 797 (USP 797), ORC 4729, and chapter 4729-16 of the Ohio Administrative Code (OAC). The violations consisted of the following:
 - a. The pharmacy did not have a policy and procedure manual.
 - b. The pharmacy did not have a sterile compounding training program.

77 South High Street, 17th Floor, Columbus, Ohio 43215

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- c. The pharmacy did not have documentation of any sterile compounding training being completed.
- d. The pharmacy did not have documentation that staff had completed and passed a didactic compounding review and exam prior to compounding and annually/semi-annually thereafter.
- e. The pharmacy did not have documentation that staff had completed and passed an initial observed gowning procedure or gloved fingertip sampling test.
- f. The pharmacy did not have documentation that staff had completed and passed an annual/semi-annual gowning procedure or gloved fingertip sampling test.
- g. The pharmacy did not have documentation that compounding personnel had passed a media fill test of appropriate breadth and depth prior to compounding and at least annually/semi-annually.
- h. The pharmacy did not have documentation that compounding personnel who had failed gloved fingertip or media fill testing were prohibited from compounding until training was performed/reviewed, and subsequent testing was performed correctly because no testing had been performed.
- i. The pharmacy did not have documentation to demonstrate employees engaged in sterile compounding have ever passed an initial or semi-annual observation compounding skills assessment.
- j. The pharmacy did not have documentation that compounding personnel had received training on the operation of any equipment that may be used when preparing compounded sterile products.
- k. Bulk active pharmaceutical ingredients (APIs) were not labeled with the date of receipt by the pharmacy.
- l. The ISO 7 ante and buffer areas certification did not identify the vendor as a CETA certified vendor or note that they test according to CETA standards.
- m. The certification report did not include information about the equipment used for performing calibration testing. The report only indicated the name of the equipment.
- n. The certification report did not identify testing was performed to determine air changes per hour (ACPH).
- o. The certification report did not indicate differential air pressures being measured and recorded during certification.
- p. The certification report did not indicate the high efficiency particulate air (HEPA) filters as having been leak tested.
- q. Surface sampling had not been conducted at the pharmacy.

- r. No soap and/or towels were located near the sink in the ante area.
 - s. There were no primary engineering controls located within the ISO 7 buffer area. High risk sterile compounding was performed on a pellet press located on a reinforced marble table within ISO 7 buffer area. No ISO 5 primary engineering control was present.
 - t. A dehumidifier was located in the buffer area.
 - u. Cleaning only occurred with non-sterile rubbing alcohol.
 - v. There was no clear line of demarcation to demonstrate the “clean vs dirty” side of the ante-room.
 - w. Sterile gloves were not used when performing sterile compounding.
 - x. The pharmacy did not use sterile 70% Isopropyl alcohol when disinfecting contaminated gloved hands.
 - y. Extended Beyond Use Dates (BUDs) were not supported with stability documentation.
 - z. Compounded Sterile Preparation (CSP) were not being verified to maintain their full chemical and physical stability during the autoclave cycle.
2. As a result of remediation efforts by Jungle Jim’s Pharmacy, the Board, on or about January 17, 2020, authorized Jungle Jim’s Pharmacy to resume sterile compounding including for hormone pellets using beyond use dates allowed by USP 797 unless sterility/stability data was present to justify otherwise.
 3. From on or about July 10, 2020 to on or about February 26, 2021, Jungle Jim’s Pharmacy sold dangerous drugs to an unlicensed entity. The dangerous drugs illegally sold were as follows:
 - a. On or about July 10, 2020, One (1) sodium bicarbonate 8.4% 100mL vial (Rx #718123).
 - b. On or about July 10, 2020, Five (5) Lidocaine 2% with epinephrine 20mL vials (Rx #718122).
 - c. On or about December 15, 2020, One (1) Lidocaine 2% with epinephrine 20mL vial (Rx #718416).
 - d. On or about February 26, 2021, Five (5) Lidocaine 2% with epinephrine 20mL vials (Rx #718539).
 4. From on or about March 15, 2021 to on or about April 6, 2021, Jungle Jim’s Pharmacy dispensed and/or sold patient specific dangerous drugs to an unlicensed entity. The patient specific dangerous drugs illegally dispensed and/or sold were as follows:
 - a. On or about March 15, 2021, the pharmacy dispensed one (1) testosterone 25mg pellet (Rx #C300352), one (1) testosterone 100mg pellet (Rx #C300353) and one (1) sterile implant kit (Rx300354) to patient C.S.

