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8	BEFORE T				
9	BOARD OF PHA DEPARTMENT OF CON	SUMER AFFAIRS			
10	STATE OF CAL	IFORNIA			
11	In the Matter of the Accusation Against:				
12	TARGET STORE #T-289	Case No. 3358			
. 13	20200 Bloomfield Ave Cerritos, CA 90703				
14	Pharmacy Permit No. PHY 45438,	ACCUSATION			
15.	and				
16	GITA PATEL a.k.a. GITA D. PATEL				
17	12033 Fairford Avenue Norwalk, CA 90650				
· 18	Pharmacist License No. RPH 31173				
19	Respondents.				
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. 21	Complainant alleges:	· · ·			
22 .	PART	TIES			
23	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity				
24	as the Executive Officer of the Board of Pharmacy, D	epartment of Consumer Affairs.			
- 25	2. On or about June 19, 2001, the Board of	Pharmacy (Board) issued Pharmacy Permit			
26	No. PHY 45438 to Target Store #T-289 (Respondent	TARGET STORE #T-289). Gita D. Patel			
27	was its Pharmacist-In-Charge, from the date the perm	it was issued, June 19, 2001, through			
28_	November 2, 2008; and Thanh-Van Pham Tran, is Ph	armacist-In-Charge, November 3, 2008 to			
	1				
		Accusation			

present. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2010, unless renewed.

3. On or about August 1, 1977, the Board of Pharmacy issued Pharmacist License No. RPH 31173 to Gita Patel a.k.a. Gita D. Patel (Respondent GITA PATEL). The Pharmacist License was in full force and effect at all times relevant to the charges brought herein and will expire on August 31, 2010, unless renewed.

JURISDICTION

4. This Accusation is brought before the 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.

STATUTORY PROVISIONS

5. Section 118, subdivision (b), provides that the suspension, expiration, surrender, or
cancellation 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.

6. Section 4005 states:

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"(a) The board may adopt rules and regulations, not inconsistent with the laws of this 17 state, as may be necessary for the protection of the public. Included therein shall be the right to 18 adopt rules and regulations as follows: for the proper and more effective enforcement and 19 administration of this chapter; pertaining to the practice of pharmacy; relating to the sanitation of 20 persons and establishments licensed under this chapter; pertaining to establishments wherein any 21 drug or device is compounded, prepared, furnished, or dispensed; providing for standards of 22 minimum equipment for establishments licensed under this chapter, pertaining to the sale of drugs 23 24 by or through any mechanical device; and relating to pharmacy practice experience necessary for licensure as a pharmacist. 25

"(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a

state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

"(c) The adoption, amendment, or repeal by the board of these or any other board rules or 4 regulations shall be in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code."

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Section 4059.5, subdivision (a), states: 7.

"Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, the designated representative may sign for and receive the delivery."

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8. Section 4081 states:

"(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs 13 or dangerous devices shall be at all times during business hours open to inspection by authorized 14 officers of the law, and shall be preserved for at least three years from the date of making. A 15 current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary 16 food-animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital, 17 institution, or establishment holding a currently valid and unrevoked certificate, license, permit, 18 registration, or exemption under Division 2 (commencing with Section 1200) of the Health and 19 Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and 20 Institutions Code who maintains a stock of dangerous drugs or dangerous devices. 21

"(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-in-charge, for maintaining the records and inventory described in this section. .24

"(c) The pharmacist-in-charge or representative-in-charge shall not be criminally 25 responsible for acts of the owner, officer, partner, or employee that violate this section and of 26 which the pharmacist-in-charge or representative-in-charge had no knowledge, or in which he or 27 she did not knowingly participate." 28

Section 4105 states: 9.

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"(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 10 pharmacist-in-charge, the pharmacist on duty if the pharmacist-in-charge is not on duty, or, in the 11 case of a veterinary food-animal drug retailer or wholesaler, the designated representative on 12 duty, shall, at all times during which the licensed premises are open for business, be able to 13 produce a hard copy and electronic copy of all records of acquisition or disposition or other drug 14 or dispensing-related records maintained electronically. 15

"(e)(1) Notwithstanding subdivisions (a), (b), and (c), the board, may upon written request, 16 grant to a licensee a waiver of the requirements that the records described in subdivisions (a), (b), 17 and (c) be kept on the licensed premises. 18

(2) A waiver granted pursuant to this subdivision shall not affect the board's authority 19 under this section or any other provision of this chapter." 20

Section 4115, subdivision (h), states that "[t]he pharmacist on duty shall be directly 10. 22 responsible for the conduct of a pharmacy technician supervised by that pharmacist.

23 11. Section 4300 states, in pertinent part, that "[e]very license issued may be suspended or revoked." 24

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Section 4301 states, in pertinent part: 12.

"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:

"(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...."

REGULATORY PROVISIONS

13. 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.

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"(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."

