

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

In the Matter of the Accusation Against:

**TOWER PHARMACY
DARIN NELLE, OWNER AND PHARMACIST-IN-
CHARGE
501 E. Olive Avenue
Turlock, California 95382
Pharmacy Permit No. PHY 54174**

**TOWER PHARMACY, INC.
dba QUESENBERRY'S WATERFORD
PHARMACY
DARIN L. NELLE,
PRESIDENT/PHARMACIST-IN-CHARGE
12641 Bentley Street
Waterford, California 95386
Pharmacy Permit No. PHY 50624
and
DARIN L. NELLE
1801 Colorado Avenue 100
Turlock, California 95382
Pharmacist License No. RPH 44309**

Respondents.

Case No. 5300 & 5301

OAH No. 2017050023 & 2017050103

DECISION AND ORDER

The attached Stipulated Settlement 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 at 5:00 p.m. on November 29, 2017.

It is so ORDERED on October 30, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Amy Gutierrez, Pharm.D.
Board President

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Attorneys for Complainant

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

In the Matter of the Accusation Against:

**TOWER PHARMACY
DARIN NELLE, OWNER AND
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Turlock, California 95382**

Pharmacist License No. RPH 44309

Respondents.

Case No. 5300 & 5301
OAH No. 2017050023 & 2017050103
**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

///

1 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
2 entitled proceedings that the following matters are true:

3 PARTIES

4 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy
5 (Board). She brought this action solely in her official capacity and is represented in this matter by
6 Xavier Becerra, Attorney General of the State of California, by Elena L. Almanzo, Deputy
7 Attorney General.

8 2. Respondents, Tower Pharmacy, Tower Pharmacy Inc., dba Quesenberry Pharmacy,
9 and Darin L. Nelle (Respondents) are represented in this proceeding by attorney Jeffrey S.
10 Kravitz, Esq., whose address is: 6747 Fair Oaks Blvd., Carmichael, CA 95608-3811

11 3. On or about August 2, 1991, the Board issued Pharmacist License No. RPH 44309 to
12 Darin L. Nelle (Respondent). The Pharmacist License was in full force and effect at all times
13 relevant to the charges brought in Accusation Nos. 5300 & 5301, and will expire on December
14 31, 2018, unless renewed.

15 4. On or about December 30, 2004, the Board issued Pharmacy Permit Number PHY
16 47000 to Darin L. Nelle, owner and pharmacist-in-charge of Tower Pharmacy ("Respondent
17 Tower"). On or about February 1, 2016, Pharmacy Permit No. PHY 54174 was issued to
18 Respondent Nelle as owner and pharmacist-in-charge of Tower Pharmacy due to a change in
19 location. The pharmacy permit was in full force and effect at all times relevant to the charges
20 brought herein and will expire on February 1, 2018 unless renewed.

21 5. On or about October 28, 2011, the Board issued Pharmacy Permit Number PHY
22 50624 to Tower Pharmacy, Inc. ("Respondent Tower Pharmacy, Inc."), doing business as
23 Quesenberry's Waterford Pharmacy, with Darin L. Nelle ("Respondent Nelle") as president and
24 pharmacist-in-charge. The pharmacy permit was in full force and effect at all times relevant to
25 the charges brought herein and will expire on October 1, 2018, unless renewed.

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JURISDICTION

6. Accusation No. 5300 & 5301 were filed before the Board, and are currently pending against Respondents Tower, Tower Inc. dba Quesenberry, and Nelle. The Accusations and all other statutorily required documents were properly served on Respondents. Respondents timely filed their Notices of Defense contesting the Accusations.

7. A copy of the Accusations in case Nos. 5300 & 5301 are attached as exhibits A and B and are incorporated herein by reference.

ADVISEMENT AND WAIVERS

8. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Accusation Nos. 5300 & 5301. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order.

9. Respondent are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in Accusation Nos. 5300 & 5301; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their 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.

10. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

11. Respondents understand and agree that the charges and allegations in the Accusation Nos. 5300 & 5301, if proven at a hearing, constitute cause for imposing discipline upon their Pharmacy Permits and Respondent Nelle's Pharmacy License.

12. For the purpose of resolving the Accusations without the expense and uncertainty of further proceedings, Respondents agree that, at a hearing, Complainant could establish a factual

1 basis for the charges in Accusation Nos. 5300 & 5301, and that Respondents hereby gives up
2 their right to contest those charges.

3 13. Respondents further agrees that in any future proceedings before the Board all
4 allegations set forth in Accusation Nos. 5300 & 5301 shall be deemed admitted.

5 14. Respondents agree that their Permits and Respondent Nelle's License are subject to
6 discipline and they agree to be bound by the Board's probationary terms as set forth in the
7 Disciplinary Order below.

8 CONTINGENCY

9 15. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents
10 understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may
11 communicate directly with the Board regarding this stipulation and settlement, without notice to
12 or participation by Respondents or their counsel. By signing the stipulation, Respondents
13 understand and agree that they may not withdraw their agreement or seek to rescind the
14 stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this
15 stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order shall be of
16 no force or effect, except for this paragraph, it shall be inadmissible in any legal action between
17 the parties, and the Board shall not be disqualified from further action by having considered this
18 matter.

19 16. The parties understand and agree that Portable Document Format (PDF) and facsimile
20 copies of this Stipulated Settlement and Disciplinary Order, including PDF and facsimile
21 signatures thereto, shall have the same force and effect as the originals.

22 17. This Stipulated Settlement and Disciplinary Order is intended by the parties to be an
23 integrated writing representing the complete, final, and exclusive embodiment of their agreement.
24 It supersedes any and all prior or contemporaneous agreements, understandings, discussions,
25 negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary
26 Order may not be altered, amended, modified, supplemented, or otherwise changed except by a
27 writing executed by an authorized representative of each of the parties.

28

1 18. In consideration of the foregoing admissions and stipulations, the parties agree that
2 the Board may, without further notice or formal proceeding, issue and enter the following
3 Disciplinary Order:

4 **DISCIPLINARY ORDER**

5 IT IS HEREBY ORDERED that Pharmacy Permit No. PHY 54174 issued to Respondent
6 Tower Pharmacy, Darin L.Nelle, owner, is revoked. However, the revocation is stayed and
7 Respondent is placed on probation for five (5) years on the following terms and conditions.

