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

In the Matter of the Accusation Against:

**THANHS PHARMACY; NGUYEN LE
633 N. Spring, Suite 5
Los Angeles, CA 90012
Pharmacy Permit No. PHY 32480,**

and

**NGUYEN LE
633 N. Spring, Suite 5
Los Angeles, CA 90012
Pharmacist License No. RPH 39548**

Respondent.

Case No. 6193

DEFAULT DECISION AND ORDER

[Gov. Code, §11520]

FINDINGS OF FACT

1. On or about May 9, 2017, Complainant Virginia Herold (“Complainant”), in her official capacity as the Executive Officer of the Board of Pharmacy (the “Board”), Department of Consumer Affairs, filed Accusation No. 6193 against Thanhs Pharmacy, Nguyen Le; and Nguyen Le (collectively “Respondent”) before the Board. ₁(Accusation attached as **Exhibit A.**)

1 2. On or about October 11, 1985, the Board issued Pharmacy Permit No. PHY 32480 to
2 Respondent. The Pharmacy Permit was in full force and effect at all times relevant to the charges
3 brought in Accusation No. 6193 and will expire on October 1, 2018, unless renewed.

4 3. On or about October 11, 1985, the Board issued Pharmacist License No. PHY 39548
5 to Respondent. The Pharmacist License was in full force and effect at all times relevant to the
6 charges brought in Accusation No. 6193 and will expire on May 31, 2019, unless renewed.

7 4. On or about September 25, 2017, Respondent was served by Certified and First Class
8 Mail copies of the Accusation No. 6193, Statement to Respondent, Notice of Defense, Request
9 for Discovery, and Discovery Statutes (Government Code sections 11507.5, 11507.6, and
10 11507.7) at Respondent's address of record which, pursuant to Business and Professions Code
11 section 4100, is required to be reported and maintained with the Board. Respondent's address of
12 record was and is:

13 633 N. Spring, Suite 5
14 Los Angeles, CA 90012.

15 5. Service of the Accusation was effective as a matter of law under the provisions of
16 Government Code section 11505, subdivision (c) and/or Business & Professions Code section
17 124.

18 6. On or about October 9, 2017, Respondent filed a notice of defense to the Accusation.
19 On or about January 25, 2018, Respondent filed withdrawals of the notice of defense.

20 7. Government Code section 11506(c) states, in pertinent part:

21 (c) The respondent shall be entitled to a hearing on the merits if the respondent
22 files a notice of defense . . . and the notice shall be deemed a specific denial of all
23 parts of the accusation . . . not expressly admitted. Failure to file a notice of defense
24 . . . shall constitute a waiver of respondent's right to a hearing, but the agency in its
25 discretion may nevertheless grant a hearing.

26 8. The Board takes official notice of its records and the fact that Respondent failed to
27 file a Notice of Defense within 15 days after service upon him of the Accusation, and therefore
28 waived his right to a hearing on the merits of Accusation No. 6193.

 9. California Government Code section 11520(a) states, in pertinent part:

 (a) If the respondent either fails to file a notice of defense . . . or to appear at
the hearing, the agency may take action based upon the respondent's express

1 admissions or upon other evidence and affidavits may be used as evidence without
2 any notice to respondent

3 10. Pursuant to its authority under Government Code section 11520, the Board finds
4 Respondent is in default. The Board will take action without further hearing and, based on the
5 relevant evidence contained in the Default Decision Evidence Packet in this matter, as well as
6 taking official notice of all the investigatory reports, exhibits and statements contained therein on
7 file at the Board's offices regarding the allegations contained in Accusation No. 6193, finds that
8 the charges and allegations in Accusation No. 6193, are separately and severally, found to be true
9 and correct by clear and convincing evidence.

10 11. Taking official notice of its own internal records, pursuant to Business and
11 Professions Code section 125.3, the Board finds that the actual costs for Investigation and
12 Enforcement are \$11,768.00 as of January 26, 2018.

13 **DETERMINATION OF ISSUES**

14 1. Based on the foregoing findings of fact, Respondent Thanhs Pharmacy; Nguyen Le
15 has subjected his Pharmacy Permit No. PHY 32480 to discipline.

16 2. Based on the foregoing findings of fact, Respondent Nguyen Le has subjected his
17 Pharmacist License No. RPH 39548 to discipline.

18 3. The agency has jurisdiction to adjudicate this case by default.

19 4. The Board of Pharmacy is authorized to revoke Respondent's Pharmacy Permit based
20 upon the following violations alleged in the Accusation which are supported by the evidence
21 contained in the Default Decision Evidence Packet in this case.:

22 a. Business and Professions Code section 4301, subdivision (o), in that Respondent
23 exhibited unprofessional conduct by failing to comply with California Code of Regulations, title
24 16, section 1707.5, subdivision (a). On or about July 28, 2016, and November 8, 2016,
25 Respondent's prescription label was not in the correct font (sans serif) and size (12-point font)
26 and did not have the necessary information offset by blank space, bold, or color.

