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

In the Matter of the Accusation Against: **SITESH BANSI PATEL** **2385 Suddaby** **Tustin, CA 92782** **Pharmacist License No. RPH 62489** Respondent.	Case No. 6109 **A C C U S A T I O N**

Complainant alleges:

PARTIES

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

2. On or about July 21, 2009, the Board issued Pharmacist License Number RPH 62489 to Sitesh Bansi Patel (Respondent). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on July 31, 2017, unless renewed.

JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

4. Section 4300, subdivision (a) of the Code states "Every license issued may be suspended or revoked."

5. Section 4300.1 of the Code 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.

STATUTORY PROVISIONS

6. Section 4301 of the Code states:

> 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:
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> . . .
>
> (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or corruption, whether the act is committed in the course of relations as a licensee or otherwise, and whether the act is a felony or misdemeanor or not.
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> . . .
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> (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. . .

REGULATORY PROVISIONS

7. 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.

COSTS

8. Section 125.3 of the Code provides, 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, with failure of the licentiate to comply subjecting the license to not being renewed or reinstated. If a case settles, recovery of investigation and enforcement costs may be included in a stipulated settlement.

FACTUAL ALLEGATIONS

9. The United States Food and Drug Administration (FDA) is an agency of the United States government responsible for enforcing the provisions of the Federal Food, Drug and Cosmetic Act (FDCA). The FDA's responsibilities include, among other things, regulating the distribution of drugs shipped, delivered and received in interstate commerce.

10. The FDCA defines a "new drug" as any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof . . ." under 21 U.S.C. § 321(p)(1). In order to be lawfully marketed, sold or dispensed in the U.S., a new drug had to be the subject of a New Drug Application which had been approved by the FDA.

11. Under the FDCA, a "dietary supplement" was deemed to be a food. The FDCA defined the term "dietary supplement" to mean a product intended to supplement the diet that contained one or more specified ingredients and, among other things, was labeled as a dietary supplement. A dietary supplement must contain one or more "dietary ingredients" (ie. a vitamin; a mineral; an herb or other botanical; an amino acid; a dietary substance for use by man to supplement the diet by increasing total dietary intake; or a concentrate, metabolite, constituent, extract, or combination of one or more of these dietary ingredients. A product was not considered a dietary supplement if it contained a synthetic steroid, including substances known as "pro-hormones."

12. Pro-hormones are a classification of precursor drugs of anabolic steroids like testosterone, which are taken to boost the body's available hormone supply. These precursors are intended to be converted to full, active hormones via an enzymatic process that occurs during metabolism. Pro-hormones are used mainly by athletes for the purpose of increasing size, strength, endurance, recovery time or to add lean body mass. They are most used for increasing

muscle mass or reducing body fat levels. Pro-hormones have similar side-effects to anabolic steroids.

13. The FDCA defined the term "interstate commerce" as "(1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body." Respondent was vice-president of SK Labs, Inc. located in Anaheim, California. Respondent's co-conspirators were Guillermo R., who owned a sports nutrition company located in Oceanside, California; and Steve W., the president and owner of a laboratory located in North, Danville, Virginia (collectively "conspirators"). Guillermo R. and his sports nutrition company were not registered with the FDA as a manufacturing facility for drugs.

14. Steve W. illegally imported raw drug powders from China for the purpose of manufacturing drugs he marketed as "M-Drol" and "H-Drol." M-Drol listed its single active ingredient as methasterone, a "designer steroid" designed to mimic the pharmacological effects of the original drug. H-Drol listed its single active ingredient as a designer drug identified as halovar, a clone of halodrol. The Drug Enforcement Administration now classifies M-Drol and H-Drol as anabolic steroids.

15. In or about 2008 and 2009, Steve W. shipped the raw drug powders to Respondent's SK Labs Inc. in California. SK Labs Inc. then encapsulated and bottled M-Drol and H-Drol and shipped the products back to Steve W. in Virginia.