8 **1. Obey All Laws**

9 Respondent owner shall obey all state and federal laws and regulations.

10 Respondent owner shall report any of the following occurrences to the board, in writing,
11 within seventy-two (72) hours of such occurrence:

- 12 an arrest or issuance of a criminal complaint for violation of any provision of the
13 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
14 substances laws
- 15 a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
16 criminal complaint, information or indictment
- 17 a conviction of any crime
- 18 discipline, citation, or other administrative action filed by any state or federal agency
19 which involves respondent's Pharmacy Permit or which is related to the practice of
20 pharmacy or the manufacturing, obtaining, handling or distributing, billing, or
21 charging for any drug, device or controlled substance.

22 Failure to timely report any such occurrence shall be considered a violation of probation.

23 **2. Report to the Board**

24 Respondent owner shall report to the board quarterly, on a schedule as directed by the board
25 or its designee. The report shall be made either in person or in writing, as directed. Among other
26 requirements, respondent owner shall state in each report under penalty of perjury whether there
27 has been compliance with all the terms and conditions of probation. Failure to submit timely
28 reports in a form as directed shall be considered a violation of probation. Any period(s) of

1 delinquency in submission of reports as directed may be added to the total period of probation.
2 Moreover, if the final probation report is not made as directed, probation shall be automatically
3 extended until such time as the final report is made and accepted by the board.

4 **3. Interview with the Board**

5 Upon receipt of reasonable prior notice, respondent owner shall appear in person for
6 interviews with the board or its designee, at such intervals and locations as are determined by the
7 board or its designee. Failure to appear for any scheduled interview without prior notification to
8 board staff, or failure to appear for two (2) or more scheduled interviews with the board or its
9 designee during the period of probation, shall be considered a violation of probation.

10 **4. Cooperate with Board Staff**

11 Respondent owner shall cooperate with the board's inspection program and with the board's
12 monitoring and investigation of respondent's compliance with the terms and conditions of his
13 probation. Failure to cooperate shall be considered a violation of probation.

14 **5. Reimbursement of Board Costs**

15 As a condition precedent to successful completion of probation, respondent owner shall pay
16 to the board its costs of investigation and prosecution in the amount of \$32,853.75. Respondent
17 Tower shall be jointly and severally liable for the costs. Respondent Tower may make payments
18 in a payment plan approved by the Board. Failure to pay costs by the deadline(s) as directed by
19 the Board shall be considered a violation of probation.

20 The filing of bankruptcy by respondent owner shall not relieve respondent of its
21 responsibility to reimburse the board its costs of investigation and prosecution.

22 **6. Probation Monitoring Costs**

23 Respondent owner shall pay any costs associated with probation monitoring as determined
24 by the board each and every year of probation. Such costs shall be payable to the board on a
25 schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as
26 directed shall be considered a violation of probation.

27 **7. Status of License**

28 Respondent owner shall, at all times while on probation, maintain current licensure with the

1 board. If respondent owner submits an application to the board, and the application is approved,
2 for a change of location, change of permit or change of ownership, the board shall retain
3 continuing jurisdiction over the license, and the respondent shall remain on probation as
4 determined by the board. Failure to maintain current licensure shall be considered a violation of
5 probation.

6 If respondent owner's license expires or is cancelled by operation of law or otherwise at any
7 time during the period of probation, including any extensions thereof or otherwise, upon renewal
8 or reapplication respondent owner's license shall be subject to all terms and conditions of this
9 probation not previously satisfied.

10 8. License Surrender While on Probation/Suspension

11 Following the effective date of this decision, should respondent owner discontinue
12 business, respondent owner may tender the premises license to the board for surrender. The
13 board or its designee shall have the discretion whether to grant the request for surrender or take
14 any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of
15 the license, respondent will no longer be subject to the terms and conditions of probation.

16 Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and
17 renewal license to the board within ten (10) days of notification by the board that the surrender is
18 accepted. Respondent owner shall further submit a completed Discontinuance of Business form
19 according to board guidelines and shall notify the board of the records inventory transfer.

20 Respondent owner shall also, by the effective date of this decision, arrange for the
21 continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written
22 notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that
23 identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating
24 as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five
25 days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy
26 of the written notice to the board. For the purposes of this provision, "ongoing patients" means
27 those patients for whom the pharmacy has on file a prescription with one or more refills
28 outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60)

1 days.

2 Respondent owner may not apply for any new licensure from the board for three (3) years
3 from the effective date of the surrender. Respondent owner shall meet all requirements applicable
4 to the license sought as of the date the application for that license is submitted to the board.

5 Respondent owner further stipulates that he or she shall reimburse the board for its costs of
6 investigation and prosecution prior to the acceptance of the surrender.

7 **9. Notice to Employees**

8 Respondent owner shall, upon or before the effective date of this decision, ensure that all
9 employees involved in permit operations are made aware of all the terms and conditions of
10 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.
11 If the notice required by this provision is posted, it shall be posted in a prominent place and shall
12 remain posted throughout the probation period. Respondent owner shall ensure that any
13 employees hired or used after the effective date of this decision are made aware of the terms and
14 conditions of probation by posting a notice, circulating a notice, or both. Additionally,
15 respondent owner shall submit written notification to the board, within fifteen (15) days of the
16 effective date of this decision, that this term has been satisfied. Failure to submit such
17 notification to the board shall be considered a violation of probation.

18 "Employees" as used in this provision includes all full-time, part-time,
19 volunteer, temporary and relief employees and independent contractors employed or
20 hired at any time during probation.

21 **10. Owners and Officers: Knowledge of the Law**

22 Respondent shall provide, within thirty (30) days after the effective date of this decision,
23 signed and dated statements from its owners, including any owner or holder of ten percent (10%)
24 or more of the interest in respondent or respondent's stock, and any officer, stating under penalty
25 of perjury that said individuals have read and are familiar with state and federal laws and
26 regulations governing the practice of pharmacy. The failure to timely provide said statements
27 under penalty of perjury shall be considered a violation of probation.

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11. Posted Notice of Probation

Respondent owner shall prominently post a probation notice provided by the board in a place conspicuous and readable to the public. The probation notice shall remain posted during the entire period of probation.

Respondent owner shall not, directly or indirectly, engage in any conduct or make any statement which is intended to mislead or is likely to have the effect of misleading any patient, customer, member of the public, or other person(s) as to the nature of and reason for the probation of the licensed entity.