14. 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."
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COST RECOVERY

15. Section 125.3 provides 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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CONTROLLED SUBSTANCES / DANGEROUS DRUGS

16. Hydrocodone with Acetaminophen is a Schedule III controlled narcotic substance pursuant to Health and Safety Code section 11056(e)(4) and a dangerous drug pursuant to section 4022. Preparations containing hydrocodone in combination with other non-narcotic medicinal ingredients are in Schedule III. Norco is the brand name for a pain medication combining narcotic Hydrocodone with non-narcotic Acetaminophen.

11 17. Codeine, generic name codeine phosphate, is a Schedule II controlled substance as
12 defined in Health and Safety Code section 11055 (b)(1)(h); or "Codeine", not more than 1.8
13 grams per 100 milliliters, Schedule III controlled substance as defined in Health and Safety Code
14 section 11056 (e)(2), and categorized as a dangerous drug pursuant to section 4022.

15 18. Lorazepam (marketed under various brand names, including Alzapam, Ativan,
16 Loraz, Lorazepam Intensol) is an anti-anxiety agent (benzodiazepines, mild tranquilizer,
17 depressant) used for the relief of anxiety. It is a Schedule IV controlled substance as defined in
18 Health and Safety Code section 11057(d)(16) and a dangerous drug according to section 4022.

19 19. Temazepam, in a class of sedative/hypnotics, is a Schedule IV controlled substance
20 pursuant to Health and Safety Code section 11057(d)(29) and a dangerous drug pursuant to
21 section 4022.

22 20. Xanax, a brand name for alprazolam, is an anti-anxiety benzodiazepin and is a
23 Schedule IV controlled substance as designated by Health and Safety Code section 11057(d)(1)
24 and is categorized as a dangerous drug pursuant to section 4022.

SUMMARY OF FACTS

21. The following facts are common to all charges of the Accusation:

a. On or about October 22, 2007, the Board received a "DEA Report of Theft or Loss of Controlled Substances" from Respondents in which they reported significant losses of

controlled substances, attributed to employee pilferage, and reported plans to improve security (including installation of surveillance cameras) to prevent future losses. Respondents reported tracking shortages since 2006. However, significant losses continued, with no effective action taken to improve pharmacy security until August of 2009.

Ъ. In August of 2007, Lisa Thomas was a licensed pharmacy technician who had been an employee of Respondent TARGET STORE #T-289 for approximately five years.

On or about August 28, 2007, a reserve pharmacist observed Thomas attempt to c. sign for a drug delivery of 19 bottles of Hydrocodone 500 count (9,500 tablets). The reserve pharmacist stopped Thomas - and the unauthorized delivery of Hydrocodone tablets she had 9 attempted to sign for was returned to the supplier/wholesaler. At or about that time, Thomas was 10 also observed concealing a bottle of Hydrocode 500 count while on duty in the pharmacy. 11

During the month of August 2007, Thomas signed for drug deliveries đ. containing controlled substances, as follows:

Delivery Dates	Controlled Substances Delivered		
August 1, 2007	Hydrocodone (3,000 tablets)		
August 2, 2007	Hydrocodone (4,000 tablets)		
August 3, 2007	Hydrocodone (4,000 tablets), Codeine (100 tablets), Lorazepam (100 tablets), Temazepam (100 tablets), Xanax (200 tablets)		
August 10, 2007	Hydrocodone (4,000 tablets)		
August 14, 2007	Hydrocodone (4,000 tablets)		
August 16, 2007	Hydrocodone (5,000 tablets)		
August 17, 2009	Hydrocodone (5,000 tablets)		
August 23, 2007	Hydrocodone (5,000 tablets)		
August 24, 2007	Hydrocodone (7,000 tablets)		

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Commencing on October 22, 2007, a selected drug audit was performed by e. Board inspectors. The audit period was from July 4, 2006 through July 3, 2008. The audit revealed that 315,429 tablets of Hydrocodone had been ordered and received at Respondent Target Store #T-289 but were not in stock and unaccounted for.

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	7/4/2006	4 .		7/3/2008	
	INVENTORY	PURCHASED	DISPENSED	INVENTORY	AMOUNT
DRUG	AMOUNT	AMOUNT	AMOUNT	AMOUNT	SHORT
Hydrocodone	2,370	441,500	124,488	3,953	315, 429

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4 f. It appears that Thomas' methodology was to order controlled substances 5 electronically from the supplier/wholesaler, using the pharmacy's account number, and arranged 6 for delivery of unauthorized orders on days when she was working and could sign for the deliveries. Thomas would then delete the electronic invoices when the products arrived. Irregular activities of this pharmacy technician were neither noticed nor questioned by Respondents until 8 9 August of 2009.

10 Presumably, Thomas destroyed or otherwise disposed of purchase invoices to g. 11 conceal losses of controlled substances through theft. That invoices were missing was not 12 discovered by Respondents.