- b. On or about March 15, 2021, the pharmacy dispensed one (1) estradiol 15mg pellet (Rx #C300355), one (1) testosterone 25mg pellet (Rx #C300356), one (1) testosterone 100mg pellet (Rx #C300357), and one (1) sterile implant kit (Rx300358) to patient M.H.
 - c. On or about March 16, 2021, the pharmacy dispensed one (1) estradiol 10mg pellet (Rx #C300349), one (1) testosterone 100mg pellet (Rx #C300350) and one (1) sterile implant kit (Rx300351) to patient S.S.
 - d. On or about March 19, 2021, the pharmacy dispensed seven (7) testosterone 200mg pellets (Rx #C300536) and one (1) sterile implant kit (Rx300354) to patient C.B.
 - e. On or about March 22, 2021, the pharmacy dispensed one (1) testosterone 100mg pellet (Rx #C300562), one (1) estradiol 12.5mg pellet (Rx #C300563) and one (1) sterile implant kit (Rx300561) to patient K.B.
 - f. On or about April 6, 2021, the pharmacy dispensed eight (8) testosterone 200mg pellets (Rx #C300971) and one (1) sterile implant kit (Rx300972) to patient P.R.
5. On or about October 19, 2023, a Specialist from the Board conducted an inspection at Jungle Jim's Pharmacy, located at 5484 Dixie Highway, Fairfield, Ohio. The following violations were found:
- a. The pharmacy had not performed verification of Pick-up Station locations and was not able to determine each site's eligibility to receive and store patient specific dangerous drugs.
 - b. The pharmacy purchased dangerous drugs from a wholesaler that does not have a license from the Board.
 - c. There was no documented elicense query of the Board's online roster prior to the purchase of dangerous drugs at wholesale.
 - d. There was only capture for positive identification with dispensing. All other required elements, prescription information entered into the record keeping system, verification of pharmacist of the prescription information entered into the record keeping system, and prospective drug utilization review as a part of pharmacist verification, were not maintained with positive identification.
 - e. Positive identification was not captured within the repackaging record of sterile products.
 - f. You had a refrigerator that is monitored with a log missing weekend entries and times.

POTENTIAL VIOLATIONS OF LAW

- 1. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57 of the ORC, effective September 29, 2017, each violation punishable by a maximum penalty of \$1,000:
 - a. Violating any rule of the board, ORC Section 4729.57(B)(2); and/or

- b. Violating any provision of this chapter, ORC Section 4729.57(B)(3); and/or
 - c. Except as provided in section 4729.89 of the Revised Code, violating any provision of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, or Chapter 3715. of the Revised Code, ORC Section 4729.57(B)(4); and/or
 - d. Ceasing to satisfy the qualifications of a TDDD set forth in section 4729.55 of the Revised Code, ORC Section 4729.57(B)(7).
- 2. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.55 of the ORC, effective April 6, 2017, March 22, 2020, and March 31, 2021, TDDD license requirements:
 - a. Adequate safeguards are assured that the applicant will carry on the business of a terminal distributor of dangerous drugs in a manner that allows pharmacists and pharmacy interns employed by the terminal distributor to practice pharmacy in a safe and effective manner, ORC 4729.55(D); and/or
 - b. If the applicant, or any agent or employee of the applicant, has been found guilty of violating section 4729.51 of the Revised Code, the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, the federal drug abuse control laws, Chapter 2925., 3715., 3719., or 4729. of the Revised Code, or any rule of the board, adequate safeguards are assured to prevent the recurrence of the violation, ORC 4729.55(E).
- 3. Such conduct as set forth in the Allegations Section, inclusive, if proven, constitutes a violation of the following sections of Rule 4729:5-2-01 of the OAC, Responsible Person of a Terminal Distributor, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000:
 - a. The responsible person shall be responsible for the practice of the profession of pharmacy, including, but not limited to, the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required, OAC Rule 4729:5-2-01(A)(2); and/or
 - b. The person to whom the terminal distributor of dangerous drugs license has been issued and all pharmacists on duty are responsible for compliance with all state and federal laws, regulations, and rules governing the distribution of drugs and the practice of pharmacy, OAC Rule 4729:5-2-01(A)(3).
- 4. Such conduct as set forth in paragraphs (1)(a) – (1)(z), inclusive, of the Allegations Section, inclusive, if proven, constitutes a violation of the following sections of Rule 4729-16-03(B) of the OAC, for all sterile compounded drug products, the pharmacy shall comply with the United States pharmacopeia chapter 797, USP 38 - NF 33, or any official supplement thereto (9/10/2015), each violation punishable by a maximum penalty of \$1,000.