Failure to post such notice shall be considered a violation of probation.

12. Violation of Probation

If a respondent owner has not complied with any term or condition of probation, the board shall have continuing jurisdiction over respondent license, and probation shall be automatically extended until all terms and conditions have been satisfied or the board has taken other action as deemed appropriate to treat the failure to comply as a violation of probation, to terminate probation, and to impose the penalty that was stayed.

If respondent owner violates probation in any respect, the board, after giving respondent owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. Notice and opportunity to be heard are not required for those provisions stating that a violation thereof may lead to automatic termination of the stay and/or revocation of the license. If a petition to revoke probation or an accusation is filed against respondent during probation, the board shall have continuing jurisdiction and the period of probation shall be automatically extended until the petition to revoke probation or accusation is heard and decided.

13. Completion of Probation

Upon written notice by the board or its designee indicating successful completion of probation, respondent license will be fully restored.

14. Ethics Course

Within sixty (60) calendar days of the effective date of this decision, respondent shall confirm that all of its licensed pharmacists are enrolled in a course in ethics, at respondent's

1 expense, approved in advance by the board or its designee. Failure to initiate the course during
2 the first year of probation, and complete it within the second year of probation, is a violation of
3 probation. Respondent shall submit a certificate of completion to the board or its designee within
4 five days after completing the course.

5 **15. Consultant for Owner or Pharmacist-in-Charge**

6 During the period of probation, Respondent Tower Pharmacy shall retain an independent
7 consultant who specializes in compounding at its own expense, who shall be responsible for
8 reviewing pharmacy operations on a monthly basis for compliance by Respondent with state and
9 federal laws and regulations governing the practice of a compounding pharmacy and for
10 compliance by Respondent with the obligations of a pharmacist-in-charge. The consultant shall
11 audit the return to stock and confirm that all billing is appropriate. A physical inspection shall be
12 completed by the consultant on a quarterly basis. The consultant shall be a pharmacist licensed by
13 and not on probation with any board of pharmacy and whose name shall be submitted to the
14 Board or its designee for prior approval within (30) days of the effective date of this decision.
15 During the period of probation, the Board or its designee retains the discretion to reduce the
16 frequency of the pharmacist consultant's review of Respondent's operations. Failure to timely
17 retain, seek approval of, or ensure timely reporting by the consultant shall be considered a
18 violation of probation.

19 IT IS FURTHER ORDERED that Pharmacy Permit No. PHY 50624 issued to Respondent
20 Tower Pharmacy, Inc. dba, Quesenberry Pharmacy, is revoked. However, the revocation is
21 stayed and Respondent Quesenberry is placed on probation for five (5) years on the following
22 terms and conditions.

23 **16. Obey All Laws**

24 Respondent owner shall obey all state and federal laws and regulations.

25 Respondent owner shall report any of the following occurrences to the board, in writing,
26 within seventy-two (72) hours of such occurrence:

- 27 an arrest or issuance of a criminal complaint for violation of any provision of the
28 Pharmacy Law, state and federal food and drug laws, or state and federal controlled

1 substances laws

- 2 a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
3 criminal complaint, information or indictment
- 4 a conviction of any crime
- 5 discipline, citation, or other administrative action filed by any state or federal agency
6 which involves respondent's Pharmacy Permit or which is related to the practice of
7 pharmacy or the manufacturing, obtaining, handling or distributing, billing, or
8 charging for any drug, device or controlled substance.

9 Failure to timely report any such occurrence shall be considered a violation of probation.

10 **17. Report to the Board**

11 Respondent owner shall report to the board quarterly, on a schedule as directed by the board
12 or its designee. The report shall be made either in person or in writing, as directed. Among other
13 requirements, respondent owner shall state in each report under penalty of perjury whether there
14 has been compliance with all the terms and conditions of probation. Failure to submit timely
15 reports in a form as directed shall be considered a violation of probation. Any period(s) of
16 delinquency in submission of reports as directed may be added to the total period of probation.
17 Moreover, if the final probation report is not made as directed, probation shall be automatically
18 extended until such time as the final report is made and accepted by the board.

19 **18. Interview with the Board**

20 Upon receipt of reasonable prior notice, respondent owner shall appear in person for
21 interviews with the board or its designee, at such intervals and locations as are determined by the
22 board or its designee. Failure to appear for any scheduled interview without prior notification to
23 board staff, or failure to appear for two (2) or more scheduled interviews with the board or its
24 designee during the period of probation, shall be considered a violation of probation.

25 **19. Cooperate with Board Staff**

26 Respondent owner shall cooperate with the board's inspection program and with the board's
27 monitoring and investigation of respondent's compliance with the terms and conditions of his
28 probation. Failure to cooperate shall be considered a violation of probation.

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20. Reimbursement of Board Costs

As a condition precedent to successful completion of probation, respondent Tower Inc. dba Quesenberry shall pay to the board its costs of investigation and prosecution in the amount of \$32,853.75. Respondent Tower Inc. dba Quesenberry shall be jointly and severally liable for the costs. Respondent may make payments in a payment plan approved by the Board. Failure to pay costs by the deadline(s) as directed by the Board shall be considered a violation of probation. The filing of bankruptcy by respondent owner shall not relieve respondent of its responsibility to reimburse the board its costs of investigation and prosecution.

21. Probation Monitoring Costs

Respondent owner shall pay any costs associated with probation monitoring as determined by the board each and every year of probation. Such costs shall be payable to the board on a schedule as directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall be considered a violation of probation.

22. Status of License

Respondent owner shall, at all times while on probation, maintain current licensure with the board. If respondent owner submits an application to the board, and the application is approved, for a change of location, change of permit or change of ownership, the board shall retain continuing jurisdiction over the license, and the respondent shall remain on probation as determined by the board. Failure to maintain current licensure shall be considered a violation of probation.

If respondent owner's license expires or is cancelled by operation of law or otherwise at any time during the period of probation, including any extensions thereof or otherwise, upon renewal or reapplication respondent owner's license shall be subject to all terms and conditions of this probation not previously satisfied.

23. License Surrender While on Probation/Suspension

Following the effective date of this decision, should respondent owner discontinue business, respondent owner may tender the premises license to the board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take

1 any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of
2 the license, respondent will no longer be subject to the terms and conditions of probation.