27 b. Business and Professions Code section 4301, subdivision (o), in that Respondent
28 exhibited unprofessional conduct by failing to comply with California Code of Regulations, title

1 16, section 1707.5, subdivision (d). On or about July 28, 2016, and November 8, 2016,
2 Respondent did not have written policies and procedures to identify the patient’s language and to
3 provide interpretive services in the patient’s language.

4 c. Business and Professions Code section 4301, subdivision (o), in that Respondent
5 exhibited unprofessional conduct by failing to comply with California Code of Regulations, title
6 16, section 1707.6, subdivision (c). On or about July 28, 2016, and November 8, 2016,
7 Respondent did not have a “point to your language” sign or notice in the pharmacy.

8 d. Business and Professions Code section 4301, subdivision (o), in that Respondent
9 exhibited unprofessional conduct by failing to comply with California Code of Regulations, title
10 16, section 1714, subdivisions (b)-(c). On or about July 28, 2016, and November 8, 2016,
11 Respondent’s pharmacy was dirty, cluttered, and maintained expired and in-date medications in
12 the bathroom.

13 e. Business and Professions Code section 4301, subdivision (o), in that Respondent
14 exhibited unprofessional conduct by failing to comply with California Code of Regulations, title
15 16, section 1715, subsections (a) and (d). On or about July 28, 2016, and November 8, 2016,
16 Respondent was not able to produce a recent self-assessment form. Respondent failed to
17 complete the necessary self-assessments before July 1 of every odd-numbered year.

18 f. Business and Professions Code section 4301, subdivision (j), in that Respondent
19 exhibited unprofessional conduct by failing to comply with Health and Safety Code section
20 111295, as it relates to Health and Safety Code, section 111285. On or about July 28, 2016, and
21 November 8, 2016, Respondent held large amounts of expired and adulterated products on its
22 shelves. These expired medications were ready to be dispensed.

23 g. Business and Professions Code section 4301, subdivision (j), in that Respondent
24 exhibited unprofessional conduct by failing to comply with Health and Safety Code section
25 11165, subdivision (d). On or about July 28, 2016, Respondent was not reporting its CURES data
26 within seven days after it dispensed controlled substances.

27 h. Business and Professions Code section 4301, subdivision (j), in that Respondent
28 exhibited unprofessional conduct by failing to comply with Business and Professions Code

1 section 4104, subdivision (b). On or about July 28, 2016, and November 8, 2016, Respondent did
2 not have written policies and procedures for addressing theft, diversion, impairment, or self-use
3 of dangerous drugs among licensed individuals employed by or with the pharmacy.

4 **ORDER**

5 IT IS SO ORDERED that Pharmacy Permit No. PHY 32480, heretofore issued to
6 Respondent Thanks Pharmacy; Nguyen Le, is revoked.

7 IT IS SO ORDERED that Pharmacist License No. RPH 39548, heretofore issued to
8 Respondent Nguyen Le, is revoked.

9 IT IS SO ORDERED that Respondent Nguyen Le is prohibited from serving as a manager,
10 administrator, owner, member, officer, director, associate, or partner of a licensee for five years
11 from the effective date of this Decision and Order, or until both Pharmacist License Number RPH
12 39548 and Pharmacy Permit Number PHY 32480 are reinstated.

13 Pursuant to Government Code section 11520, subdivision (c), Respondent may serve a
14 written motion requesting that the Decision be vacated and stating the grounds relied on within
15 seven (7) days after service of the Decision on Respondent. The agency in its discretion may
16 vacate the Decision and grant a hearing on a showing of good cause, as defined in the statute.

17 This Decision shall become effective at 5:00 p.m. on August 2, 2018.

18 It is so ORDERED on July 3, 2018.

19 BOARD OF PHARMACY
20 DEPARTMENT OF CONSUMER AFFAIRS
21 STATE OF CALIFORNIA

22 

23 By _____

24 Victor Law, R.Ph.
25 Board President

26 52774897.DOCX
27 DOJ Matter ID:LA2017604883

28 Attachment:
Exhibit A: Accusation

Exhibit A

Accusation

(THANHS PHARMACY, NGUYEN LE and NGUYEN LE)

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7 *Attorneys for Complainant*

8 **BEFORE THE**
9 **BOARD OF PHARMACY**
10 **DEPARTMENT OF CONSUMER AFFAIRS**
11 **STATE OF CALIFORNIA**

12 In the Matter of the Accusation Against:

Case No. 6193

13 **NGUYEN LE DBA THANHS PHARMACY**
633 N. Spring, Suite 5
14 Los Angeles, CA 90012

ACCUSATION

15 Pharmacy Permit No. PHY 32480,

16 **and**

17 **NGUYEN LE**
633 N. Spring, Suite 5
18 Los Angeles, CA 90012

19 Pharmacist License No. RPH 39548

20 Respondents.

21 Complainant alleges:

22 **PARTIES**

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

26 2. On or about August 28, 1985, the Board issued Pharmacist License Number RPH
27 39548 to Respondent Nguyen Le ("Respondent Le"). The Pharmacist License was in full force
28

1 and effect at all times relevant to the charges brought herein and will expire on May 31, 2019,
2 unless renewed.

