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Kansas
Board of Pharmacy

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Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

November 1, 2023

Excite Pharma Services
1205 State Ave
Tonganoxie KS 66086

RE: Case No. 23-316

To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

cc: kkoehler@excitepharma.com

BEFORE THE KANSAS STATE BOARD OF PHARMACY

In the Matter of Exite Pharma Services, LLC Applicant	)	Case No. 23-316

SUMMARY ORDER

NOW, on this 1st day of November 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Excite Pharma Services, LLC ("Applicant").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.,* and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.,* the Board enters this Summary Order of Denial in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. On July 21, 2023, the Board received Applicant's application for registration as an outsourcing facility in the State of Kansas ("Applicant's Application").

2. Applicant answered "yes" to the following questions on Applicant's Application:

   a. Has the applicant complied with all registration requirements under any previous or current licenses or registrations?

   b. Has the applicant complied with all requirements to maintain and make available to the Board or to any federal, state, or local law enforcement officials those records required by the Food, Drug, and Cosmetic Act?

   c. Has each employee or associated engaged in any distribution activity had

education, training, or experience sufficient for that individual to perform assigned functions in such a manner as to provide assurance that the product, quality, safety, and security will at all times be maintained as required by any federal or state law?

3. Applicant's Application included certifications from the pharmacist-in-charge, designated representative, and owner that they each accepted responsibility for the operations of the facility and ensured compliance with relevant laws.

4. On July 25, 2023, the Board's inspectors conducted an in-person, pre-opening inspection of Applicant's facility.

5. During the inspection, the Board's inspectors observed and noted the following in the facility:

a. Gap between the floor and an external door. Daylight could be seen through the gap.

b. Exterior doors with gaps at bottom large enough to see outside light coming through.

c. Hormone compounding being performed in area that is not negative pressure room (plastic meat locker strips are the "walls" with no ventilation to outside through roof. Board staff were told "only males work in this area" and is part of manufacturing, but all facility staff must pass through this area to get to the prospective outsourcing compounding area.

d. Storage area was extremely warm. Board staff were informed that the air conditioning had gone out. No alarms or notification systems in place to alert quality staff or pharmacist-in-charge ("PIC"). Temperature recorded by

inspector was greater than 85 degrees Fahrenheit.

e. Ceiling security where controlled substance safes are located is suspect. Unclear whether control room can be accessed via hallway ceiling. Main door requires codes from two people to enter. However, there is a second door to the room which can be accessed from a separate room, that is a keyed lock. Key is held by owner. Room also has used and uncertified equipment stored.

6. During the inspection, the Board's inspectors observed and noted the following in the facility's designated clean room area:

a. Handwashing prior to garbing is performed in bathroom down the hall from the entrance to the garbing area. Bathroom sink is next to toilet.

b. Room adjacent to ISO 7 room where garbing is performed is not even controlled non-classified (CNC). No sink to wash hands; requirement to sign book with pen that could be touched multiple times by multiple people throughout the day.

c. In compounding area ISO 6 room, the ceiling tiles are not sealed and several were popping up to where space above ceiling was visible. Facility staff informed a Board inspector that the facility was waiting for someone to come and "fix" so they were "working dirty" at the present time. Facility staff indicated that they had work orders in for the room but had no anticipated timeline for completion.

d. Faucet fixture in ISO 6 room with floor basin and drain. Faucet was said to be capped off, but floor drain is not. Media fill was reportedly performed in this room.

7. During the inspection, the Board's inspectors observed and noted the following

equipment and components for sterile compounding:

a. Facility uses pre-sterilized vials, however there was no dry heat oven for glass depyrogenation. Glassware cleaning process is to wipe down with alcohol and then spray with anti-fungal spray and dwell for 10 minutes. No documentation of certification of oven, mapping, or load configuration since no oven at facility.

b. Cleaned glassware was sitting uncovered in a hallway next to a large sink. When asked about cleaning, facility staff indicated that they cleaned it, rinsed it with alcohol, then sprayed it with a sporicidal. They did not mention rinsing off the sporicidal.

c. Equipment sitting out in random areas with no evidence of certification.

d. Rolls of labels in storage room on shelf and not secured in locked cage. Other rolls of labels are in a rolling locked cage. Quality Assurance has keys to label cage housed in controlled substance room.