3 Upon acceptance of the surrender, respondent owner shall relinquish the premises wall and
4 renewal license to the board within ten (10) days of notification by the board that the surrender is
5 accepted. Respondent owner shall further submit a completed Discontinuance of Business form
6 according to board guidelines and shall notify the board of the records inventory transfer.

7 Respondent owner shall also, by the effective date of this decision, arrange for the
8 continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written
9 notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that
10 identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating
11 as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five
12 days of its provision to the pharmacy's ongoing patients, Respondent owner shall provide a copy
13 of the written notice to the board. For the purposes of this provision, "ongoing patients" means
14 those patients for whom the pharmacy has on file a prescription with one or more refills
15 outstanding, or for whom the pharmacy has filled a prescription within the preceding sixty (60)
16 days.

17 Respondent owner may not apply for any new licensure from the board for three (3) years
18 from the effective date of the surrender. Respondent owner shall meet all requirements applicable
19 to the license sought as of the date the application for that license is submitted to the board.

20 Respondent owner further stipulates that he or she shall reimburse the board for its costs of
21 investigation and prosecution prior to the acceptance of the surrender.

22 **24. Notice to Employees**

23 Respondent owner shall, upon or before the effective date of this decision, ensure that all
24 employees involved in permit operations are made aware of all the terms and conditions of
25 probation, either by posting a notice of the terms and conditions, circulating such notice, or both.
26 If the notice required by this provision is posted, it shall be posted in a prominent place and shall
27 remain posted throughout the probation period. Respondent owner shall ensure that any
28 employees hired or used after the effective date of this decision are made aware of the terms and

1 conditions of probation by posting a notice, circulating a notice, or both. Additionally,
2 respondent owner shall submit written notification to the board, within fifteen (15) days of the
3 effective date of this decision, that this term has been satisfied. Failure to submit such notification
4 to the board shall be considered a violation of probation.

5 "Employees" as used in this provision includes all full-time, part-time,
6 volunteer, temporary and relief employees and independent contractors employed or
7 hired at any time during probation.

8 **25. Owners and Officers: Knowledge of the Law**

9 Respondent shall provide, within thirty (30) days after the effective date of this decision,
10 signed and dated statements from its owners, including any owner or holder of ten percent (10%)
11 or more of the interest in respondent or respondent's stock, and any officer, stating under penalty
12 of perjury that said individuals have read and are familiar with state and federal laws and
13 regulations governing the practice of pharmacy. The failure to timely provide said statements
14 under penalty of perjury shall be considered a violation of probation.

15 **26. Posted Notice of Probation**

16 Respondent owner shall prominently post a probation notice provided by the board in a
17 place conspicuous and readable to the public. The probation notice shall remain posted during
18 the entire period of probation.

19 Respondent owner shall not, directly or indirectly, engage in any conduct or make any
20 statement which is intended to mislead or is likely to have the effect of misleading any patient,
21 customer, member of the public, or other person(s) as to the nature of and reason for the probation
22 of the licensed entity.

23 Failure to post such notice shall be considered a violation of probation.

24 **27. Violation of Probation**

25 If a respondent owner has not complied with any term or condition of probation, the board
26 shall have continuing jurisdiction over respondent license, and probation shall be automatically
27 extended until all terms and conditions have been satisfied or the board has taken other action as
28 deemed appropriate to treat the failure to comply as a violation of probation, to terminate

1 probation, and to impose the penalty that was stayed.

2 If respondent owner violates probation in any respect, the board, after giving respondent
3 owner notice and an opportunity to be heard, may revoke probation and carry out the disciplinary
4 order that was stayed. Notice and opportunity to be heard are not required for those provisions
5 stating that a violation thereof may lead to automatic termination of the stay and/or revocation of
6 the license. If a petition to revoke probation or an accusation is filed against respondent during
7 probation, the board shall have continuing jurisdiction and the period of probation shall be
8 automatically extended until the petition to revoke probation or accusation is heard and decided.

9 **28. Completion of Probation**

10 Upon written notice by the board or its designee indicating successful completion of
11 probation, respondent license will be fully restored.

12 **29. Ethics Course**

13 Within sixty (60) calendar days of the effective date of this decision, respondent shall
14 confirm that all of its licensed pharmacists are enrolled in a course in ethics, at respondent's
15 expense, approved in advance by the board or its designee. Failure to initiate the course during
16 the first year of probation, and complete it within the second year of probation, is a violation of
17 probation. Respondent shall submit a certificate of completion to the board or its designee within
18 five days after completing the course.

19 **30. Consultant for Owner or Pharmacist-in-Charge**

20 During the period of probation, Respondent Tower Inc. dba Quesenberry Pharmacy shall
21 retain an independent consultant at its own expense, who shall be responsible for reviewing
22 pharmacy operations on a monthly basis for compliance by Respondent with state and federal
23 laws and regulations governing the practice of the pharmacy and for compliance by Respondent
24 with the obligations of a pharmacist-in-charge. The consultant shall audit the return to stock and
25 confirm that all billing is appropriate. A physical inspection shall be completed by the consultant
26 on a quarterly basis. The consultant shall be a pharmacist licensed by and not on probation with
27 any board of pharmacy and whose name shall be submitted to the Board or its designee for prior
28 approval within (30) days of the effective date of this decision. During the period of probation,

1 the Board or its designee retains the discretion to reduce the frequency of the pharmacist
2 consultant's review of Respondent's operations. Failure to timely retain, seek approval of, or
3 ensure timely reporting by the consultant shall be considered a violation of probation.

4 IT IS FURTHER ORDERED that Pharmacist License No. RPH 44309 issued to
5 Respondent Darin L. Nelle is revoked. However, the revocation is stayed and Respondent Nelle
6 is placed on probation for five (5) years on the following terms and conditions.

7 **31. Suspension**

8 As part of probation, respondent is suspended from the practice of pharmacy for thirty (30)
9 days beginning the effective date of this decision. During suspension, respondent shall not enter
10 any pharmacy area or any portion of the licensed premises of a wholesaler, veterinary food-
11 animal drug retailer or any other distributor of drugs which is licensed by the board, or any
12 manufacturer, or where dangerous drugs and devices or controlled substances are maintained.
13 Respondent shall not practice pharmacy nor do any act involving drug selection, selection of
14 stock, manufacturing, compounding, dispensing or patient consultation; nor shall respondent
15 manage, administer, or be a consultant to any licensee of the board, or have access to or control
16 the ordering, manufacturing or dispensing of dangerous drugs and devices or controlled
17 substances.