3 3. On or about October 11, 1985, the Board issued Pharmacy Permit Number PHY
4 32480 to Respondent doing business as Thanks Pharmacy (“Respondent Thanks”).¹ Respondent
5 Le is and has been the Individual Licensed Owner and Pharmacist-in-Charge of Respondent Thanks
6 since October 11, 1985. The Pharmacy Permit was in full force and effect at all times relevant to
7 the charges brought herein and will expire on October 1, 2017, unless renewed.

8 **JURISDICTION**

9 4. This Accusation is brought before the Board, under the authority of the following
10 laws. All section references are to the Business and Professions Code unless otherwise indicated.

11 5. Section 4300 provides, in pertinent part, that every license issued by the Board is
12 subject to discipline, including suspension or revocation.

13 6. Section 4300.1 of the Code states:

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

19 7. Section 4307 of the Code states in pertinent part:

20 “(a) Any person who has been denied a license or whose license has been revoked or is
21 under suspension, or who has failed to renew his or her license while it was under suspension, or
22 who has been a manager, administrator, owner, member, officer, director, associate, partner, or
23 any other person with management or control of any partnership, corporation, trust, firm, or
24 association whose application for a license has been denied or revoked, is under suspension or has
25 been placed on probation, and while acting as the manager, administrator, owner, member, officer,
26 director, associate, partner, or any other person with management or control had knowledge of or

27 _____
28 ¹ Respondent Le and Respondent Thanks shall be collectively referred to herein as “Respondents.”

1 knowingly participated in any conduct for which the license was denied, revoked, suspended, or
2 placed on probation, shall be prohibited from serving as a manager, administrator, owner, member,
3 officer, director, associate, partner, or in any other position with management or control of a
4 licensee as follows:

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

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

9 “(b) ‘Manager, administrator, owner, member, officer, director, associate, partner, or any
10 other person with management or control of a license’ as used in this section and Section 4308,
11 may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.”

12 STATUTORY PROVISIONS

13 8. Section 4036.5 of the Code states:

14 “‘Pharmacist-in-charge’ means a pharmacist proposed by a pharmacy and approved by the
15 board as the supervisor or manager responsible for ensuring the pharmacy’s compliance with all
16 state and federal laws and regulations pertaining to the practice of pharmacy.”

17 9. Section 4040.5 of the Code states:

18 “‘Reverse distributor’ means every person who acts as an agent for pharmacies, drug
19 wholesalers, third-party logistics providers, manufacturers, and other entities by receiving,
20 inventorying, warehousing, and managing the disposition of outdated or nonsaleable dangerous
21 drugs.”

22 10. Section 4104 of the Code states:

23 “(a) Every pharmacy shall have in place procedures for taking action to protect the public
24 when a licensed individual employed by or with the pharmacy is discovered or known to be
25 chemically, mentally, or physically impaired to the extent it affects his or her ability to practice the
26 profession or occupation authorized by his or her license, or is discovered or known to have
27 engaged in the theft, diversion, or self-use of dangerous drugs.

1 “(b) Every pharmacy shall have written policies and procedures for addressing chemical,
2 mental, or physical impairment, as well as theft, diversion, or self-use of dangerous drugs, among
3 licensed individuals employed by or with the pharmacy.”

4 11. Section 4301 of the Code states:

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

8 “....

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

11 “....

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

16 “....”

17 12. Section 11165, subdivision (d), of the Health and Safety Code states:

18 “For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance,
19 as defined in the controlled substances schedules in federal law and regulations, specifically
20 Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal
21 Regulations, the dispensing pharmacy, clinic, or other dispenser shall report the following
22 information to the Department of Justice as soon as reasonably possible, but not more than seven
23 days after the date a controlled substance is dispensed, in a format specified by the Department of
24 Justice:

25 “(1) Full name, address, and, if available, telephone number of the ultimate user or
26 research subject, or contact information as determined by the Secretary of the United States
27 Department of Health and Human Services, and the gender, and date of birth of the ultimate
28 user.

1 (2) The prescriber's category of licensure, license number, national provider identifier
2 (NPI) number, if applicable, the federal controlled substance registration number, and the
3 state medical license number of any prescriber using the federal controlled substance
4 registration number of a government-exempt facility.

5 (3) Pharmacy prescription number, license number, NPI number, and federal
6 controlled substance registration number.