13 h. During the approximately summer of 2006 through the summer of 2008, Respondent TARGET STORE #T-289 rarely dispensed Hydrocodone 500 count – perhaps two to 14 15 three bottles per month - and kept a minimal amount of the drug in stock, generally one or two 16 bottles.

FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Complete and Accurate Records)

Respondents TARGET STORE #T-289 and GITA PATEL are subject to disciplinary 22. action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with sections 4005, 4081 and 4105, and California Code of Regulations, title 16, section 1718 for failure to maintain a complete and accurate record for all controlled substances/dangerous drugs received, sold, or otherwise disposed of by them. As described in paragraph 22, above, Respondents were unable to account for 315,429 doses of Hydrocodone, a controlled substance and dangerous drug, per a selected drug audit performed by Board inspectors. The audit period was from July 4, 206 to July 4, 2008. The audit revealed that 315,429

doses of Hydrocodone had been ordered and received but were not in stock and not accounted for.

SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Complete Acquisition/Disposition Records)

23. Respondents TARGET STORE #T-289 and GITA PATEL are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (j) and (o), in conjunction with sections 4081, subdivision (a), and 4105 for failure to maintain all records of acquisition and disposition for three (3) years from date of making and to keep a current inventory of dangerous drugs. Respondents' employee stole and/or destroyed purchase invoices to conceal losses of controlled substances through theft. Neither the missing invoices, nor the large volume of controlled substances ordered without authorization by Thomas and delivered to the pharmacy, were discovered by Respondents during the subject time period, as described in paragraph 22, above.

<u>THIRD CAUSE FOR DISCIPLINE</u> (Allowing a Non-Pharmacist to Order and Receive Controlled Substances)

24. Respondents TARGET STORE #T-289 and GITA PATEL are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (o), in conjunction with section 4059.5, subdivision (a), for allowing a non pharmacist, pharmacy technician Lisa Thomas, to order and sign for the delivery (on 8/1/07, 8/2/07, 8/3/07, 8/10/07, 8/14/07, 8/17/07 and 8/24/07) of controlled substances and dangerous drugs, as described in paragraph 22 above.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Properly Supervise Pharmacy Staff)

25. Respondents TARGET STORE #T-289 and GITA PATEL are subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (o); in conjunction with section 4115, subdivision (h), for failing to properly supervise pharmacy technician Lisa Thomas' activities while working in the pharmacy, allowing her to steal Hydrocodone, a controlled substance and dangerous drug, failing to institute theft and loss controls, and not maintaining complete inventory controls. Complainant refers to and by this

reference incorporates allegations of paragraphs 22 - 25 above as though fully set forth. 1 FIFTH CAUSE FOR DISCIPLINE 2 (Failure to Maintain Security of Pharmacy) 3 Respondents TARGET STORE #T-289 and GITA PATEL are subject to disciplinary 26. 4 action under section 4300 for unprofessional conduct as defined in section 4301, subdivision (o), 5

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in conjunction with section 4005 and California Code of Regulations, title 16, section 1714, subdivision (b), for failing to maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured. Respondents failed to secure and maintain its facilities from diversion and theft. Complainant refers to and by this reference incorporates allegations of paragraphs 22 - 26 above as though fully set forth.

SIXTH CAUSE FOR DISCIPLINE

(Failure to Maintain Security of Controlled Substances)

27. Respondent GITA PATEL is subject to disciplinary action under section 4300 for unprofessional conduct as defined in section 4301, subdivisions (o), in conjunction with section 14 4005 and California Code of Regulations, title 16, section 1714, subdivision (d), for failing to 15 secure the prescription department and provide effective controls to prevent theft or diversion of 16 315,429 doses of Hydrocodone, a controlled substance and dangerous drug, between July 4, 2006 17 and July 3, 2008, and maintain records for such drugs. Complainant refers to and by this reference 18 incorporates allegations of paragraphs 22 - 27 above as though fully set forth. 19

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:

Revoking or suspending Pharmacy Permit No. PHY 45438, issued to Target Store 1. 23 #T-289; 24

2. Revoking or suspending Pharmacist License No. RPH 31173, issued to Gita Patel a.k.a. Gita D. Patel Gita D. Patel;

Ordering Target Store #T-289 and Gita D. Patel to pay the Board of Pharmacy the 27 3 reasonable costs of the investigation and enforcement of this case, pursuant to Business and -28

Professions Code section 125.3; and 1 Taking such other and further action as deemed necessary and proper. 4. 2 3 4 1/29/10 DATED: 5[.] VIRGINIA HER D Executive Officer Board of Pharmacy б Department of Consumer Affairs 7 State of California Complainant 8 9 LA2009603201 7/31/2009 10 50482238.doc 11 12 13 14 15 16 17 18 19 · 20 21 22 23 24 ·25 26 27 28 11 Accusation