18 Respondent shall not engage in any activity that requires the professional judgment of a
19 pharmacist. Respondent shall not direct or control any aspect of the practice of pharmacy.
20 Respondent shall not perform the duties of a pharmacy technician or a designated representative
21 for any entity licensed by the board. Subject to the above restrictions, respondent may continue to
22 own or hold an interest in any licensed premises in which he or she holds an interest at the time
23 this decision becomes effective unless otherwise specified in this order. Failure to comply with
24 this suspension shall be considered a violation of probation

25 **32. Obey All Laws**

26 Respondent shall obey all state and federal laws and regulations.

27 Respondent shall report any of the following occurrences to the board, in writing, within
28 seventy-two (72) hours of such occurrence:

- 1 • an arrest or issuance of a criminal complaint for violation of any provision of the
- 2 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
- 3 substances laws
- 4 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
- 5 criminal complaint, information or indictment
- 6 • a conviction of any crime
- 7 • discipline, citation, or other administrative action filed by any state or federal agency
- 8 which involves respondent's Pharmacist license or which is related to the practice of
- 9 pharmacy or the manufacturing, obtaining, handling, distributing, billing, or charging
- 10 for any drug, device or controlled substance.

11 Failure to timely report such occurrence shall be considered a violation of probation.

12 **33. Report to the Board**

13 Respondent shall report to the board quarterly, on a schedule as directed by the board or its
14 designee. The report shall be made either in person or in writing, as directed. Among other
15 requirements, respondent shall state in each report under penalty of perjury whether there has
16 been compliance with all the terms and conditions of probation. Failure to submit timely reports
17 in a form as directed shall be considered a violation of probation. Any period(s) of delinquency
18 in submission of reports as directed may be added to the total period of probation. Moreover, if
19 the final probation report is not made as directed, probation shall be automatically extended until
20 such time as the final report is made and accepted by the board.

21 **34. Interview with the Board**

22 Upon receipt of reasonable prior notice, respondent shall appear in person for interviews
23 with the board or its designee, at such intervals and locations as are determined by the board or its
24 designee. Failure to appear for any scheduled interview without prior notification to board staff,
25 or failure to appear for two (2) or more scheduled interviews with the board or its designee during
26 the period of probation, shall be considered a violation of probation.

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35. Cooperate with Board Staff

Respondent shall cooperate with the board's inspection program and with the board's monitoring and investigation of respondent's compliance with the terms and conditions of their probation. Failure to cooperate shall be considered a violation of probation.

36. Continuing Education

Within six months of the effective date of the decision, Respondent must complete 6 hours of aseptic training "in person" or minimally one class. In addition, Respondent shall complete 6 additional hours, 50 % in person, each year of probation in compounding and pharmacy law.

37. Notice to Employers

During the period of probation, respondent shall notify all present and prospective employers of the decision in case number 5300 & 5301 and the terms, conditions and restrictions imposed on respondent by the decision, as follows:

Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment, respondent shall cause their direct supervisor, pharmacist-in-charge (including each new pharmacist-in-charge employed during respondent's tenure of employment) and owner to report to the board in writing acknowledging that the listed individual(s) has/have read the decision in case number 5300 & 5301, and terms and conditions imposed thereby. It shall be respondent's responsibility to ensure that their employer(s) and/or supervisor(s) submit timely acknowledgment(s) to the board.

If respondent works for or is employed by or through a pharmacy employment service, respondent must notify their direct supervisor, pharmacist-in-charge, and owner at every entity licensed by the board of the terms and conditions of the decision in case number 5300 & 5301 in advance of the respondent commencing work at each licensed entity. A record of this notification must be provided to the board upon request.

Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen (15) days of respondent undertaking any new employment by or through a pharmacy employment service, respondent shall cause their direct supervisor with the pharmacy employment service to report to the board in writing acknowledging that they have read the decision in case number

1 5300 & 5301 and the terms and conditions imposed thereby. It shall be respondent's
2 responsibility to ensure that their employer(s) and/or supervisor(s) submit timely
3 acknowledgment(s) to the board.

4 Failure to timely notify present or prospective employer(s) or to cause that/those
5 employer(s) to submit timely acknowledgments to the board shall be considered a violation of
6 probation.

7 "Employment" within the meaning of this provision shall include any full-time,
8 part-time, temporary, relief or pharmacy management service as a pharmacist or any
9 position for which a pharmacist license is a requirement or criterion for employment,
10 whether the respondent is an employee, independent contractor or volunteer.

11 **38. No Supervision of Interns, Serving as Pharmacist-in-Charge**
12 **(PIC), Serving as Designated Representative-in-Charge, or**
13 **Serving as a Consultant**

14 During the period of probation, respondent shall not supervise any intern pharmacist,
15 be the pharmacist-in-charge or designated representative-in-charge of any entity licensed by
16 the board nor serve as a consultant unless otherwise specified in this order. Assumption of
17 any such unauthorized supervision responsibilities shall be considered a violation of
18 probation.

19 **39. Probation Monitoring Costs**

20 Respondent shall pay any costs associated with probation monitoring as determined by the
21 board each and every year of probation. Such costs shall be payable to the board on a schedule as
22 directed by the board or its designee. Failure to pay such costs by the deadline(s) as directed shall
23 be considered a violation of probation.

24 **40. Status of License**

25 Respondent shall, at all times while on probation, maintain an active, current license with
26 the board, including any period during which suspension or probation is tolled. Failure to
27 maintain an active, current license shall be considered a violation of probation.

28 If respondent's license expires or is cancelled by operation of law or otherwise at any time
during the period of probation, including any extensions thereof due to tolling or otherwise, upon

1 renewal or reapplication respondent's license shall be subject to all terms and conditions of this
2 probation not previously satisfied.

3 **41. License Surrender While on Probation/Suspension**

4 Following the effective date of this decision, should respondent cease practice due to
5 retirement or health, or be otherwise unable to satisfy the terms and conditions of probation,
6 respondent may tender his license to the board for surrender. The board or its designee shall have
7 the discretion whether to grant the request for surrender or take any other action it deems
8 appropriate and reasonable. Upon formal acceptance of the surrender of the license, respondent
9 will no longer be subject to the terms and conditions of probation. This surrender constitutes a
10 record of discipline and shall become a part of the respondent's license history with the board.