7 (4) National Drug Code (NDC) number of the controlled substance dispensed.

8 (5) Quantity of the controlled substance dispensed.

9 (6) International Statistical Classification of Diseases, 9th revision (ICD-9) or 10th
10 revision (ICD-10) Code, if available.

11 (7) Number of refills ordered.

12 (8) Whether the drug was dispensed as a refill of a prescription or as a first-time
13 request.

14 (9) Date of origin of the prescription.

15 (10) Date of dispensing of the prescription."

16 13. Section 111285 of the Health and Safety Code states:

17 "Any drug or device is adulterated if its strength differs from, or its purity or quality is
18 below, that which it is represented to possess."

19 \\
20 \\
21

22 14. Section 111295 of the Health and Safety Code states:

23 "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or
24 device that is adulterated."

25 REGULATORY PROVISIONS

26 15. California Code of Regulations, title 16, section 1707.5, states:

27 "(a) Labels on drug containers dispensed to patients in California shall conform to the
28 following format:

1 “(1) Each of the following items, and only these four items, shall be clustered into
2 one area of the label that comprises at least 50 percent of the label. Each item shall be
3 printed in at least a 12-point sans serif typeface, and listed in the following order:

4 “(A) Name of the patient

5 “(B) Name of the drug and strength of the drug. For the purposes of this
6 section, “name of the drug” means either the manufacturer's trade name of the drug,
7 or the generic name and the statement “generic for _____” where the brand name
8 is inserted and the name of the manufacturer. In the professional judgment of the
9 pharmacist:

10 “(i) If the brand name is no longer widely used, the label may list
11 only the generic name of the drug, and

12 “(ii) The manufacturer's name may be listed outside of the patient-
13 centered area.

14 “(C) The directions for the use of the drug.

15 “(D) The condition or purpose for which the drug was prescribed if the
16 condition or purpose is indicated on the prescription.

17 “(2) For added emphasis, the label shall also highlight in bold typeface or color, or
18 use blank space to set off the items listed in subdivision (a)(1).

19 “(3) The remaining required elements for the label specified in section 4076 of the
20 Business and Professions Code, as well as any other items of information appearing on the
21 label or the container, shall be printed so as not to interfere with the legibility or emphasis of
22 the primary elements specified in paragraph (1) of subdivision (a). These additional elements
23 may appear in any style, font, and size typeface.

24 “....

25 “(d) The pharmacy shall have policies and procedures in place to help patients with limited
26 or no English proficiency understand the information on the label as specified in subdivision (a) in
27 the patient's language. The pharmacy's policies and procedures shall be specified in writing and
28 shall include, at minimum, the selected means to identify the patient's language and to provide

1 interpretive services and translation services in the patient's language. The pharmacy shall, at
2 minimum, provide interpretive services in the patient's language, if interpretive services in such
3 language are available, during all hours that the pharmacy is open, either in person by pharmacy
4 staff or by use of a third-party interpretive service available by telephone at or adjacent to the
5 pharmacy counter.”

6 16. California Code of Regulations, title 16, section 1707.6, states in part:

7 “(c) Every pharmacy, in a place conspicuous to and readable by a prescription drug
8 consumer, at or adjacent to each counter in the pharmacy where dangerous drugs are dispensed or
9 furnished, shall post or provide a notice containing the following text:

10 *Point to your language. Interpreter services will be provided to you upon request at no cost.*

11 “This text shall be repeated in at least the following languages: Arabic, Armenian,
12 Cambodian, Cantonese, Farsi, Hmong, Korean, Mandarin, Russian, Spanish, Tagalog, and
13 Vietnamese. Each pharmacy shall use the standardized notice provided or made available by the
14 board, unless the pharmacy has received prior approval of another format or display methodology
15 from the board. The board may delegate authority to a committee or to the Executive Officer to
16 give the approval.

17 “The pharmacy may post this notice in paper form or on a video screen if the posted notice
18 or video screen is positioned so that a consumer can easily point to and touch the statement
19 identifying the language in which he or she requests assistance. Otherwise, the notice shall be made
20 available on a flyer or handout clearly visible from and kept within easy reach of each counter in
21 the pharmacy where dangerous drugs are dispensed or furnished, available at all hours that the
22 pharmacy is open. The flyer or handout shall be at least 8 1/2 inches by 11 inches.”

23 17. California Code of Regulations, title 16, section 1714, states in part:

24 “(b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and
25 equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The
26 pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of
27 pharmacy.

28

1 “(c) The pharmacy and fixtures and equipment shall be maintained in a clean and orderly
2 condition. The pharmacy shall be dry, well-ventilated, free from rodents and insects, and properly
3 lighted. The pharmacy shall be equipped with a sink with hot and cold running water for
4 pharmaceutical purposes.”

