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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation and Statement of Issues Against**:** **LSE INC. DBA WELLS PHARMA OF HOUSTON LLC;** **GARY LEE SHAPIRO, PRESIDENT;** **JOHN CHRISTOPHER KIRKES, VICE-PRESIDENT;** **ANTHONY ROBERT SCHWARTZ, VICE-PRESIDENT** 9265 Kirby Drive Houston, TX 77054 **Nonresident Outsourcing Facility Permit No. NSF 144** **Nonresident Outsourcing Facility Permit Applicant** Respondent.	Case No. 8029 **ACCUSATION AND STATEMENT OF ISSUES**

PARTIES

1. Anne Sodergren (Complainant) brings this Accusation and Statement of Issues solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

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2. On or about July 25, 2022, Board of Pharmacy issued Nonresident Outsourcing Facility Permit Number NSF 144 to LSE Inc. doing business as (dba) Wells Pharma of Houston LLC (Respondent); with Gary Lee Shapiro, President; John Christopher Kirkes, Vice-President; Anthony Robert Schwartz, Vice-President. The Nonresident Outsourcing Facility Permit was in full force and effect at all times relevant to the charges brought herein and will expire on July 1, 2025.

3. On or about April 24, 2025, the Board Pharmacy received a renewal application for a Nonresident Outsourcing Facility Permit from Respondent; with Gary Lee Shapiro, as President, John Christopher Kirkes, as Vice-President, and Anthony Robert Schwartz, as Vice-President. Gary Shapiro and Andrea Corbin, on behalf of Respondent, certified under penalty of perjury to the truthfulness of all statements, answers, and representations in the application. The Board denied the application on May 27, 2025.

JURISDICTION

4. This Accusation and Statement of Issues are brought before the Board of Pharmacy (Board) for the, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Code section 4011 provides that the Board shall administer and enforce both the Pharmacy Law (Business and Professions Code sections 4400, et seq.) and the Uniform Controlled Substances Act (Health and Safety Code sections 11000, et seq.).

6. Code section 4300 states, in pertinent part:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.

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(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

(c) The board may refuse a license to any applicant guilty of unprofessional conduct. The board may, in its sole discretion, issue a probationary license to any applicant for a license who is guilty of unprofessional conduct and who has met all other requirements for licensure. The board may issue the license subject to any terms or conditions not contrary to public policy, including, but not limited to, the following:

…

(7) Compliance with laws and regulations governing the practice of pharmacy.

…

7. Code section 4300.1 states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

8. Code section 4307 states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in

this section and Section 4308 , may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

BUSINESS AND PROFESSIONS CODE

9. Section 4129.2 of the Code states, in pertinent part:

…

(b) A nonresident outsourcing facility shall compound all sterile products and nonsterile products to be distributed or used in this state in compliance with regulations of the board and with federal current good manufacturing practices applicable to outsourcing facilities.

(c) A license for a nonresident outsourcing facility shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident outsourcing facility shall reimburse the board for all actual and necessary costs incurred by the board in conducting an inspection of the nonresident outsourcing facility at least once annually pursuant to subdivision (x) of Section 4400.

…

10. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

…

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

…

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

…

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

…

CODE OF FEDERAL REGULATIONS (CFR)

11. Section 211.100 of Title 21 of the CFR states, in pertinent part:

(a) There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit.

…

12. Section 211.42 of Title 21 of the CFR states, in pertinent part:

…

(c) Operations shall be performed within specifically defined areas of adequate size. There shall be separate or defined areas or such other control systems for the firm's operations as are necessary to prevent contamination or mixups during the course of the following procedures:

…

(10) Aseptic processing, which includes as appropriate:

…

(v) A system for cleaning and disinfecting the room and equipment to produce aseptic conditions;

…

13. Section 211.67 of Title 21 of the CFR states, in pertinent part:

(a) Equipment and utensils shall be cleaned, maintained, and, as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

14. Section 211.22 of Title 21 of the CFR states, in pertinent part:

(c) The quality control unit shall have the responsibility for approving or rejecting all procedures or specifications impacting on the identity, strength, quality, and purity of the drug product.

15. Section 211.192 of Title 21 of the CFR states, in pertinent part:

All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in

master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be thoroughly investigated, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that may have been associated with the specific failure or discrepancy. A written record of the investigation shall be made and shall include the conclusions and followup.