5. Such conduct as set forth in paragraphs (3)(a), (3)(b), (3)(c), (3)(d), (4)(a), (4)(b), (4)(c), (4)(d), (4)(e), and (4)(f) of the Allegations Section, if proven, each constitutes a violation of Section 4729.51(A) of the ORC, No person other than a licensed manufacturer of dangerous drugs, outsourcing facility, third-party logistics provider, repackager of dangerous drugs, or wholesale distributor of dangerous drugs shall possess for sale, sell, distribute, or deliver, at wholesale, dangerous drugs or investigational drugs or products, each punishable by a maximum fine of \$5,000, if committed by an organization.
6. Such conduct as set forth in paragraphs (3)(a), (3)(b), (3)(c), (3)(d), (4)(a), (4)(b), (4)(c), (4)(d), (4)(e), and (4)(f) of the Allegations Section, if proven, each constitutes a violation of Section 4729.51(B)(1) of the ORC, No licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor shall possess for sale, sell, or distribute, at wholesale, dangerous drugs or investigative drugs or products to any person other than the following, a licensed terminal distributor of dangerous drugs, each punishable by a maximum fine of \$5,000, if committed by an organization.
7. Such conduct as set forth in Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-4-01 of the OAC, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:
 - a. Violating any rule of the board, OAC Rule 4729:5-4-01(B)(2); and/or
 - b. Violating any provision of Chapter 4729. of the Revised Code, OAC Rule 4729:5-4-01(B)(3); and/or
 - c. The method used by the terminal distributor to store, possess, or distribute dangerous drugs poses serious harm to others, OAC Rule 4729:5-4-01(B)(25).
8. Such conduct as set forth in paragraphs (3)(a), (3)(b), (3)(c), and (3)(d) of the Allegations Section, if proven, each constitutes a violation of 4729:5-3-09(A) of the OAC, Occasional Sales, effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000.
9. Such conduct as set forth in paragraphs (4)(a), (4)(b), (4)(c), (4)(d), (4)(e), (4)(f), and (5)(a) of the Allegations Section, if proven, each constitutes a violation of Rule 4729:5-5-14(B)(1) of the OAC, Prescription Processes, no pharmacist shall dispense dangerous drugs to a place which offers, in any manner, its services as a “pick-up station” or intermediary for the purpose of having prescriptions filled or delivered unless such place is a pharmacy as defined in section 4729.01 of the Revised Code or, if not a pharmacy, the site is licensed as a terminal distributor of dangerous drugs pursuant to Chapter 4729. of the Revised Code, unless exempted pursuant to section 4729.541 of the Revised Code or a waiver is granted by the Board, each violation is punishable by a maximum penalty of \$1,000.
10. Such conduct as set forth in paragraph (5)(b) of the Allegations Section, if proved, each constitutes a violation of Rule 4729:5-3-04(B), Verification of licensure prior to sale or purchase, if no documented query is conducted before a purchase is made, it shall be presumed that the purchase of dangerous drugs by the terminal distributor is in violation of 4729.51 of the Revised Code, effective, March 1, 2019, each violation is punishable by a maximum penalty of \$1,000.
11. Such conduct as set forth in paragraph (5)(c) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-3-04(A) of the OAC, Verification of licensure prior to sale

or purchase, as effective March 1, 2019, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:

- a. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the boards online roster (available on the boards website: www.pharmacy.ohio.gov) to confirm the seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code, OAC Rule 4729:5-3-04(A)(1); and/or
- b. Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall query the boards online roster (available on the boards website: www.pharmacy.ohio.gov) to confirm the seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code, OAC Rule 4729:5-3-04(A)(2).

