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

In the Matter of the Accusation Agai	inst:
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Case No. 3430

SAVCO GENERIC DRUGS

2101 Forest Avenue, No. 122 San Jose, CA 95128

Pharmacy Permit No. PHY 32506

Respondent.

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This decision shall become effective on August 25, 2010.

It is so ORDERED on July 26, 2010.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

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STANLEY C. WEISSER Board President

$_{1}\parallel$	EDMUND G. BROWN JR.				
2	Attorney General of California FRANK H. PACOE				
3	Supervising Deputy Attorney General				
	CHAR SACHSON Deputy Attorney General				
4	State Bar No. 161032 455 Golden Gate Avenue, Suite 11000				
5	San Francisco, CA 94102-7004 Telephone: (415) 703-5558				
6	Facsimile: (415) 703-5480 Attorneys for Complainant				
7	BEFORE THE				
8	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS				
9	STATE OF CALIFORNIA				
10					
11	In the Matter of the Accusation Against:	Case No. 3430			
12	SAVCO GENERIC DRUGS 2101 Forest Avenue, No. 122	OAH No. 2010020464			
13	San Jose, CA 95128 Pharmacy Permit No. PHY 32506	STIPULATED SURRENDER OF LICENSE AND ORDER AND FULL			
14	Respondents.	SETTLEMENT OF CASE NO. 3430			
15	icespondents.				
16	IT IS HEREBY STIPULATED AND AGREED by and between the parties in this				
17	proceeding that the following matters are true:				
18	<u>PARTIES</u>				
19	1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy.				
20	She brought this action solely in her official capacity and is represented in this matter by Edmund				
21	G. Brown Jr., Attorney General of the State of California, by Char Sachson, Deputy Attorney				
22	General.				
23	2. Savco Generic Drugs (Respondent) is represented in this proceeding by attorney Ann				
24	Koo, whose address is 199 River Oaks Parkway, San Jose, CA 95134.				
25	3. On or about December 3, 1985, the	Board of Pharmacy issued Pharmacy Permit No.			
26	PHY 32506 to Respondent Savco Generic Drugs. The Pharmacy Permit was in full force and				
27	effect at all times relevant to the charges brought in Accusation No. 3430 and will expire on				
28	December 1, 2010, unless renewed.				

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JURISDICTION

4. Accusation No. 3430 was filed before the Board of Pharmacy (Board), Department of Consumer Affairs, and is currently pending against Respondent. The Accusation and all other statutorily required documents were properly served on Respondent on December 21, 2009. Respondent timely filed its Notice of Defense contesting the Accusation. A copy of Accusation No. 3430 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

- 5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in Accusation No. 3430. Respondent also has carefully read, fully discussed with counsel, and understands the effects of this Stipulated Surrender of License and Order.
- 6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel, at its own expense; the right to confront and cross-examine the witnesses against it; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.
- 7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

- 8. Respondent admits the truth of each and every charge and allegation in Accusation No. 3430, agrees that cause exists for discipline and hereby surrenders its Pharmacy Permit No. PHY 32506 for the Board's formal acceptance.
- 9. Respondent understands that by signing this stipulation it enables the Board to issue an order accepting the surrender of their Pharmacy Permit without further process.

CONTINGENCY

- 10. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and surrender, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that it may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Disciplinary Order shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.
- 11. The parties understand and agree that facsimile copies of this Stipulated Surrender of License and Order, including facsimile signatures thereto, shall have the same force and effect as the originals.
- 12. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 13. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Order:

ORDER

IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 32506, issued to Respondent Savco Generic Drugs, is surrendered and accepted by the Board of Pharmacy.

14. The surrender of Respondent's Pharmacy Permit and the acceptance of the surrendered license by the Board shall constitute the imposition of discipline against Respondent. This stipulation constitutes a record of the discipline and shall become a part of Respondent's license history with the Board.

- 15. Respondent shall lose all rights and privileges as a pharmacy at 2101 Forest Avenue, No 122 in San Jose, California as of the effective date of the Board's Decision and Order.
- 16. Respondent shall cause to be delivered to the Board both its wall license certificate and, if one was issued, pocket license on or before the effective date of the Decision and Order.
- 17. If Respondent ever files an application for licensure or a petition for reinstatement in the State of California, the Board shall treat it as a new application for licensure. Respondent must comply with all the laws, regulations and procedures for reinstatement of a revoked license in effect at the time the application is filed, and all of the charges and allegations contained in Accusation No. 3430 shall be deemed to be true, correct and admitted by Respondent when the Board determines whether to grant or deny the application. Respondent may not apply, reapply, or petition for any licensure or registration of the Board for three (3) years from the effective date of the Decision and Order.
- 18. If Respondent should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation No. 3430 shall be deemed to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any other proceeding seeking to deny or restrict licensure.
- 19. Respondent shall pay the Board its costs of investigation and enforcement in the amount of \$9,103.50 prior to issuance of a new or reinstated license.

ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorney, Ann Koo. I understand the stipulation and the effect it will have on my Pharmacy Permit. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of

1 2	Pharmacy.		
3	DATED: 06/07/10 SAVEO GENERIC DRUGS		
4	Respondent		
5	I have read and fully discussed with Respondent Savco Generic Drugs the terms and		
6	conditions and other matters contained in this Stipulated Surrender of License and Order. I		
7	approve its form and content.		
-8	DATED:		
9	ANN KOO Attorney for Respondent		
10			
11	ENDORSEMENT		
2	The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted		
13	for consideration by the Board of Pharmacy of the Department of Consumer Affairs.		
14	Dated: May 26, 2010 Respectfully submitted,		
15	EDMUND G. BROWN JR. Attorney General of California		
16	FRANK H. PACOE Supervising Deputy Attorney General		
17			
18	CHAR SACHSON		
19.	Deputy Attorney General Attorneys for Complainant		
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}			
1 2	Pharmacy.		
3	DATED:		
4	SAVCO GENERIC DRUGS Respondent		
5	I have read and fully discussed with Respondent Savco Generic Drugs the terms and		
6	conditions and other matters contained in this Stipulated Surrender of License and Order. I		
7	approve its form and content.		
8	DATED: /0/7/2010 Succession.		
9	ANN KOO		
ro	Attorney for Respondent		
1	ENDORSEMENT		
12	The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted		
13	for consideration by the Board of Pharmacy of the Department of Consumer Affairs.		
4	Dated: May 26, 2010 Respectfully submitted,		
5	Edmund G. Brown Jr.		
6	Attorney General of California FRANK H. PACOE		
7	Supervising Deputy Attorney General		
18			
19	Char Sachson Deputy Attorney General		
20	Attorneys for Complainant		
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Exhibit A

Accusation No. 3430

II					
	•				
1	EDMUND G. BROWN JR. Attorney General of California				
2	FRANK H. PACOE Supervising Deputy Attorney General CHAR SACHSON Deputy Attorney General				
3					
4	State Bar No. 161032 455 Golden Gate Avenue, Suite 11000				
5	San Francisco, CA 94102-7004 Telephone: (415) 703-5558				
6	Facsimile: (415) 703-5480				
7	Attorneys for Complainant				
8	BEFORE THE BOARD OF PHARMACY				
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA				
10		•			
11	In the Matter of the Accusation Against:	Case No. 3430			
12	JOHN MICHAEL PUCCINELLI	ACCUSATION			
13	22477 Santa Paula Ave. Cupertino, CA 95014				
14	Pharmacist License No. RPH 26552				
15	and				
16	SAVCO GENERIC DRUGS 2101 Forest Avenue, No. 122				
17	San Jose, CA 95128				
18	Pharmacy Permit No. PHY 32506				
19	Respondents.				
20	Complainant alleges:				
21	PARTIES				
22	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity				
23	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.				
24	2. On or about July 16, 1970, the Board of Pharmacy issued Pharmacist License				
25	Number RPH 26552 to John Michael Puccinelli (Respondent Puccinelli). The Pharmacist				
26	License was in full force and effect at all times relevant to the charges brought herein and will				
27	expire on March 31, 2011, unless renewed.				
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3. On or about December 3, 1985, the Board of Pharmacy issued Pharmacy Permit No. PHY 32506 to Savco Generic Drugs (Respondent Savco), with James W. Junker, RPH 24929 as President of the company, Lloyd Ando as Vice President, and Ron Sakamoto as Secretary. The Savco Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on December 1, 2009, unless renewed.

JURISDICTION

- 4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.
- 5. Section 4300(a) of the Code provides that every license issued by the Board may be suspended or revoked.
 - 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 procured by fraud or misrepresentation or issued by mistake.

Unprofessional conduct shall include, but is not limited to, any of the following:

"(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.

"(j) The violation of any of the statutes of this state, or 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."