8. During the inspection, the Board's inspectors observed and noted the following related to quality control and operations of the facility:

a. Facility staff failed to demonstrate appropriate level of understanding of what is required to maintain compliance in an outsourcing facility. The Vice President of Quality seemed more well-versed than the rest and understood CGMP verbiage.

b. Quality Assurance staff said they had completed temperature mapping of the warehouse and multiple points of excursions were noted. They were working on getting the space to appropriate temperatures.

c. After pointing out that it was too warm to store drugs in the area of the facility

where the air conditioner had gone out, the Board inspector was informed by facility staff that drugs were not stored in the warehouse, but a large container of Metformin powder was directly in front of inspector. When facility staff were questioned about the Metformin, the Board inspector was told that it was a "sample" and that it was in the quarantine area.

d. There were unlabeled vials of drugs with completed release paperwork in the storage area. When Board staff brought this to the PIC's attention and asked if re-assessment of the drugs would be performed based on the storage conditions, the PIC merely indicated the facility did not manufacture the drugs and failed to identify that since the temperature excursion occurred at their facility, that needed to be considered before releasing the drug regardless of where it was manufactured.

e. Facility staff had to call upper management to determine who provided security system.

f. In the warehouse was a tray of vials that had a paper on top of it that indicated they contained tromethamine placebo for IV infusion. This was just one of the many observed trays in the warehouse with what appeared to be injectable medications.

9. On October 10, 2023, the Board's inspectors conducted a follow-up, in-person inspection of the facility. Issues noted during the initial inspection still existed.

10. On or around June 29, 2023, the Florida Department of Health and Investigative Services conducted an inspection of the facility and recorded several observations also noted by the Board inspectors.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1627(f)(1), the Board may deny the application of an outsourcing facility upon a finding that the facility has attempted to obtain a registration by false or fraudulent means, including misrepresentation of a material fact or falsification of any application.

2. Pursuant to K.S.A. 65-1627(f)(6), the Board may deny the application of an outsourcing facility upon a finding that the facility has violated the pharmacy act of the state of Kansas or rules and regulations adopted by the state board of pharmacy under the pharmacy act of the state of Kansas, has violated the uniform controlled substances act or rules and regulations adopted by the state board of pharmacy under the uniform controlled substances act, has violated the federal uniform controlled substances act, has violated the federal or state food, drug and cosmetic act or any rules and regulations adopted under any such act, or has violated a provision of the federal drug supply chain security act or any rule or regulation adopted under such act.

3. Pursuant to K.S.A. 65-1655b(b)(8), in reviewing the qualifications for applicants for initial registration as an outsourcing facility, the board shall consider any other factors or qualifications the board considers relevant to and consistent with the public health and safety.

4. Pursuant to K.S.A. 65-1655b(c), after consideration of the qualifications for applicants for registration as an outsourcing facility, the Board may deny an initial application for registration if the board determines that the granting of such registration would not be in the public interest.

5. Pursuant to K.S.A. 65-668(a), a drug or device shall be deemed to be adulterated:

   a. If it consists in whole or in part of any filthy, putrid, or decomposed substance;

   b. if it has been produced, prepared, packed or held under insanitary conditions

whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health, or if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this act as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess; or

c. if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

6. K.A.R. 68-13-3 and K.A.R. 68-13-4 outline all requirements for compounding nonsterile preparations and nonsterile preparations.

7. Pursuant to K.A.R. 68-20-15a, each pharmacy shall provide effective controls and procedures to guard against theft and diversion of controlled substances in conformance with the security requirements of federal law, including the requirements of 21 CFR 1301.71 as in effect on April 1, 1999, which are hereby adopted by reference.

8. Pursuant to K.A.R. 68-14-8, each registrant who is the owner of an outsourcing facility shall meet the following minimum requirements for operation and the maintenance of records:

a. Facilities. Each outsourcing facility shall meet the following requirements:

i. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

ii. have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security

conditions;

iii. have a quarantine area for storage of prescription-only drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, or deemed unfit for distribution;

iv. have a quarantine area designated for holding products waiting for testing data before being released for distribution;

v. be maintained in a clean and orderly condition; and

vi. be free from infestation by insects, rodents, birds, or vermin of any kind.

b. Security.

i. Each facility used for outsourcing shall be secure from unauthorized entry.