16. Section 211.137 of Title 21 of the CFR states, in pertinent part:

(a) To assure that a drug product meets applicable standards of identity, strength, quality, and purity at the time of use, it shall bear an expiration date determined by appropriate stability testing described in § 211.166.

17. Section 211.188 of Title 21 of the CFR states, in pertinent part:

Batch production and control records shall be prepared for each batch of drug product produced and shall include complete information relating to the production and control of each batch. These records shall include:

(a) An accurate reproduction of the appropriate master production or control record, checked for accuracy, dated, and signed;

(b) Documentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished, including:

(1) Dates;

(2) Identity of individual major equipment and lines used;

(3) Specific identification of each batch of component or in-process material used;

(4) Weights and measures of components used in the course of processing;

(5) In-process and laboratory control results;

(6) Inspection of the packaging and labeling area before and after use;

(7) A statement of the actual yield and a statement of the percentage of theoretical yield at appropriate phases of processing;

(8) Complete labeling control records, including specimens or copies of all labeling used;

(9) Description of drug product containers and closures;

(10) Any sampling performed;

(11) Identification of the persons performing and directly supervising or checking each significant step in the operation, or if a significant step in the operation is performed by automated equipment under § 211.68, the identification of the person checking the significant step performed by the automated equipment.

(12) Any investigation made according to § 211.192.

(13) Results of examinations made in accordance with § 211.134.

18. Section 211.103 of Title 21 of the CFR states, in pertinent part:

Actual yields and percentages of theoretical yield shall be determined at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product. Such calculations shall either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment under § 211.68, be independently verified by one person.

19. Section 211.84 of Title 21 of the CFR states, in pertinent part:

(a) Each lot of components, drug product containers, and closures shall be withheld from use until the lot has been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

20. Section 211.125 of Title 21 of the CFR states, in pertinent part:

(a) Strict control shall be exercised over labeling issued for use in drug product labeling operations.

21. Section 211.186 of Title 21 of the CFR states, in pertinent part:

(b) Master production and control records shall include:

(1) The name and strength of the product and a description of the dosage form;

(2) The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the drug product, and a statement of the total weight or measure of any dosage unit;

(3) A complete list of components designated by names or codes sufficiently specific to indicate any special quality characteristic;

(4) An accurate statement of the weight or measure of each component, using the same weight system (metric, avoirdupois, or apothecary) for each component. Reasonable variations may be permitted, however, in the amount of components necessary for the preparation in the dosage form, provided they are justified in the master production and control records;

(5) A statement concerning any calculated excess of component;

(6) A statement of theoretical weight or measure at appropriate phases of processing;

(7) A statement of theoretical yield, including the maximum and minimum percentages of theoretical yield beyond which investigation according to § 211.192 is required;

(8) A description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the person or persons responsible for approval of such labeling;

(9) Complete manufacturing and control instructions, sampling and testing procedures, specifications, special notations, and precautions to be followed.

22. Section 211.166 of Title 21 of the CFR states, in pertinent part:

(a) There shall be a written testing program designed to assess the stability characteristics of drug products. The results of such stability testing shall be used in determining appropriate storage conditions and expiration dates. The written program shall be followed and shall include:

(1) Sample size and test intervals based on statistical criteria for each attribute examined to assure valid estimates of stability;

(2) Storage conditions for samples retained for testing;

(3) Reliable, meaningful, and specific test methods;

(4) Testing of the drug product in the same container-closure system as that in which the drug product is marketed;

(5) Testing of drug products for reconstitution at the time of dispensing (as directed in the labeling) as well as after they are reconstituted.

TEXAS OCCUPATIONAL CODE

23. Texas Occupational Code, section 565.001 states, in pertinent part:

(a) The board may discipline an applicant for or the holder of a current or expired license to practice pharmacy if the board finds that the applicant or license holder has:

…

(12) violated any pharmacy or drug statute or rule of this state, another state, or the United States;

…

COST RECOVERY

24. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

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DANGEROUS DRUGS

25. Nicotinamide Riboside Chloride is a precursor to Nicotinamide Adenine Dinucleotide (NAD+) which is an essential coenzyme that plays important roles in various metabolic pathways. It is a form of vitamin B3. It is a dangerous drug pursuant to Code section 4022.

