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

In the Matter of the Statement of Issues Against: **K & S OWL INC., DBA OWL HOMECARE PHARMACY,** **MAHER HALIM KALDAS, OWNER,** **ALBERT SOLIMAN, OWNER,** **Pharmacy Permit Number PHY 45091;** and **MAHER HALIM KALDAS,** **Pharmacist-In-Charge,** **Pharmacist License Number RPH 39184;** and **ALBERT SOLIMAN,** **Pharmacist License Number RPH 44883;** Sterile Compounding Pharmacy License Applicant. and **MINACEUTICALS WHOLESALE,** **MAHER HALIM KALDAS, OWNER,** **ALBERT SOLIMAN, OWNER,** **Permit Number WLS 4527;** Affiliated Party.	Case No. 5511 **STATEMENT OF ISSUES**

Complainant alleges:

PARTIES

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

K and S Owl Inc., doing business as (dba) Owl Homecare Pharmacy

2. On or about March 12, 1985, the Board issued Pharmacist License Number RPH 39184 to Maher Halim Kaldas. Pharmacist License Number 39184 will expire on February 28, 2017, unless renewed.

3. On or about September 17, 1991, the Board issued Pharmacist License Number RPH 44883 to Albert Soliman. Pharmacist License Number RPH 44883 will expire on August 31, 2017, unless renewed.

4. On or about April 28, 2004, the Board issued Original Permit Number PHY 45091 to K and S Owl Inc., dba Owl Homecare Pharmacy. The permit will expire on April 1, 2017, unless renewed. K and S Owl Inc., dba Owl Homecare Pharmacy, is co-owned by Maher Halim Kaldas and Albert Soliman. Kaldas has been the Chief Executive Officer and Pharmacist-In-Charge of K and S Owl Inc., dba Owl Homecare Pharmacy, since April 28, 2004. Soliman has been the Treasurer and Chief Financial Officer of K and S Owl Inc. dba Owl Homecare Pharmacy, since April 28, 2004.

5. On or about May 16, 2014, the Board received an application for a new licensed sterile compounding license filed by Applicant K and S Owl Inc., dba Owl Healthcare Pharmacy, Pharmacy Permit number PHY 45091, with Kaldas, Pharmacist License number RPH 39184, as the Pharmacist-In-Charge (Applicant). On or about May 1, 2014, Kaldas certified that the policies and procedures of the sterile compounding are consistent with California Code of Regulations, title 16, section 1735 et seq. and 1751 et seq.

6. The Board denied the application on April 17, 2015.

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Minaceuticals Wholesale

7. On or about December 1, 2004, the Board issued Permit Number WLS 4527 to Minaceuticals Wholesale. The permit will expire on December 1, 2016, unless renewed.

8. Minaceuticals Wholesale is co-owned by Kaldas and Soliman. Kaldas has been the designated representative-in-charge since December 1, 2004.

JURISDICTIONAL AND STATUTORY PROVISIONS

9. This Statement of Issues is brought before the Board, under the authority of the following laws.

10. Business and Professions Code section 4300[1] states:

> (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.
>
> (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:
>
> (1) Medical or psychiatric evaluation.
>
> (2) Continuing medical or psychiatric treatment.
>
> (3) Restriction of type or circumstances of practice.
>
> (4) Continuing participation in a board-approved rehabilitation program.

[1] All further statutory references are to the Business and Professions Code unless otherwise indicated.

(5) Abstention from the use of alcohol or drugs.

(6) Random fluid testing for alcohol or drugs.

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

(d) The board may initiate disciplinary proceedings to revoke or suspend any probationary certificate of licensure for any violation of the terms and conditions of probation. Upon satisfactory completion of probation, the board shall convert the probationary certificate to a regular certificate, free of conditions.

(e) The proceedings under this article shall be conducted in accordance with Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board shall have all the powers granted therein. The action shall be final, except that the propriety of the action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil Procedure.

11. 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.

12. Section 4402, subdivision (a), provides that any license that is not renewed within three years following its expiration may not be renewed, restored, or reinstated and shall be canceled by operation of law at the end of the three-year period.

13. Section 4302 states:

The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee.