11 Upon acceptance of the surrender, respondent shall relinquish their pocket and wall license
12 to the board within ten (10) days of notification by the board that the surrender is accepted.
13 Respondent may not reapply for any license from the board for three (3) years from the effective
14 date of the surrender. Respondent shall meet all requirements applicable to the license sought as
15 of the date the application for that license is submitted to the board, including any outstanding
16 costs.

17 **42. Notification of a Change in Name, Residence Address, Mailing
18 Address or Employment**

19 Respondent shall notify the board in writing within ten (10) days of any change of
20 employment. Said notification shall include the reasons for leaving, the address of the new
21 employer, the name of the supervisor and owner, and the work schedule if known. Respondent
22 shall further notify the board in writing within ten (10) days of a change in name, residence
23 address, mailing address, or phone number.

24 Failure to timely notify the board of any change in employer(s), name(s), address(es), or
25 phone number(s) shall be considered a violation of probation.

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1 **43. Tolling of Probation**

2 Except during periods of suspension, respondent shall, at all times while on probation, be
3 employed as a pharmacist in California for a minimum of 40 hours per calendar month. Any
4 month during which this minimum is not met shall toll the period of probation, i.e., the period of
5 probation shall be extended by one month for each month during which this minimum is not met.
6 During any such period of tolling of probation, respondent must nonetheless comply with all
7 terms and conditions of probation.

8 It is a violation of probation for respondent's probation to remain tolled pursuant to the
9 provisions of this condition for a total period, counting consecutive and non-consecutive months,
10 exceeding thirty-six (36) months.

11 "Cessation of practice" means any calendar month during which respondent is
12 not practicing as a pharmacist for at least 40 hours, as defined by Business and
13 Professions Code section 4000 et seq. "Resumption of practice" means any calendar
14 month during which respondent is practicing as a pharmacist for at least 40 hours as a
15 pharmacist as defined by Business and Professions Code section 4000 et seq.

16 **44. Violation of Probation**

17 If a respondent has not complied with any term or condition of probation, the board shall
18 have continuing jurisdiction over respondent, and probation shall automatically be extended, until
19 all terms and conditions have been satisfied or the board has taken other action as deemed
20 appropriate to treat the failure to comply as a violation of probation, to terminate probation, and
21 to impose the penalty that was stayed.

22 If respondent violates probation in any respect, the board, after giving respondent notice
23 and an opportunity to be heard, may revoke probation and carry out the disciplinary order that
24 was stayed. Notice and opportunity to be heard are not required for those provisions stating that a
25 violation thereof may lead to automatic termination of the stay and/or revocation of the license. If
26 a petition to revoke probation or an accusation is filed against respondent during probation, the
27 board shall have continuing jurisdiction and the period of probation shall be automatically
28 extended until the petition to revoke probation or accusation is heard and decided.

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45. No New Ownership of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the board. If Respondent currently owns or has legal or beneficial interest in, or serves as a manager, administrator, member, officer, director, trustee, associate, or partner of any business, firm, partnership, or corporation currently or hereinafter licensed by the board, Respondent may continue to serve in such capacity or hold that interest, but only to the extent of that position or interest as of the effective date of this decision. A violation of this restriction shall be considered a violation of probation.

46. Supervised Practice

During the period of probation, respondent shall practice only under the supervision of a licensed pharmacist not on probation with the board. Upon and after the effective date of this decision, respondent shall not practice pharmacy and his or her license shall be automatically suspended until a supervisor is approved by the board or its designee. The supervision shall be, as required by the board or its designee, either:

- Continuous – At least 75% of a work week
- Substantial - At least 50% of a work week
- Partial - At least 25% of a work week
- Daily Review - Supervisor's review of probationer's daily activities within 24 hours

Within thirty (30) days of the effective date of this decision, respondent shall have his supervisor submit notification to the board in writing stating that the supervisor has read the decision in case numbers 5300 & 5301 and is familiar with the required level of supervision as determined by the board or its designee. It shall be the respondent's responsibility to ensure that his or her employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to the board. Failure to cause the direct supervisor and the pharmacist-in-charge to submit timely acknowledgements to the board shall be considered a violation of probation.

If respondent changes employment, it shall be the respondent's responsibility to ensure that

1 his employer(s), pharmacist-in-charge and/or supervisor(s) submit timely acknowledgement(s) to
2 the board. Respondent shall have his or her new supervisor, within fifteen (15) days after
3 employment commences, submit notification to the board in writing stating the direct supervisor
4 and pharmacist-in-charge have read the decision in case numbers 5300 & 5301 and is familiar
5 with the level of supervision as determined by the board. Respondent shall not practice pharmacy
6 and his or her license shall be automatically suspended until the board or its designee approves a
7 new supervisor. Failure to cause the direct supervisor and the pharmacist-in-charge to submit
8 timely acknowledgements to the board shall be considered a violation of probation.

9 Within ten (10) days of leaving employment, respondent shall notify the board in writing.

10 During suspension, respondent shall not enter any pharmacy area or any portion of the
11 licensed premises of a wholesaler, veterinary food-animal drug retailer or any other distributor of
12 drugs which is licensed by the board, or any manufacturer, or where dangerous drugs and devices
13 or controlled substances are maintained. Respondent shall not practice pharmacy nor do any act
14 involving drug selection, selection of stock, manufacturing, compounding, dispensing or patient
15 consultation; nor shall respondent manage, administer, or be a consultant to any licensee of the
16 board, or have access to or control the ordering, manufacturing or dispensing of dangerous
17 drugs and controlled substances. Respondent shall not resume practice until notified by the
18 board.

19 During suspension, respondent shall not engage in any activity that requires the
20 professional judgment of a pharmacist. Respondent shall not direct or control any aspect of the
21 practice of pharmacy. Respondent shall not perform the duties of a pharmacy technician or a
22 designated representative for any entity licensed by the board.

23 Subject to the above restrictions, respondent may continue to own or hold an interest in any
24 licensed premises in which he or she holds an interest at the time this decision becomes
25 effective unless otherwise specified in this order.