16. Pursuant to 21 U.S.C. § 352, the M-Drol and H-Drol labels were false and misleading in that they claimed the products were the more lightly regulated dietary supplements but, in fact, were intended to be used as drugs. M-Drol and H-Drol were misbranded drugs because (a) their labeling was false and misleading; (b) their labels did not contain the name and place of business of the manufacturer, packer or distributor; (c) their labeling did not bear adequate directions for use; and/or warnings against use in those pathological conditions or by children where its use may be dangerous to health; and (d) they were manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under 21 U.S.C. § 360, and they were not included in a list required by 21 U.S.C. § 360(j) and 21 U.S.C. § 352(o).

17. At some point, Respondent and SK Labs Inc. ceased manufacturing M-Drol and H-Drol for Steve W. In or about December 2010, Steve W. contacted Respondent and requested that he restart the manufacture of M-Drol and H-Drol. Respondent indicated he did not want his company to be involved in this activity, but agreed to locate someone that could do so.

18. Respondent subcontracted with Guillermo R. and his sports nutrition company to manufacture the M-Drol and H-Drol capsules for Steve W. On or about December 8, 2010, Respondent sent e-mails to Steve W. stating "I know they are also involved in the otherside of the business (hinthint) so I'm sure the PH [prohormone] thing is something they are used to." Respondent also stated: "Let me know how the first run goes. I will work directly with him [Guillermo R.] to make sure it goes smooth (overview the formulation, etc.) As for the compensation I really don't care if it works out and the contact is beneficial to you, whatever you think is cool is cool with me."

19. In or about December 2010, Respondent and Steve W. agreed to have the material (payment, bottle labels, raw drug powders), shipped directly to Respondent for the first few orders to make sure everything worked out. Steve W. caused 10 kilograms of raw drug powder to be sent to Respondent for the production of M-Drol capsules.

20. From December 2010 through August 2011, Guillermo R. manufactured 40,676 bottles of M-Drol and H-Drol capsules in California and shipped them to Steve W. in Virginia. Steve W. sent cash payments of approximately $16,000 to Respondent as a finder's fee for locating Guillermo R. to manufacture these products.

21. On July 6, 2016, in the United States District Court, Western District of Virginia, in case number 1:16cr00034, a five-count indictment was filed against Respondent and his co-conspirators as follows: Count 1 – conspiracy to commit an offense against the United States and to defraud the United States (18 U.S.C. § 37); Count 2 – conspiracy to commit mail fraud (21 U.S.C. §§ 1341 and 1349); and Counts 3, 4, and 5 – mail fraud (21 (U.S.C. § 1341).

22. On March 10, 2017, the grand jury delivered a verdict of guilty on all five counts. The court entered judgment on June 6, 2017. Respondent was committed to the custody of the Federal Bureau of Prisons for a total term of eight months. Following his release, Respondent is

required to serve supervised released for a term of two years on standard conditions, and special conditions that require he submit to a Fourth Amendment waiver, and pay an assessment of $500.00 and a fine of $50,000. The court also issued an Order of Forfeiture seeking a money judgment in the amount of $77,000, which represents proceeds of the offenses of conviction attributable to Respondent. Respondent filed an appeal of his conviction on June 16, 2017.

FIRST CAUSE FOR DISCIPLINE

(Commission of Acts Involving Dishonesty, Fraud & Deceit)

23. Respondent has subjected his license to discipline under section 4301, subdivision (f) of the Code in that his conduct, as described in paragraphs 9-22, above, involved dishonesty, fraud, and deceit.

SECOND CAUSE FOR DISCIPLINE

(Violating Federal & State Laws & Regulations Governing Pharmacy)

24. Respondent is subject to disciplinary action under section 4301, subdivision (o) of the Code for unprofessional conduct in that he violated the United States Code, and Board of Pharmacy Regulations (California Code of Regulations, Title 16, Section 1700, et seq.), when he conspired to formulate and manufacture anabolic steroids labeled as dietary supplements, but, in fact, were intended to be used as drugs, as described in paragraphs 9-22, above.

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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 Pharmacist License Number RPH 62489, issued to Sitesh Bansi Patel;

2. Ordering Sitesh Bansi Patel 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,

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

DATED: 7/14/17

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

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