26. Indomethacin is a non-steroidal anti-inflammatory drug typically used to treat pain or inflammation. It is a dangerous drug pursuant to Code section 4022.

FACTUAL ALLEGATIONS

27. On or about March 25-27, 2025, a nonresident outsourcing license renewal inspection was conducted at Respondent's facility in Houston, Texas. Board inspectors found that Respondent was in violation of good manufacturing practices. Inspectors provided a written notice to Respondent with seventeen observations including repeat or similar observations going back to the 2022 pre-licensure inspection of Respondent. Respondent provided responses to these observations on or about April 28, 2025.

ACCUSATION

FIRST CAUSE FOR DISCIPLINE

(Failure to Comply with Federal Current Good Manufacturing Practices)

28. Respondent is subject to disciplinary for unprofessional conduct pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent has violated Code section 4129.2, subdivision (b), by failing to ensure compliance with cGMP. The circumstances are as follows:

a. CFR section 211.100, subdivision (a), Written procedures; deviations: Respondent failed to appropriately maintain written procedures for production and process control design to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess.

i. During inspection, Board inspectors observed that Respondent failed to maintain procedures for terminal sterilization via electron beam.

b. CFR section 211.42, subdivision (c)(10)(v), Design and construction features: Respondent failed to maintain adequate control systems for cleaning and disinfecting the room and equipment to produce aseptic conditions.

i. During inspection, Board inspectors observed Respondent's system for cleaning and disinfection was inadequate, including approximately 20 instances of inadequate contact times, missed weekly and/or monthly cleanings, and incomplete documentation.

c. CFR section 211.67, subdivision (a), Equipment cleaning and maintenance: Respondent failed to clean and maintain equipment and utensils as appropriate for the nature of the drug, sanitized and/or sterilized at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements.

i. During inspection, Board inspectors observed that the Respondent's autoclaved loads for glassware failed to meet minimum sterilization times.

d. CFR section 211.22, subdivision (c), Responsibilities of quality control unit: Respondent failed to have appropriate standard operating procedures (SOPs) and protocols applicable to the quality control unit.

i. During inspection, Board inspectors observed that Respondent's shipping study was inadequate as it was not performed according to the required procedures. Additionally, there was no executed shipping study available for the newly commercialized vials.

ii. During inspection, Board inspectors observed that Respondent's labels for Nicotinamide Riboside Chloride products were missing in-use times.

iii. During inspection, Board inspectors observed that Respondent's master production records for Nicotinamide Riboside Chloride 100 mg and 500 mg were not available prior to the start of production. The master production records were signed and approved by Quality on December 31, 2024. The first commercial batches of Nicotinamide Riboside Chloride products were compounded between July 2, 2024, and July 3, 2024.

iv. During inspection, Board inspectors observed that Respondent's abatement of non-penicillin beta-lactam production cross contamination was inadequate.

v. During inspection, Board inspectors observed that Respondent's visual inspection program was inadequate. Specifically, Respondent lacked a physical defect kit and/or qualification kit for vials, lacked additional consideration for intrinsic versus extrinsic

particulates; calculation of acceptable false rejects during qualification is not justified; and visual inspector qualification did not account for categorization of defects.

e. CFR section 211.192, Production record review: Respondent failed to comply with written procedures before a batch was released or distributed.

i. During inspection, Board inspectors observed that Respondent released Nicotinamide Riboside Chloride 100 mg Lot# 080824144601547 for commercial distribution despite having an open investigation on the lot. SOP HOU-QA-003 Deviation Investigation and Reporting section 7.5.1 states "Impacted lots cannot be released for distribution until the deviation or incident report is closed." SOP HOU-QC-005 section 8.2 requires an investigation when environmental/personnel monitoring action level is met or exceeded. At least 312 units of this lot were shipped to California.

ii. During inspection, Board inspectors observed at least four incidents where investigations were not performed and/or were incomplete including:

A. Investigation PC-HOU-2025-003 for loose caps on vials. The investigation was inadequate and failed to identify or attempt to identify a root cause.

B. During investigation PC-HOU-2025-001 there was inadequate label control and the investigation failed to extend to other batches which may have been impacted. Additionally, the beyond use date was changed without justification or explanation.