26 Failure to comply with this suspension shall be considered a violation of probation

27 **47. Ethics Course**

28 Within sixty (60) calendar days of the effective date of this decision, respondent shall enroll

1 in a course in ethics, at respondent's expense, approved in advance by the board or its designee.
2 Failure to initiate the course during the first year of probation, and complete it within the second
3 year of probation, is a violation of probation.

4 Respondent shall submit a certificate of completion to the board or its designee within five
5 days after completing the course.

6 **48. Remedial Education**

7 Within fifteen days of the effective date of this decision, respondent shall submit to the
8 board or its designee, for prior approval, an appropriate program of remedial education related to
9 pharmacy law and operation. The program of remedial education shall consist of at least 6 hours,
10 which shall be completed within the thirty-day suspension and 4 hours each year thereafter at
11 respondent's own expense. Fifty percent of the remedial education must be in person training. All
12 remedial education shall be in addition to, and shall not be credited toward, continuing education
13 (CE) courses used for license renewal purposes.

14 Failure to timely submit or complete the approved remedial education shall be considered
15 a violation of probation. The period of probation will be automatically extended until such
16 remedial education is successfully completed and written proof, in a form acceptable to the
17 board, is provided to the board or its designee.

18 Following the completion of each course, the board or its designee may require the
19 respondent, at his or her own expense, to take an approved examination to test the respondent's
20 knowledge of the course. If the respondent does not achieve a passing score on the examination,
21 this failure shall be considered a violation of probation. Any such examination failure shall
22 require respondent to take another course approved by the board in the same subject area.

23 **49. Reimbursement of Board Costs**

24 As a condition precedent to successful completion of probation, respondent Nelle shall pay
25 to the board its costs of investigation and prosecution in the amount of \$32,853.75. Respondent
26 Nelle shall be jointly and severally liable for the costs. Respondent Nelle may make payments in
27 a payment plan approved by the Board. Failure to pay costs by the deadline(s) as directed by the
28 Board shall be considered a violation of probation.

1 The filing of bankruptcy by respondent owner shall not relieve respondent of its
2 responsibility to reimburse the board its costs of investigation and prosecution.

3 50. Completion of Probation

4 Upon written notice by the board or its designee indicating successful completion of
5 probation, respondent's license will be fully restored.

6 ACCEPTANCE

7 I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully
8 discussed it with my attorney, Jeffrey S. Kravitz, Esq. I understand the stipulation and the effect it
9 will have on my Pharmacist License, and Pharmacy Permits. I enter into this Stipulated
10 Settlement and Disciplinary Order voluntarily, knowingly, and intelligently, and agree to be
11 bound by the Decision and Order of the Board of Pharmacy.

12
13 DATED: 9-8-17

D. L. NELLE
TOWER PHARMACY, DARIN L. NELLE, OWNER
Respondent

14
15
16 DATED: 9-8-17

D. L. NELLE
TOWER PHARMACY, INC. dba QUESENBERRY
PHARMACY, DARIN L. NELLE, PRESIDENT
Respondent

17
18
19
20 DATED: 9-8-17

D. L. NELLE
DARIN L. NELLE
Respondent

21
22 I have read and fully discussed with Respondents, Tower Pharmacy, Tower Pharmacy, Inc.
23 dba Quesenberry Pharmacy, and Darin L. Nelle the terms and conditions and other matters
24 contained in the above Stipulated Settlement and Disciplinary Order. I approve its form and
25 content.

26 DATED: 9-8-17

J. S. KRAVITZ
JEFFREY S. KRAVITZ, ESQ.
Attorney for Respondent

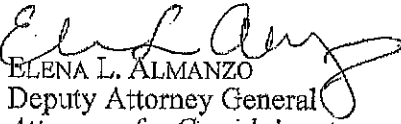
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ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order is hereby respectfully submitted for consideration by the Board of Pharmacy.

Dated: 9/8/17

Respectfully submitted,
XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General


ELENA L. ALMANZO
Deputy Attorney General
Attorneys for Complainant

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EXHIBIT A

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2 KENT D. HARRIS
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6 Telephone: (916) 322-5524
Facsimile: (916) 327-8643
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. 5300

13 **TOWER PHARMACY, INC.,**
14 **dba QUESENBERRY'S WATERFORD PHARMACY**

15 **DARIN L. NELLE,**
16 **PRESIDENT/PHARMACIST-IN-CHARGE**
17 **12641 Bentley Street**
18 **Waterford, California 95386**

19 **Pharmacy Permit No. PHY 50624**

20 **and**

21 **DARIN L. NELLE**
22 **1801 Colorado Avenue 100**
23 **Turlock, California 95382**

24 **Pharmacist License No. RPH 44309**

25 Respondents.

26 **A C C U S A T I O N**

27 Complainant alleges:

28 **PARTIES**

1. Virginia Herold ("Complainant") brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy ("Board"), Department of Consumer Affairs.
2. On or about October 28, 2011, the Board issued Pharmacy Permit Number PHY 50624 to Tower Pharmacy, Inc. ("Respondent Tower Pharmacy, Inc."), doing business as

1 Quesenberry's Waterford Pharmacy, with Darin L. Nelle ("Respondent Nelle") as president and
2 pharmacist-in-charge. The pharmacy permit was in full force and effect at all times relevant to
3 the charges brought herein and will expire on October 1, 2015, unless renewed.

4 3. On or about August 2, 1991, the Board issued Pharmacist License Number RPH
5 44309 to Respondent Nelle. The pharmacist license was in full force and effect at all times
6 relevant to the charges brought herein and will expire on December 31, 2016, unless renewed.

7 JURISDICTION

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

10 STATUTORY AND REGULATORY PROVISIONS

11 5. Code section 4300 states, in pertinent part:

12 (a) Every license issued may be suspended or revoked.

13 (b) The board shall discipline the holder of any license issued by the
14 board, whose default has been entered or whose case has been heard by the board and
found guilty, by any of the following methods:

15 (1) Suspending judgment.

16 (2) Placing him or her upon probation.

17 (3) Suspending his or her right to practice for a period not exceeding one
18 year.

19 (4) Revoking his or her license.

20 (5) Taking any other action in relation to disciplining him or her as the
board in its discretion may deem proper . . .

21 6. Code section 4300.1 states:

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

26 7. Code section 4301 states, in pertinent part:

27 The board shall take action against any holder of a license who is guilty
28 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.