5 18. California Code of Regulations, title 16, section 1715, states in pertinent part:

6 “(a) The pharmacist-in-charge of each pharmacy as defined under section 4029 or section
7 4037 of the Business and Professions Code shall complete a self-assessment of the pharmacy's
8 compliance with federal and state pharmacy law. The assessment shall be performed before July 1
9 of every odd-numbered year. The primary purpose of the self-assessment is to promote
10 compliance through self-examination and education.

11 “. . . .

12 “(d) Each self-assessment shall be kept on file in the pharmacy for three years after it is
13 performed.”

14 COST RECOVERY

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

19 FACTS

20 *Inspection on May 13, 2010*

21 20. On or about May 13, 2010, a Board inspector performed an inspection at
22 Respondents' pharmacy. As a result of the inspection, the inspector issued a notice of non-
23 compliance to Respondents for, *inter alia*, the following violations:

- 24 i. *California Code of Regulations, title 16, section 1715*: No self-assessment since 2006; this
25 was the second time Respondents were written up for this violation.
26 ii. *Section 4342 of the Code*: Large amount of expired products (filled 12 x 12 x 12 box); this
27 was the second time Respondents were written up for this violation.
28

1 iii. *California Code of Regulations, title 16, section 1714*: dirty shelves; this was the second
2 time Respondents were written up for this violation.

3 iv. *Health and Safety Code, section 11165*: Failure to conduct CURES reporting; this was
4 the second time Respondents were written up for this violation.

5 ***Complaint Against Respondent on October 15, 2015***

6 21. On October 15, 2015, the Board received a complaint regarding Respondents from the
7 PBM OptumRx (“Optum”). Optum performed an audit at Respondents’ pharmacy and found one
8 pharmacist (Respondent Le), no technician, expired medications on the shelves, prescriptions
9 taped to the wall with patient information exposed to the public, no use of signature or delivery
10 logs, no logging of refrigerator temperature, prescription back tags were not used, HIPAA²
11 information was not posted or printed for patients, and improper disposal of HIPAA information
12 because the pharmacist – Respondent Le – shreds documents by hand, and improper record
13 keeping.

14 ***Inspection on July 28, 2016***

15 22. On July 28, 2016, a Board inspector went to Respondents’ pharmacy to perform an
16 inspection. Respondent Le was present during the inspection.

17 23. The inspector went through the shelves of the pharmacy, and observed many expired
18 drugs on the pharmacy shelves. She asked Respondent Le for an empty box, and he provided her
19 with one. The inspector filled the box with drugs from one side of the shelving unit. Eventually,
20 after spot checking four of the shelving units (about half the drug stock in the pharmacy), the
21 inspector was able to fill an entire desktop and two large boxes with drugs that had expired. The
22 drugs had expiration dates which were over six months old, and some of the drugs had expired in
23 2008. The inspector estimated that approximately 40% of the pharmacy’s drug supply had
24 expired. The inspector asked Respondent Le who his reverse distributor was, and he gave the
25 inspector a job sheet dated 2010 for Reverse Distributors, Inc. Respondent Le stated he had not
26 returned anything through them yet. Respondent Le stated he returns items to his wholesaler,

27 _____
28 ² “HIPAA” refers to the Health Insurance Portability and Accountability Act of 1996.

1 Bergen, and he throws away³ whatever he cannot return. The inspector advised Respondent Le to
2 be aware of the expiration dates of his stock and not to dispense drugs which were outdated. She
3 also asked him to go through the entire pharmacy and remove all expired products from the
4 dispensing shelves and keep all the expired items in a separate area so he would not accidentally
5 dispense them. The inspector instructed Respondent Le to send the medications to a licensed
6 reverse distributor or back to the wholesaler.

7 24. During the inspection, Respondent Le could not find any self-assessment completed
8 after 2006, which means he could not find the ones he should have completed in 2011, 2013, and
9 2015. In a statement he prepared at the end of the inspection, Respondent Le admitted that he
10 last completed a self-assessment in 2006. The inspector asked Respondent Le to complete a self-
11 assessment and send it to her within 14 days.

12 25. During the inspection, the shelves in the pharmacy were very dirty, and the pharmacy
13 was cluttered.

14 26. Respondent Le informed the inspector that he was submitting CURES⁴ reports
15 monthly. The inspector informed Respondent Le that he was required to submit CURES report
16 weekly, and Respondent Le seemed shocked at this information.

17 27. The inspector asked Respondent Le for copies of Respondents' policies and
18 procedures. After reviewing Respondents' policies, the inspector determined that Respondents did
19 not have policies and procedures for the following: Interpretive services, absence of a pharmacist,
20 technician job duties, impairment, and theft. In a statement he prepared at the end of the
21 inspection, Respondent Le admitted that he did not have policies or procedures for Quality
22 Assurance, temporary absence of a pharmacist, or interpretive services.