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7. Section 4081 of the Code states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or dangerous devices shall be at all times during business hours open to inspection by authorized officers of the law, and shall be preserved for at least three years from the date of making. A current inventory shall be kept by every ... pharmacy ... who maintains a stock of dangerous drugs or dangerous devices.

- "(b) The owner, officer, and partner of any pharmacy, wholesaler, or veterinary food-animal drug retailer shall be jointly responsible, with the pharmacist-in-charge or representative-incharge, for maintaining the records and inventory described in this section.
- "(c) The pharmacist-in-charge or representative-in-charge shall not be criminally responsible for acts of the owner, officer, partner, or employee that violate this section and of which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or she did not knowingly participate."
 - 8. Section 4104(b) of the Code states:

"Every pharmacy shall have written policies and procedures for addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among licensed individuals employed by or with the pharmacy."

- 9. Section 4105 of the Code states:
- "(a) All records or other documentation of the acquisition and disposition of dangerous drugs and dangerous devices by any entity licensed by the board shall be retained on the licensed premises in a readily retrievable form.
- "(b) The licensee may remove the original records or documentation from the licensed premises on a temporary basis for license-related purposes. However, a duplicate set of those records or other documentation shall be retained on the licensed premises.
- (c) The records required by this section shall be retained on the licensed premises for a period of three years from the date of making.

"(d) Any records that are maintained electronically shall be maintained so that the pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the case of a veterinary food-animal drug retailer or wholesaler, the designated representative on duty, shall, at all times during which the licensed premises are open for business, be able to produce a hard copy and electronic copy of all records of acquisition or disposition or other drug or dispensing-related records maintained electronically.

- "(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), and (c) be kept on the licensed premises.
- (2) A waiver granted pursuant to this subdivision shall not affect the board's authority under this section or any other provision of this chapter."
 - 10. California Code of Regulations, title 16, section 1714, states, in pertinent part:
- "(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed.

 The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy.

"(d) Each pharmacist while on duty shall be responsible for the security of the prescription department, including provisions for effective control against theft or diversion of dangerous drugs and devices, and records for such drugs and devices. Possession of a key to the pharmacy where dangerous drugs and controlled substances are stored shall be restricted to a pharmacist."

11. California Code of Regulations, title 16, section 1715.6, states:

"The owner shall report to the Board within thirty (30) days of discovery of any loss of the controlled substances, including their amounts and strengths."

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12. California Code of Regulations, title 16, section 1718, states:

"'Current Inventory' as used in Sections 4081 and 4332 of the Business and Professions Code shall be considered to include complete accountability for all dangerous drugs handled by every licensee enumerated in Sections 4081 and 4332.

"The controlled substances inventories required by Title 21, CFR, Section 1304 shall be available for inspection upon request for at least 3 years after the date of the inventory."

13. California Health and Safety Code section 11208 states:

"In a prosecution under this division, proof that a defendant received or has had in his possession at any time a greater amount of controlled substances than is accounted for by any record required by law or that the amount of controlled substances possessed by the defendant is a lesser amount than is accounted for by any record required by law is prima facie evidence of guilt."

- 14. 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.
- 15. Section 118, subdivision (b), of the Code provides that the expiration of a license shall not deprive the Board of jurisdiction to proceed with a disciplinary action during the period within which the license may be renewed, restored, reissued or reinstated.

CONTROLLED SUBSTANCES/DANGEROUS DRUGS

6. Section 4022 of the Code states:

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

- "(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a ______," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
- "(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."
- 17. Vicodin, Lortab, Lorcet, and Norco are brand names for compounds of varying dosages of acetaminophen and hydrocodone bitartrate, also known as Hydrocodone-APAP, a Schedule III controlled substance as designated by Health and Safety Code section 11056(e)(4) and a dangerous drug as designated by Business and Professions Code section 4022, used for pain relief.

FACTUAL BACKGROUND

- 18. Respondent John Puccinelli was the Pharmacist-in-Charge (PIC) employed by and responsible for Respondent Savco, at 2101 Forest Avenue, No. 122 in San Jose, California, from August 21, 2006 until February 10, 2009.
- 19. On or about October 2, 2008, Respondent Puccinelli discovered that Aimee Riaski, an employee of Respondent Savco, had pilfered a large quantity of the controlled substance Hydrocodone/APAP. On or about January 29, 2009, Respondent Puccinelli reported to the Board theft or loss of 16,000 tablets of Hydrocodone-APAP 10/500, and 142,500 tablets of Hydrocodone-APAP 10/325 from Respondent Savco, due to employee pilferage.
- 20. Further internal controlled substance audits conducted at Respondent Savco for the periods April 30, 2007 to May 14, 2009 and April 30, 2005 to May 14, 2009 substantiated a total shortage (acquisitions greater than dispositions) as follows:

Hydrocodone/APAP 10/325: 135,771 tablets missing;

Hydrocodone/APAP 10/500: 16,740 tablets missing;

Hydrocodone/APAP 5/500: 24,775 tablets missing; and

Hydrocodone/APAP 7.5/750: 7,393 tablets missing.