12. Such conduct as set forth in paragraph (5)(d) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-04(A) of the OAC, Record Keeping, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:

- a. There shall be positive identification of the licensed or registered individuals responsible for performing prescription information entered into the record keeping system, OAC Rule 4729:5-5-04(A)(1); and/or
- b. There shall be positive identification of the licensed or registered individuals responsible for performing verification by the pharmacist of the prescription information entered into the record keeping system, OAC Rule 4729:5-5-04(A)(2); and/or
- c. There shall be positive identification of the licensed or registered individuals responsible for performing prospective drug utilization review, which shall be captured as a standalone action or part of the pharmacist verification of prescription information in paragraph (A)(2) of this rule, OAC Rule 4729:5-5-04(A)(3)(a).

13. Such conduct as set forth in paragraph (5)(e) of the Allegations Section, if proven, each constitutes a violation of the following sections of Rule 4729:5-5-17(F) of the OAC, Drugs repackaged or relabeled by a pharmacy, as effective December 1, 2020, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:

- a. A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be kept in a readily retrievable manner for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include the positive identification of the individual responsible for the repackaging of the drugs, OAC Rule 4729:5-5-17(F)(8); and/or
- b. A record of all drugs repackaged and stored within a pharmacy prior to being dispensed shall be kept in a readily retrievable manner for at least three years or one year past manufacturer's expiration date, whichever is greater. This record shall include the positive identification of the pharmacist conducting the final verification of the repackaged drug to confirm the accuracy of the

drug and conformity to the requirements of this rule prior to dispensing or distribution, OAC Rule 4729:5-5-17(F)(9).

14. Such conduct as set forth in paragraph (5)(f) of the Allegations Section, if proved, each constitutes a violation of Rule 4729:5-5-23(B)(1)(a), Security, control and storage of dangerous drugs in an outpatient pharmacy, Refrigerators and freezers used for the storage of dangerous drugs shall maintain temperature logs with, at a minimum, daily observations, to ensure proper refrigeration and/or freezer temperatures are maintained, effective, December 1, 2020, each violation is punishable by a maximum penalty of \$1,000.
15. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of the following divisions of Section 3715.52 of the ORC, constituting a misdemeanor of the fourth degree, each punishable by a maximum fine of \$2,000, if committed by an organization:
 - a. The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded, ORC 3715.52(A)(1); and/or
 - b. The adulteration or misbranding of any food, drug, device, or cosmetic, ORC 3715.52(A)(2).

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty (30) days of the date of the service of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (please note faxes will **not** be accepted). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE SERVICE DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a business entity, including but not limited to a corporation, limited liability company, or a limited partnership, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the service of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing, and may adopt a final order that contains the board's findings. In the final order, the board may impose any of the sanctions listed in division RC 4729.57(A).

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY


Steven W. Schierholt, Esq., Executive Director

SWS/jak/kll



IN THE MATTER OF:

CASE No. A-2020-0405

Jungle Jim's Pharmacy
c/o Amandeep Sharma
5484 Dixie Highway
Fairfield, OH 45014

License No. 02-1513150

SETTLEMENT AGREEMENT WITH THE STATE OF OHIO BOARD OF PHARMACY

This Settlement Agreement (Agreement) is entered into by the State of Ohio Board of Pharmacy (Board) and Jungle Jim's Pharmacy for the purpose of resolving all issues between the parties relating to the Board investigation of illegal purchases of Vivitrol, a dangerous drug, from two unlicensed entities, Dr. Aziz Pharmacy and Go Beyond Medicine. Together, the Board and Jungle Jim's Pharmacy are referred to hereinafter as "the parties."

JURISDICTION

1. Pursuant to Section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to Section 4729.54 of the Ohio Revised Code.
2. Jungle Jim's Pharmacy is a licensed Terminal Distributor of Dangerous Drugs under license number 02-1513150.

FACTS

1. The Board initiated an investigation of Jungle Jim's Pharmacy, Terminal Distributor of Dangerous Drugs license number 02-1513150, related to Jungle Jim's Pharmacy's illegal purchases of Vivitrol, a dangerous drug, from two unlicensed entities, Dr. Aziz Pharmacy and Go Beyond Medicine.
2. On or about February 24, 2021 the Board sent a Notice of Opportunity for Hearing to Jungle Jim's Pharmacy, which outlined the allegations and provided notice of its right to a hearing, its rights in such hearing, and its right to submit contentions in writing.