1. Access from outside the premises shall be kept to a minimum and be well controlled.

2. Entry into areas where prescription-only drugs and devices are held shall be limited to authorized personnel.

ii. Each facility shall be equipped with an alarm system to detect entry after hours.

iii. Each facility shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

c. Storage. All prescription-only drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with

manufacturer's recommendations to preserve the stability of these drugs and devices.

d. Examination of materials.

    i. Upon receipt, each outside shipping container shall be visually examined to identify and to prevent the acceptance of prescription-only drugs or devices that are contaminated or otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

    ii. Each outgoing shipment shall be carefully inspected to identify the prescription-only drugs or devices and to ensure that there is no delivery of prescription-only drugs or devices that have been damaged in storage or held under improper conditions.

e. Returned, damaged, and outdated prescription-only drugs and devices.

    i. Prescription-only drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription-only drugs and devices until they are destroyed.

    ii. Each prescription-only drug or device whose immediate or sealed outer or sealed secondary container has been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription-only drugs until the drug or device is either destroyed or returned to the supplier.

    iii. If the conditions under which a prescription-only drug or device has been

returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, then the drug or device shall be destroyed, unless examination, testing, or other investigations prove that the drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not the conditions under which a drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, the registrant shall consider, among other factors, the conditions under which the drug or device has been held, stored, or shipped before or during its return and the condition of the drug or device and its container, carton, or labeling, as a result of storage or shipping.

f. Responsible persons. Each registrant shall establish and maintain a list of officers, directors, managers, pharmacists, pharmacy technicians, and other persons in charge of drug compounding, distribution, storage, and handling, including a description of their duties and a summary of their qualifications. This list shall be made available for inspection by the Board.

9. During the pre-opening inspection, Board inspectors were routinely misinformed by facility staff and facility staff demonstrated that they did not have adequate education and training related to outsourcing facility operations. Facility staff repeatedly had to request assistance from leadership because they were unable to answers basic questions and reported "working dirty" an made other concerning comments concerning the level of compliance of the facility. This is a basis to deny Applicant's Application pursuant to K.S.A. 65-1627(f)(8) and K.S.A. 65-1655b.

10. Furthermore, since Applicant certified Applicant's Application was true, correct, and

complete and Applicant answered "yes" to indicate their staff had adequate training and education, this was a material misrepresentation on the Application and is a basis to deny Applicant's Application pursuant to K.S.A. 65-1627(f)(1).

11. During the pre-opening inspection, multiple observations were made concerning the facility's operations, including but not limited to: cleanliness, gaps under doors, risk of infestation or vermin, lack of proper ventilation, temperature excursions throughout the facility, loose ceiling tiles, cluttered rooms, lack of sterilization and cleaning procedures, improperly stored and uncertified equipment, lack of handwashing sink in the clean room area, ineffective garbing, rolls of unsecured medication labels, and unlabeled vials of drugs in open unsecured areas. These are each individual bases to deny Applicant's Application pursuant to K.S.A. 65-1627(f)(6) as violations of K.S.A. 65-1655b, K.A.R. 68-13-3, K.A.R. 68-13-4, and K.A.R. 68-14-8. However, when considered in total, these violations are collectively a serious risk to the public health and safety and are a basis to deny Applicant's Application pursuant to K.S.A. 65-1627(f)(8) and K.S.A. 65-1655b(c).

12. Since Florida observed many of these violations during their June 2023 inspection, it is concerning to the Board that many of these observations remained at the facility, uncorrected, almost 30 days later during the Board's preopening inspection and again upon the Board inspectors return visit to the facility in October. This demonstrates a knowing disregard for the public health and safety and is further basis to deny Applicant's Application pursuant to K.S.A. 65-1627(f)(8) and K.S.A. 65-1655b(c).

13. Multiple access points were observed to the secured area for storing controlled substances and facility staff reported the facility owner had a key to the area, all in violation of K.A.R. 68-20-15a, which is a basis to deny Applicant's Application pursuant to K.S.A. 65-1627(f)(6).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's Application is hereby DENIED.

NOTICES

Applicant is hereby notified as follows:

1. Applicant may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Applicant, costs of the proceedings shall be charged to Applicant.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

11/1/2023
Date

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 1st day of November 2023, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Excite Pharma Services, LLC
1205 State Ave
Tonganoxie KS 66086

Kansas Board of Pharmacy Staff