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21. Respondent Savco did not have written policies and procedures on theft, diversion or self-use in place at the time of the employee pilferage. Respondent Savco also failed to have in place an effective control on the security of controlled substances, and failed to adequately maintain inventory of controlled substances.

CAUSES FOR DISCIPLINE AS TO RESPONDENT PUCCINELLI

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Controlled Substances)

22. Respondent Puccinelli is subject to disciplinary action under sections 4301(j) and/or (o) of the Code, section 11208 of the Health and Safety Code, and/or California Code of Regulations, title 16, section 1714, subdivision (d), in that, as described in paragraphs 18-20 above, Respondent Puccinelli failed to maintain the security of the controlled substances received, dispensed and/or otherwise handled therein.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Current Inventory of Controlled Substances)

23. Respondent Puccinelli is subject to disciplinary action under sections 4301(j) and/or (o) of the Code, section 11208 of the Health and Safety Code, and/or California Code of Regulations, title 16, section 1718, in that, as described in paragraphs 18-20 above, Respondent Puccinelli failed to maintain an accurate and complete inventory of controlled substances received, dispensed and/or otherwise handled therein.

THIRD CAUSE FOR DISCIPLINE

(Failure to Maintain Policies and Procedures)

24. Respondent Puccinelli is subject to disciplinary action under sections 4301(j) and/or (o), and/or 4104(b) of the Code, in that, as described in paragraph 21 above, Respondent Puccinelli failed to have written policies and procedures on theft/diversion or self-use in place.

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CAUSES FOR DISCIPLINE AS TO RESPONDENT SAVCO

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Controlled Substances)

25. Respondent Savco is subject to disciplinary action under sections 4301(j) and/or (o), and 4081 of the Code, section 11208 of the Health and Safety Code, and/or California Code of Regulations, title 16, section 1714, subdivision (b), in that, as described in paragraphs 18-20 above, Respondent Savco failed to maintain the security of the controlled substances received, dispensed and/or otherwise handled therein.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Accurate Controlled Substances Inventory)

26. Respondent Savco is subject to disciplinary action under sections 4301(j) and/or (o), and 4081 of the Code, section 11208 of the Health and Safety Code, and/or California Code of Regulations, title 16, section 1718 in that, as described in paragraphs 18-20 above, Respondent Savco failed to maintain an accurate and complete inventory of controlled substances received, dispensed and/or otherwise handled therein.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Policies and Procedures)

27. Respondent Savco is subject to disciplinary action under sections 4301(j) and/or (o), and 4104(b) of the Code, in that, as described in paragraph 21 above, Respondent Savco failed to have written policies and procedures on theft/diversion or self-use in place.

SEVENTH CAUSE FOR DISCIPLINE

(Failure to Report Drug Loss)

28. Respondent Savco is subject to disciplinary action under sections 4301(j) and/or (o), and California Code of Regulations, title 16, section 1715.6, in that, as described in paragraphs 18-20 above, Respondent Savco failed to report the loss of controlled substances to the Board within 30 days.

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 26552, issued to John Michael Puccinelli (Respondent Puccinelli);
- 2. Revoking or suspending Pharmacy Permit Number PHY 32506, issued to Respondent Savco Generic Drugs (Respondent Savco);
- 3. Forbidding Respondent Puccinelli and Savco owners and officers (James W. Junker, Lloyd Ando, and Ron Sakamoto) from serving as a manager, administrator, owner, member, officer, director, associate, or partner of Respondent Savco or of any other Board licensee, pursuant to Business and Professions Code section 4307;
- 4. Ordering John Michael Puccinelli and Savco Generic Drugs jointly and severally 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;
 - 5. Taking such other and further action as deemed necessary and proper.

DATED: 12/8/09

Executive Officer

Executive Officer Board of Pharmacy

Department of Consumer Affairs

State of California Complainant

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