14. Section 480 states, in pertinent part:

(a) A board may deny a license regulated by this code on the grounds that the applicant has one of the following:

. . .

(3) (A) Done any act that if done by a licentiate of the business or profession in question, would be grounds for suspension or revocation of license.

(B) The board may deny a license pursuant to this subdivision only if the crime or act is substantially related to the qualifications, functions, or duties of the business or profession for which application is made.

15. Section 4342 states:

(a) The board may institute any action or actions as may be provided by law and that, in its discretion, are necessary, to prevent the sale of pharmaceutical preparations and drugs that do not conform to the standard and tests as to quality and strength, provided in the latest edition of the United States Pharmacopoeia or the National Formulary, or that violate any provision of the Sherman Food, Drug, and Cosmetic Law (Part 5 (commencing with Section 109875) of Division 104 of the Health and Safety Code).

16. Section 4127, subdivision (a), states, "A pharmacy that compounds sterile drug products for injection, administration into the eye, or inhalation shall possess a sterile compounding pharmacy license as provided in this article."

17. 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, or partner of any partnership, corporation, 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, or partner 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, or partner 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, or partner, as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in that 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.

REGULATIONS

18. California Code of Regulations, title 16, section 1770, states:

For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare.

19. California Code of Regulations, title 16, section 1735.7, states:

(a) Any pharmacy engaged in compounding shall maintain written documentation sufficient to demonstrate that pharmacy personnel have the skills and training required to properly and accurately perform their assigned responsibilities relating to compounding.

(b) The pharmacy shall develop and maintain an on-going competency evaluation process for pharmacy personnel involved in compounding, and shall maintain documentation of any and all training related to compounding undertaken by pharmacy personnel.

(c) Pharmacy personnel assigned to compounding duties shall demonstrate knowledge about processes and procedures used in compounding prior to compounding any drug product.

FACTS

20. On January 27, 2016, the Board filed Accusation number 4668 against K & S Owl Inc., dba Owl Homecare Pharmacy, Kaldas, and Soliman. The Accusation alleged 21 causes for discipline and disciplinary considerations for acts warranting discipline on K & S Owl Inc., dba Owl Homecare Pharmacy's, Kaldas', and Soliman's licenses. Accusation number 4668 is attached as exhibit A and is incorporated by reference herein.

FIRST CAUSE FOR DENIAL OF APPLICATION

(Acts Warranting Revocation of Licensure: Accusation No. 4668)

21. Applicant's application for a new licensed sterile compounding license is subject to denial under section 480, subdivision (a)(3), in that while holding Pharmacy Permit Number PHY 45091, Pharmacist License Number RPH 39184, Pharmacist License Number RPH 44883, and Permit Number WLS 4527, Applicant committed acts that warrant revocation of licensure. Complainant refers to, and by this reference incorporates, the allegations set forth in paragraph 20, above, and all of the statutory and regulatory violations and factual allegations in Accusation number 4668.

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SECOND CAUSE FOR DENIAL OF APPLICATION

(Unprofessional Conduct)

22. Applicant's application for a new licensed sterile compounding license is subject to denial under section 4300, subdivision (c), in that Applicant is guilty of unprofessional conduct in running its business K & S Owl Inc., dba Owl Homecare Pharmacy. Complainant refers to, and by this reference incorporates the allegations set forth in paragraph 20, above, and Accusation number 4668, paragraphs 46–99 and 101–124.

THIRD CAUSE FOR DENIAL OF APPLICATION

(Existing Conditions in Relation to Officer or Director that Constitute Grounds for Disciplinary Action)

23. Applicant's application for a new licensed sterile compounding license is subject to denial under section 4302, in that Applicant's corporate officer or director or person holding 10 percent or more of the corporate stock of K & S Owl Inc. engaged in conduct that constitutes grounds for disciplinary action. Complainant refers to, and by this reference incorporates the allegations set forth in paragraph 20, above, and all of the statutory and regulatory violations and factual allegations in Accusation number 4668.

PRAYER

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

1. Denying Applicant's application, which was signed and dated by Maher Halim Kaldas on May 1, 2014, for a new licensed sterile compounding pharmacy license;

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

DATED: 6/13/16

Virginia Herold

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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