23
24
25 ³ Throwing medications in the trash is not an appropriate method of disposing of drugs in a pharmacy.
26 ⁴ "CURES" stands for Controlled Substance Utilization Review and Evaluation System. CURES
27 is a database of Schedule II, III and IV controlled substance prescriptions dispensed in California
28 serving the public health, regulatory oversight agencies, and law enforcement. CURES assists the
government in reducing prescription drug abuse and diversion without affecting legitimate medical
practice or patient care.

1 28. The inspector observed that Respondents' prescription labels were not in sans serif
2 font. She talked to Respondent Le about the size and font, and asked him to fix it immediately and
3 to send her proof within 14 days.

4 29. The inspector also noted there was no "point to your language" poster in the
5 pharmacy; she asked Respondent Le to obtain one and post it in the pharmacy.

6 30. At the end of the inspection, the inspector issued Respondents a notice of non-
7 compliance for the following:

- 8 i. *California Code of Regulations, title 16, section 1715*: No self-assessment since 2006;
9 this was the third time Respondents were written up for this violation.
- 10 ii. *Code of Federal Regulations, title 21, section 1306.22*: No controlled substance printout
11 being done every three days; this was the second time Respondents were cited for this
12 violation.
- 13 iii. *Section 4342 of the Code*: Large amount of expired products; this was the third time
14 Respondents were written up for this violation.
- 15 iv. *California Code of Regulations, title 16, section 1714*: dirty shelves; this was the third
16 time Respondents were written up for this violation.
- 17 v. *Health and Safety Code, section 11165*: Failure to conduct CURES reporting; this was
18 the third time Respondents were written up for this violation.
- 19 vi. *California Code of Regulations, title 16, section 1793.7*: No technician job description.
- 20 vii. *Section 4104 of the Code*: No policy for theft and impairment.
- 21 viii. *California Code of Regulations, title 16, section 1707.5*: No policy for interpretive
22 services; label not compliant.
- 23 ix. *California Code of Regulations, title 16, section 1707.6*: No point to your language
24 sign.
- 25 x. *California Code of Regulations, title 16, section 1714.1*: No policy for temporary
26 absence of a pharmacist.

27 31. All Respondents were to submit to the Board proof of compliance with the issues
28 outlined in the notice of non-compliance by August 11, 2016. As of September 20, 2016,

1 Respondents did not show proof of correction or compliance with the following items: complete a
2 self-assessment; controlled substance printout every three days; proper disposal of expired
3 medications; create a policy on theft and impairment; create a policy on interpretive services; edit
4 label to comply with regulations; create a policy regarding the temporary absence of a pharmacist;
5 draft technician job duties.

6 *Inspection on November 8, 2016*

7 32. On November 8 2016, two Board inspectors went to Respondents' pharmacy to
8 perform a follow-up inspection and to inquire why Respondent failed to comply with the
9 inspector's previous request for proof of compliance.

10 33. During this inspection, Respondent Le admitted that he had not completed a new self-
11 assessment.

12 34. Respondent Le also admitted that he had not written a policy for interpretive services.

13 35. The inspectors also observed that Respondents failed to post the "point to your
14 language" sign.

15 36. Respondents' prescription labels were the same as the labels Respondents were using
16 during the inspection on July 28, 2016. Respondents' prescription labels were not in sans serif
17 font. The inspector asked Respondent Le to contact his software vendor, Care Company, to
18 change the label.

19 37. Respondents also failed to properly dispose of the expired medications. Respondent
20 Le indicated that he kept the expired medications in four boxes at the front of the pharmacy.

21 38. The two inspectors inspected the medications on the pharmacy shelves. They
22 observed that many of the medications on the pharmacy's shelves were expired. The inspectors
23 pulled approximately 20% to 25% of the pharmacy stock off the shelves because they were
24 expired. Some of these medications expired in 2008.

25 39. During the inspection, the pharmacy was cluttered and there were many items on the
26 ground. One inspector wiped the shelving with a wet paper towel to remove the stuck layer of dirt
27 which was on the shelves. The other inspector's hands were black after pulling medications off the
28 shelves.

1 40. The inspectors also observed that the bathroom was dirty and Respondents were
2 storing expired medications and in-date Metformin in boxes in the bathroom.

3 41. Because many of the problems from the July 2016 inspection were not corrected, the
4 inspector issued another notice of non-compliance to Respondents for the following issues:

- 5 i. *California Code of Regulations, title 16, section 1715:* No self-assessment since 2006;
6 this was the fourth time Respondents were written up for this violation.
7 ii. *Code of Federal Regulations, title 21, section 1306.22:* No controlled substance printout
8 being done every three days; this was the third time Respondents were cited for this
9 violation.
10 iii. *Section 4342 of the Code:* Large amount of expired products; this was the fourth time
11 Respondents were written up for this violation.
12 iv. *California Code of Regulations, title 16, section 1714:* dirty shelves; this was the fourth
13 time Respondents were written up for this violation.
14 v. *California Code of Regulations, title 16, section 1793.7:* No technician job description.
15 vi. *Section 4104 of the Code:* No policy for theft and impairment.
16 vii. *California Code of Regulations, title 16, section 1707.5:* No policy for interpretive
17 services; label not compliant.
18 viii. *California Code of Regulations, title 16, section 1707.6:* No point to your language
19 sign.
20 ix. *California Code of Regulations, title 16, section 1714.1:* No policy for temporary absence
21 of a pharmacist.