C. During investigation DEV-2024-012 a change in cleaning chemical and dwells times were changed without adequate justification documented.

D. Respondent failed to investigate regarding environmental monitoring plates utilized for Lot 121124131102603 that had an approximately 15-day gap between the incubation cycles of 30-35C and 20-25C without adequate explanation or investigation.

f. CFR section 211.137, subdivision (a), Expiration dating: Respondent failed to assure that a drug product met applicable standards of identity, strength, quality, and purity at the time of use, and that it shall bear an expiration date determined by appropriate stability testing described in § 211.166.

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i. During inspection, Board inspectors observed that Nicotinamide Riboside Chloride 500 mg Lot# 102824146612240 was assigned an expiration date of 120-days whereas the firm only had stability data to support a 90-days expiration date.

g. CFR section 211.188, Batch production and control records: Respondent failed to maintain batch production and control records as required by this section.

i. During inspection, Board inspectors observed that batch production records for Nicotinamide Riboside Chloride products were missing weights and measures of components used in the course of processing, in-process and laboratory control results, a statement of actual yield, a statement of the percentage of theoretical yield at appropriate phases of processing, and complete labeling control records including specimens of copies or all labeling used.

h. CFR section 211.103, Calculation of Yield: Respondent failed to establish actual yields and percentages of theoretical yield at the conclusion of each appropriate phase of manufacturing, processing, packaging, or holding of the drug product.

i. During inspection, Board inspectors observed that the yield specification for indomethacin suppositories was not scientifically justified.

i. CFR section 211.84, subdivision (a), Testing and approval or rejection of components, drug product containers, and closures: Respondent failed to withhold each lot of components, drug product containers, and closures until the lot had been sampled, tested, or examined, as appropriate, and released for use by the quality control unit.

i. During inspection, Board inspectors observed Respondent did not have a procedure for testing of incoming components or active pharmaceutical ingredients.

j. CFR section 211.125, subdivision (a), Labeling issuance: Respondent failed to appropriately exercise strict control over labeling issued for drug product labeling operations.

i. During inspection, Board inspectors observed that primary labels were printed at least three different times for Nicotinamide Riboside Chloride 500 mg Lot# 010225146610002 and label reconciliation was only completed for one print session.

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k. CFR section 211.186, subdivision (b), Master production and control records: Respondent failed to maintain master production and control records containing the information required by this section.

i. During inspection, Board inspectors observed that master production records for Nicotinamide Riboside Chloride were missing an accurate statement of the weight or measure of each component; a statement of theoretical yield, including the maximum and minimum percentages of theoretical yield; and a description of the drug product containers, closures, and packaging materials, including a specimen or copy of each label and all other labeling signed and dated by the persons or persons responsible for approval of such labeling.

l. CFR section 211.166, subdivision (a), Stability testing: Respondent failed to maintain written testing program designed to assess the stability characteristics of drug products.

i. During inspection, Board inspectors observed Respondent failed to have the stability data to support the assigned beyond use date or expiration dates for Nicotinamide Riboside Chloride products. At least 291 units from Lot# 080824146611548 and 104 units from Lot# 012325146610223 were shipped to California

SECOND CAUSE FOR DISCIPLINE

(False or Misleading Certificate of Analysis)

29. Respondent is subject to disciplinary action for unprofessional conduct pursuant to Code section 4301, subdivision (g), in that Respondent knowingly made or signed a certificate or other document that falsely represents the existence or nonexistence of a state of fact. Specifically, Board investigators observed that the certificates of analysis for Nicotinamide Riboside Chloride 100 mg Lot# 080824144601547 and Nicotinamide Riboside Chloride 500 mg Lot# 010225146610002 contained incorrect or misleading information. The certificates of analysis stated the product underwent and passed pH, USP <791> testing, but in actuality no pH testing actually occurred as a condition of release.

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THIRD CAUSE FOR DISCIPLINE

(Pattern of Noncompliance)

30. Respondent is subject to disciplinary action pursuant to Code section 4301, subdivisions (j) and (o), in that Respondent has violated Code section 4129.2, subdivision (c), in that Respondent was found not in compliance with the Code and the regulations of the Board after the renewal investigation. Specifically, the Board investigators observed a persistent pattern of noncompliance with cGMP and the emergence of new issues during each inspection. Including, but not limited to, inadequate validation and testing procedures, poor documentation and cleaning practices, insufficient or ineffective training, recurring failures to conduct thorough investigations into deviations or product complaints, and inadequate quality control processes.