WHEREFORE, the parties desire to resolve the issues relating to the above-referenced findings without resorting to further administrative or judicial proceedings.

77 South High Street, 17th Floor, Columbus, Ohio 43215

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1. The recitals set forth above are incorporated in this Settlement Agreement as though fully set forth herein.
2. Jungle Jim's Pharmacy neither admits nor denies the allegations stated in the Notice of Opportunity for Hearing letter dated February 24, 2021; however, the Board has evidence sufficient to sustain the allegations, finds them to violate Ohio's pharmacy law as set forth in the Notice, and hereby adjudicates the same.
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4. Jungle Jim's Pharmacy agrees and acknowledges that this Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction, as required by any such state or jurisdiction, in which it currently holds a professional license, including the Board on renewal applications or applications for a new license.
5. Jungle Jim's Pharmacy agrees to comply with all federal and state requirements related to Terminal Distributors of Dangerous Drugs, including but not limited to, Ohio Revised Code Chapter 4729. and the Rules adopted thereunder, Chapter 3719. and the Rules adopted thereunder, Chapter 3715. and the Rules adopted thereunder as well as the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301 and Chapter 21, Section 360 of the United States Code, and Section 207.20 of the Code of Federal Regulations. Any violation by Jungle Jim's Pharmacy of the terms of one or more federal or state requirements may constitute sufficient grounds for further enforcement action related to any licenses granted to Jungle Jim's Pharmacy by the Board and will NOT discharge Jungle Jim's Pharmacy from any obligation under the terms of this Agreement.
6. Jungle Jim's Pharmacy agrees to pay all reasonable costs associated with the collection of any payment, and of the prosecution of any violation of this Agreement.
7. Jungle Jim's Pharmacy understands that it has the right to be represented by counsel for review and execution of this agreement.
8. This Agreement is binding upon any and all successors, assigns, affiliates, and subsidiaries of the parties or any other corporation through whom or with whom Jungle Jim's Pharmacy will operate.

9. Jungle Jim's Pharmacy waives its right to a hearing and an opportunity to be heard pursuant to Chapter 119. of the Ohio Revised Code and waives any right to an appeal.
10. This Agreement may be executed in counterparts or facsimiles, each of which shall be deemed an original, but all of which shall constitute one and the same instrument.
11. All parties to this Agreement understand that this document is a public record pursuant to Ohio Revised Code Section 149.43.
12. This Agreement contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies the terms of this Agreement.
13. This Agreement shall become effective upon the date of the Board President's signature below.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties to this Agreement have executed it and/or cause it to be executed by their duly authorized representatives.

Approved by:

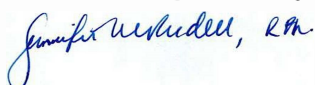


Amandeep Sharma, on behalf of,
Jungle Jim's Pharmacy, Respondent

03/10/2021

Date of Signature

Attorney for Respondent (if applicable)




Jennifer M. Rudell, RPh, President,
State of Ohio Board of Pharmacy

Date of Signature

3/11/2021

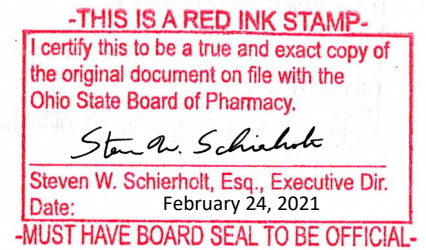
Date of Signature



Henry Appel, Ohio Assistant Attorney General

3/11/2021

Date of Signature



**NOTICE OF OPPORTUNITY FOR HEARING
PROPOSAL TO TAKE DISCIPLINARY ACTION AGAINST LICENSEE**

IN THE MATTER OF:

CASE No. A-2020-0405

Jungle Jim's Pharmacy
c/o Amandeep Sharma
5484 Dixie Highway
Fairfield, OH 45014

License No. 02-1513150

February 24, 2021

Dear Jungle Jim's Pharmacy and Amandeep Sharma:

You are hereby notified, in accordance with the provisions of Section 119.07 of the Ohio Revised Code the State of Ohio Board of Pharmacy (Board) proposes to take action against your license as a Terminal Distributor of Dangerous Drugs (TDDD) under authority of Section 4729.57 of the Revised Code.