22 **FIRST CAUSE FOR DISCIPLINE**

23 **(Unprofessional Conduct – Violating California Regulations Applicable to Pharmacy**

24 **-- Respondent Thanks)**

25 42. Respondent Thanks' Pharmacy Permit is subject to disciplinary action pursuant to
26 section 4301, subdivision (o), in that Respondent Thanks exhibited unprofessional conduct by
27 failing to comply with the provisions of the California Code of Regulations, title 16, as follows:
28

1 (a) Section 1707.5, subdivision (a): On or about July 28, 2016, and November 8,
2 2016, Respondent Thanks's prescription label was not in the correct font (sans serif) and size (12-
3 point font) and did not have the necessary information offset by blank space, bold, or color.

4 (b) Section 1707.5, subdivision (d): On or about July 28, 2016, and November 8,
5 2016, Respondent Thanks did not have written policies and procedures to identify the patient's
6 language and to provide interpretive services in the patient's language.

7 (c) Section 1707.6, subdivision (c): On or about July 28, 2016, and November 8,
8 2016, Respondent Thanks did not have a "point to your language" sign or notice in the pharmacy.

9 (d) Section 1714, subdivisions (b)-(c): On or about July 28, 2016, and November 8,
10 2016, Respondent Thanks' pharmacy was dirty, cluttered, and maintained expired and in-date
11 medications in the bathroom.

12 (e) Section 1715, subsections (a) and (d): On or about July 28, 2016, and
13 November 8, 2016, Respondent Thanks was not able to produce a recent self-assessment form.
14 Respondent Thanks failed to complete the necessary self-assessments before July 1 of every odd-
15 numbered year.

16 Complainant realleges paragraphs 19-40, above, as if fully set forth herein.

17 **SECOND CAUSE FOR DISCIPLINE**

18 **(Unprofessional Conduct – Violating California Statutes Applicable to Pharmacy**
19 **-- Respondent Thanks)**

20 43. Respondent Thanks' Pharmacy Permit is subject to disciplinary action pursuant to
21 section 4301, subdivision (j), in that Respondent Thanks exhibited unprofessional conduct by
22 failing to comply with the provisions of the following California statutes:

23 (a) Health and Safety Code, section 111295, as it relates to Health and Safety Code,
24 section 111285: On or about July 28, 2016, and November 8, 2016, Respondent Thanks held
25 large amounts of expired and adulterated products on its shelves. These expired medications were
26 ready to be dispensed.

1 (b) Health and Safety Code, section 11165, subdivision (d): On or about July 28,
2 2016, Respondent Thanks was not reporting its CURES data within seven days after it dispensed
3 controlled substances.

4 (c) Section 4104, subdivision (b), of the Code: On or about July 28, 2016, and
5 November 8, 2016, Respondent Thanks did not have written policies and procedures for
6 addressing theft, diversion, impairment, or self-use of dangerous drugs among licensed individuals
7 employed by or with the pharmacy.

8 Complainant realleges paragraphs 19-40, above, as if fully set forth herein.

9 **THIRD CAUSE FOR DISCIPLINE**

10 **(Unprofessional Conduct – Violating California Regulations Applicable to Pharmacy**

11 **-- Respondent Le)**

12 44. Respondent Le's Pharmacist License is subject to disciplinary action pursuant to
13 section 4301, subdivision (o), in that Respondent Le exhibited unprofessional conduct by failing to
14 comply with the provisions of the California Code of Regulations, title 16, as follows:

15 (a) Section 1707.5, subdivision (a): On or about July 28, 2016, and November 8,
16 2016, Respondent Le's prescription label was not in the correct font (sans serif) and size (12-point
17 font) and did not have the necessary information offset by blank space, bold, or color.

18 (b) Section 1707.5, subdivision (d): On or about July 28, 2016, and November 8,
19 2016, Respondent Le did not have written policies and procedures to identify a patient's language
20 and to provide interpretive services in the patient's language.

21 (c) Section 1707.6, subdivision (c): On or about July 28, 2016, and November 8,
22 2016, Respondent Le did not have a "point to your language" sign or notice in his pharmacy.

23 (d) Section 1714, subdivisions (b)-(c): On or about July 28, 2016, and November 8,
24 2016, Respondent Le's pharmacy was dirty, cluttered, and maintained expired and in-date
25 medications in the bathroom.