STATEMENT OF ISSUES

FIRST CAUSE FOR DENIAL OF APPLICATION

(Failure to Comply with Federal Current Good Manufacturing Practices)

31. Respondent's renewal application is subject to denial for unprofessional conduct pursuant to Code section 4300, subdivision (c)(7), in that Respondent has violated Code section 4129.2, subdivisions (b) and (c), by failing to ensure compliance with cGMP. The circumstances are more fully set forth in paragraphs 27, a-*l*, above.

SECOND CAUSE FOR DENIAL OF APPLICATION

(False or Misleading Certificate of Analysis)

32. Respondent's renewal application is subject to denial for unprofessional conduct pursuant to Code sections 4300, subdivision (c)(7), and 4301, subdivision (g), in that Respondent knowingly made or signed a certificate or other document that falsely represents the existence or nonexistence of a state of fact, as more fully set forth above in paragraph 29.

THIRD CAUSE FOR DENIAL OF APPLICATION

(Pattern of Noncompliance) 33. Respondent's renewal application is subject to denial for unprofessional conduct pursuant to Code section 4300, subdivision (c), in that Respondent has violated Code section 4129.2, subdivision (c), in that Respondent was found not in compliance

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with the Code and the regulations of the Board after the renewal investigation, as more fully set forth above in paragraph 30

DISCIPLINE CONSIDERATIONS

34. To determine the degree of discipline, if any, to be imposed on Respondent, Complainant alleges that on or about January 30, 2024, in a prior action, the Board of Pharmacy issued Citation Number CI 2022 100826 for Respondent's utilization of unvalidated sterility testing methods to release sterile drug product into commercial distribution. Respondent was issued a $2,000 fine. That Citation is now final.

OTHER MATTERS

35. Pursuant to section 4307 of the Code, if discipline is imposed on Nonresident Outsourcing Facility Permit Number NSF 144 issued to LSE Inc. dba Wells Pharma of Houston LLC, LSE Inc. dba Wells Pharma of Houston shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for 1) a period not to exceed five (5) years if Nonresident Outsourcing Facility Permit number NSF 144 is placed on probation; or, 2) if the pharmacy permit is revoked, the prohibition shall continue until the nonresident outsourcing facility permit is reinstated.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Nonresident Outsourcing Facility Permit Number NSF 144, issued to LSE Inc. dba Wells Pharma of Houston LLC;

2. Denying the renewal application of LSE Inc. dba Wells Pharma of Houston LLC for a Nonresident Outsourcing Facility Permit;

3. Prohibiting LSE Inc. dba Wells Pharma of Houston LLC from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Nonresident Outsourcing Facility Permit Number NSF 144 is placed on probation or until Nonresident Outsourcing Facility Permit Number NSF 144 is reinstated if Nonresident Outsourcing Facility Permit Number NSF 144 is revoked;

4. Prohibiting Gary Lee Shapiro from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years Nonresident Outsourcing Facility Permit Number NSF 144 is placed on probation or until Nonresident Outsourcing Facility Permit Number NSF 144 is reinstated Nonresident Outsourcing Facility Permit Number NSF 144 is revoked

5. Prohibiting John Christopher Kirkes from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years Nonresident Outsourcing Facility Permit Number NSF 144 is placed on probation or until Nonresident Outsourcing Facility Permit Number NSF 144 is reinstated Nonresident Outsourcing Facility Permit Number NSF 144 is revoked

6. Prohibiting Anthony Robert Schwartz from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years Nonresident Outsourcing Facility Permit Number NSF 144 is placed on probation or until Nonresident Outsourcing Facility Permit Number NSF 144 is reinstated Nonresident Outsourcing Facility Permit Number NSF 144 is revoked

7. Ordering LSE Inc. dba Wells Pharma of Houston LLC to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3 and if placed on probation, the costs of probation monitoring; and,

8. Taking such other and further action as deemed necessary and proper.

DATED: 7/30/2025

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2025.07.30 20:40:42 -07'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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