JURISDICTION

1. Pursuant to section 4729.57 of the Ohio Revised Code and the rules adopted thereunder, the Board has the authority to suspend, revoke, or refuse to grant or renew any license issued pursuant to section 4729.55 of the ORC to practice as a TDDD in the state of Ohio. Additionally, Section 4729.57 of the Revised Code grants the Board the authority to impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or \$1,000 if the acts committed have not been classified as an offense by the ORC.
2. Jungle Jim's Pharmacy has an active TDDD license with the Board under license number 02-1513150, which lists Amandeep Sharma as the Responsible Person.

ALLEGATIONS

1. From on or about March 23, 2016 through on or about August 2, 2016, Jungle Jim's Pharmacy, located at 5484 Dixie Highway, Fairfield, Ohio, purchased Vivitrol, a dangerous drug, from an unlicensed entity, Dr. Aziz Pharmacy, located at 7320 E. 82nd Street, Suite D, Indianapolis, Indiana, as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. A total of 509 syringes of Vivitrol were purchased from Dr. Aziz Pharmacy while Dr. Aziz Pharmacy did not have an active Wholesale Distributor of Dangerous Drugs (WDDD) License.

77 South High Street, 17th Floor, Columbus, Ohio 43215

T: (614) 466.4143 | F: (614) 752.4836 | contact@pharmacy.ohio.gov | www.pharmacy.ohio.gov



2. From on or about September 20, 2016 through on or about December 14, 2016, Jungle Jim's Pharmacy, located at 5484 Dixie Highway, Fairfield, Ohio, purchased Vivitrol, a dangerous drug, from an unlicensed entity, Go Beyond Medicine, located at 737 Buttermilk Pike, Ft. Mitchell, Kentucky, as set forth in Attachment A, attached hereto and incorporated as though fully set forth herein. A total of 360 syringes of Vivitrol were purchased from Go Beyond Medicine while Go Beyond Medicine did not have an active Wholesale Distributor of Dangerous Drugs (WDDD) License.

POTENTIAL VIOLATIONS OF LAW

1. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.51(D) of the ORC, effective February 1, 2016 and August 9, 2016, No licensed terminal distributor of dangerous drugs shall purchase dangerous drugs from any person other than a licensed manufacturer, outsourcing facility, third-party logistics provider, repackager, or wholesale distributor, each violation is a misdemeanor of the first degree, punishable by a maximum penalty of \$5,000 if committed by an organization.
2. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of Section 4729.60(B) of the ORC, effective February 1, 2016 and September 8, 2016, Before a licensed terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale, the terminal distributor shall obtain from the seller and the seller shall furnish to the terminal distributor the number of the seller's registration certificate to engage in the sale of distribution of drugs, each violation punishable by a maximum penalty of \$1,000 if committed by an organization.
3. Such conduct as set forth in the Allegations Section, if proven, each constitutes a violation of the following section of Rule 4729-9-12(B) of the OAC, as effective October 5, 2015, each violation punishable by a maximum penalty of \$1,000 if committed by an organization: Before a terminal distributor of dangerous drugs may make a purchase of dangerous drugs at wholesale, the purchaser must obtain from the seller the wholesale distributor registration number pursuant to division (B) of section 4729.60 of the Revised Code.
4. Such conduct as set forth in Allegations Section, if proven, constitutes a violation of each of the following divisions of Section 4729.57(A) of the ORC, as effective March 13, 2013, each violation punishable by a maximum penalty of \$1,000 if committed by an organization:
 - a. Violating any rule of the board, ORC Section 4729.57(A)(2); and/or
 - b. Violating any provision of this chapter, ORC Section 4729.57(A)(3).
5. Such conduct as set forth in the Allegations Section, if proven, constitutes a violation of Rule 4729-9-19(A)(4) of the OAC, as effective October 5, 2015, punishable by a maximum penalty of \$1,000 if committed by an organization: Is not of good moral character and habits.

YOU ARE FURTHER NOTIFIED, in accordance with the provisions of Chapters 119. and 4729. of the Ohio Revised Code, that you are entitled to a hearing before the State of Ohio Board of Pharmacy, if you request such a hearing within thirty 30 days of the date of the mailing of this notice.