26 (e) Section 1715, subsections (a) and (d): On or about July 28, 2016, and
27 November 8, 2016, Respondent Le was not able to produce a recent self-assessment form.

28

1 Respondent Le failed to complete the necessary self-assessments before July 1 of every odd-
2 numbered year.

3 Complainant realleges paragraphs 19-40, above, as if fully set forth herein.

4 **FOURTH CAUSE FOR DISCIPLINE**

5 **(Unprofessional Conduct – Violating California Statutes Applicable to Pharmacy**
6 **-- Respondent Le)**

7 45. Respondent Le's Pharmacist License is subject to disciplinary action pursuant to
8 section 4301, subdivision (j), in that Respondent Le exhibited unprofessional conduct by failing to
9 comply with the provisions of the following California statutes:

10 (a) Health and Safety Code, section 111295, as it relates to Health and Safety Code,
11 section 111285: On or about July 28, 2016, and November 8, 2016, Respondent Le held large
12 amounts of expired and adulterated products on the shelves of his pharmacy. These expired
13 medications were ready to be dispensed.

14 (b) Health and Safety Code, section 11165, subdivision (d): On or about July 28,
15 2016, Respondent Le was not reporting his CURES data within seven days after he dispensed
16 controlled substances.

17 (c) Section 4104, subdivision (b), of the Code: On or about July 28, 2016, and
18 November 8, 2016, Respondent Le did not have written policies and procedures for addressing
19 theft, diversion, or self-use of dangerous drugs among licensed individuals employed by or with the
20 pharmacy.

21 Complainant realleges paragraphs 19-40, above, as if fully set forth herein.

22 **OTHER MATTERS**

23 46. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
24 PHY 32480 issued to Nguyen Le, dba Thanks Pharmacy, while Nguyen Le was an owner and had
25 knowledge of or knowingly participated in any conduct for which the licensee was disciplined,
26 Nguyen Le shall be prohibited from serving as a manager, administrator, owner, member, officer,
27 director, associate, or partner of a licensee for five years if Pharmacy Permit Number PHY 32480
28 is placed on probation or until Pharmacy Permit Number PHY 32480 is reinstated if it is revoked.

1 47. Pursuant to Code section 4307, if discipline is imposed on Pharmacist License Number
2 RPH 39548 issued to Nguyen Le, Nguyen Le shall be prohibited from serving as a manager,
3 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
4 Pharmacist License Number RPH 39548 is placed on probation or until Pharmacist License
5 Number RPH 39548 is reinstated if it is revoked.

6 **DISCIPLINE CONSIDERATIONS**

7 48. To determine the degree of discipline, if any, to be imposed on Respondent Thanks,
8 Complainant alleges that on or about August 5, 2010, in a prior action, the Board issued Citation
9 Number CI 2009 41745 and ordered Respondent Thanks to pay a fine of \$5,000.00 for violating
10 the following statutes and regulations: Business and Professions Code, sections 4076, subdivisions
11 (a) & (11)(A), and 4342, subdivision (a); Health and Safety Code, section 11165, subdivision (b);
12 Code of Federal Regulations, title 21, section 1306.22; California Code of Regulations, title 16,
13 sections 1715, subdivision (a), 1711, subdivision (c)(1), 1714, subdivision (c), 1707.2, and 1717,
14 subdivision (b). That Citation is now final and is incorporated by reference as if fully set forth.

15 **PRAYER**

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

18 1. Revoking or suspending Pharmacy Permit Number PHY 32480, issued to Nguyen Le,
19 dba Thanks Pharmacy;

20 2. Revoking or suspending Pharmacist License Number RPH 39548, issued to Nguyen
21 Le;

22 3. Prohibiting Nguyen Le, dba Thanks Pharmacy, from serving as a manager,
23 administrator, owner, member, officer, director, associate, or partner of a licensee for five years if
24 Pharmacy Permit Number PHY 32480, is placed on probation or until Pharmacy Permit Number
25 PHY 32480 is reinstated if Pharmacy Permit Number PHY 39226 issued to issued to Nguyen Le,
26 dba Thanks Pharmacy, is revoked;

27 4. Prohibiting Nguyen Le from serving as a manager, administrator, owner, member,
28 officer, director, associate, or partner of a licensee for five years if Pharmacist License Number

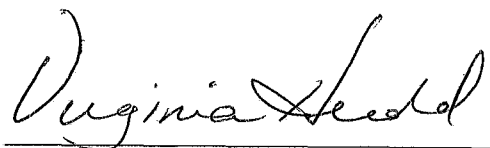
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RPH 39548, is placed on probation or until Pharmacist License Number RPH 39548 is reinstated if Pharmacist License Number RPH 39548 issued to issued to Nguyen Le is revoked;

5. Ordering Nguyen Le, dba Thanks Pharmacy, and Nguyen Le 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,

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

DATED: 9/5/17



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

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