IF YOU DESIRE A HEARING, such request shall either be mailed to the State of Ohio Board of Pharmacy, Attn: Legal, 77 South High Street, 17th Floor, Columbus, Ohio 43215-6126 or an e-mail request may be sent to legal@pharmacy.ohio.gov (please note faxes will not be accepted). **YOUR REQUEST MUST BE RECEIVED ON OR PRIOR TO THE 30TH DAY FOLLOWING THE MAILING DATE OF THIS NOTICE.** Please note that if you submit a request via email, your request will be acknowledged within one business day of receipt. If you do not receive an acknowledgment, please contact the Board offices at 614-466-4143 and request the legal department. You may appear at such hearing in person, by your attorney, or by such other representative as is permitted to practice before the agency, or you may present your position, arguments, or contentions in writing; and, at this hearing, you may also present evidence and examine any witnesses appearing for and against you. **If you are a corporation, you must be represented at the hearing by an attorney licensed to practice in the state of Ohio.**

YOU ARE FURTHER ADVISED that if there is no request for such a hearing received by the Board on or prior to the 30th day following the mailing of this notice, the State of Board of Pharmacy, upon consideration of the aforementioned allegations against you, may take action without such a hearing.

If you have questions regarding the Chapter 119. Administrative Hearing process, please e-mail your questions to legal@pharmacy.ohio.gov or call the Board office at 614-466-4143 and ask for the legal department.

BY ORDER OF THE STATE BOARD OF PHARMACY



Steven W. Schierholt, Esq., Executive Director

SWS/mls/pae

Encl: Attachment A

CMRRR: 7020 3160 0000 6109 0632

			Attachment A		
		Case No. A-2020-0405	Jungle Jim's Pharmacy	License No. 02-1513150	
			Purchases made by Jungle Jim's Pharmacy		
Wholesaler	Date	Invoice Number	Medication	Package Size	Quantity
Dr. Aziz Pharmacy	3/23/2016	32316	Vivitrol	380 mg Susp	10
Dr. Aziz Pharmacy	3/29/2016	32916	Vivitrol	380 mg Susp	20
Dr. Aziz Pharmacy	4/14/2016	4142016	Vivitrol	380 mg Susp	15
Dr. Aziz Pharmacy	4/25/2016	4252016	Vivitrol	380 mg Susp	30
Dr. Aziz Pharmacy	5/4/2016	5042016	Vivitrol	380 mg Susp	30
Dr. Aziz Pharmacy	5/18/2016	5182016	Vivitrol	380 mg Susp	30
Dr. Aziz Pharmacy	5/25/2016	5252016	Vivitrol	380 mg Susp	20
Dr. Aziz Pharmacy	6/2/2016	6022016	Vivitrol	380 mg Susp	20
Dr. Aziz Pharmacy	6/6/2016	6062016	Vivitrol	380 mg Susp	40
Dr. Aziz Pharmacy	6/21/2016	6212016	Vivitrol	380 mg Susp	40
Dr. Aziz Pharmacy	7/1/2016	7012016	Vivitrol	380 mg Susp	40
Dr. Aziz Pharmacy	7/7/2016	7072016	Vivitrol	380 mg Susp	40
Dr. Aziz Pharmacy	7/15/2016	7152016	Vivitrol	380 mg Susp	33
Dr. Aziz Pharmacy	7/20/2016	7202016	Vivitrol	380 mg Susp	21
Dr. Aziz Pharmacy	7/26/2016	7262016	Vivitrol	380 mg Susp	40
Dr. Aziz Pharmacy	7/27/2016	7272016	Vivitrol	380 mg Susp	40
Dr. Aziz Pharmacy	8/2/2016	8022016	Vivitrol	380 mg Susp	40
				TOTAL	509
Wholesaler	Date	Invoice Number	Medication	Package Size	Quantity
Go Beyond Medicine	9/20/2016	231	Vivitrol	380 mg Susp	30
Go Beyond Medicine	9/28/2016	233	Vivitrol	380 mg Susp	50
Go Beyond Medicine	10/11/2016	241	Vivitrol	380 mg Susp	60
Go Beyond Medicine	11/1/2016	256	Vivitrol	380 mg Susp	60
Go Beyond Medicine	11/7/2016	258	Vivitrol	380 mg Susp	60
Go Beyond Medicine	11/9/2016	259	Vivitrol	380 mg Susp	50
Go Beyond Medicine	12/14/2016	273	Vivitrol	380 mg Susp	50
				TOTAL	360