....

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or non-existence of a state of facts.

....

(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

8. Code section 4307 (a) of the Code provides in pertinent part:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, or partner of any partnership, corporation, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, or partner had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee as follows:

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

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

....

9. Code section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

10. Health and Safety Code section 11165, subdivision (d), states:

(d) For each prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, as defined in the controlled substances schedules in federal law and regulations, specifically Sections 1308.12, 1308.13, and 1308.14, respectively, of Title 21 of the Code of Federal

1 Regulations, the dispensing pharmacy, clinic, or other dispensers, shall report the following

2 information to the Department of Justice as soon as reasonably possible but not more
3 than seven days after the date a controlled substance is dispensed, in a format
4 specified by the Department of Justice:

4 (1) Full name, address, and, if available, telephone number of the ultimate user or
5 research

5 subject, or contact information as determined by the Secretary of the United States
6 Department of Health and Human Services, and the gender, and date of birth of the
7 ultimate user.

8 (2) The prescribers category of licensure, license number, national provider identifier
(NPI)

9 Number, if applicable, the federal controlled substance registration number, and the
10 state medical

11 license number of any prescriber using the federal controlled substance registration
12 number of a government-exempt facility.

12 (3) Pharmacy prescription number, license number,

13 (3) Pharmacy prescription number, license number, NPI number, and federal
14 controlled substance registration number.

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

15 (5) Quantity of the controlled substance dispensed.

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

18 (7) Number of refills ordered.

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

21 (9) Date of origin of the prescription.

22 (10) Date of dispensing of the prescription.

23 11. Code of Federal Regulations, title 21, section 1305.05 provides in pertinent part:

24 (a) A registrant may authorize one or more individuals, whether or not located at his
25 or her registered location, to issue orders for Schedule I and II controlled substances
26 on the registrant's behalf by executing a power of attorney for each such individual, if
the power of attorney is retained in the files, with executed Forms 222 where
applicable, for the same period as any order bearing the signature of the attorney. The
power of attorney must be available for inspection together with other order records.

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12. California Code of Regulations, title 16, section 1707.2 states, in pertinent part:

(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in all care settings:

(1) upon request; or

(2) whenever the pharmacist deems it warranted in the exercise of his or her professional judgment.

(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

(A) whenever the prescription drug has not previously been dispensed to a patient; or

(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy . . .

13. California Code of Regulations, title 16, section 1716 states, in pertinent part:

Pharmacists shall not deviate from the requirements of a prescription except upon the prior consent of the prescriber or to select the drug product in accordance with Section 4073 of the Business and Professions Code.

14. California Code of Regulations, title 16, section 1711 states:

(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

1 (4) If a pharmacist is notified of a prescription error by the patient, the patient's agent,
2 or a prescriber, the pharmacist is not required to communicate with that individual as
3 required in paragraph (2) of this subdivision.

4 (d) Each pharmacy shall use the findings of its quality assurance program to develop
5 pharmacy systems and workflow processes designed to prevent medication errors. An
6 investigation of each medication error shall commence as soon as is reasonably
7 possible, but no later than 2 business days from the date the medication error is
8 discovered. All medication errors discovered shall be subject to a quality assurance
9 review.

10 (e) The primary purpose of the quality assurance review shall be to advance error
11 prevention by analyzing, individually and collectively, investigative and other
12 pertinent data collected in response to a medication error to assess the cause and any
13 contributing factors such as system or process failures. A record of the quality
14 assurance review shall be immediately retrievable in the pharmacy. The record shall
15 contain at least the following:

- 16 1. the date, location, and participants in the quality assurance review;
- 17 2. the pertinent data and other information relating to the medication error(s)
18 reviewed and documentation of any patient contact required by subdivision (c);
- 19 3. the findings and determinations generated by the quality assurance review; and,
- 20 4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

21 The pharmacy shall inform pharmacy personnel of changes to pharmacy policy,
22 procedure, systems, or processes made as a result of recommendations generated in
23 the quality assurance program.

24 (f) The record of the quality assurance review, as provided in subdivision (e) shall be
25 immediately retrievable in the pharmacy for at least one year from the date the record
26 was created.

27 COST RECOVERY

28 15. Code section 125.3 provides, in pertinent part, that a 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.

CONTROLLED SUBSTANCE

16. "Marinol", a brand of dronabinol, is a Schedule III controlled substance as designated
by Health and Safety Code section 11056, subdivision (h). Marinol is used as an appetite
stimulant and to treat nausea.

1 17. "Lexapro", a brand of Escitalopram, is a dangerous drug as defined in Business and
2 Professions Code section 4022. Lexapro is used as an anti-depressant.

3 18. "Vasotec", a brand of Enalapril, is a dangerous drug as defined in Business and
4 Professions Code section 4022. Vasotec is used as a Blood Pressure medication.

5 **BOARD INSPECTION OF SEPTEMBER 25, 2013**

6 19. On or about July 22, 2013, the Board received a complaint from a former employee
7 of Quesenberry's Waterford Pharmacy ("Quesenberry's"), alleging, among other things, that the
8 pharmacy was engaging in fraudulent billing practices.

9 20. On or about September 25, 2013, an inspector of the Board went to Quesenberry's to
10 conduct an inspection and was assisted by pharmacist R. J. and pharmacy technician J. S. The
11 inspector began reviewing the pharmacy's drug inventory, and noticed numerous prescription
12 vials marked "RTS" (return to stock) on the drug shelves. The inspector selected two bottles with
13 the same prescription number from the shelf marked "RTS; one bottle had a fill date of July 27,
14 2013, and the other had a fill date of September 3, 2013. The inspector asked J. S. to retrieve the
15 prescription information in the computer for the two bottles. When J. S. pulled up the transaction
16 information, the record for the July 27, 2013 fill date showed that it was processed, but not
17 reversed.

18 21. The inspector continued looking through the drug inventory and found additional
19 prescription vials with "RTS" written on the labels. The inspector asked J. S. to retrieve screen
20 prints for each vial pulled by the inspector. While J. S. was printing the transaction information,
21 the inspector observed pharmacy clerk B. A. selling prescriptions to several patients without
22 offering consultation by a pharmacist (the inspector did not hear the clerk call the pharmacist for
23 consultation). The inspector asked B. A. for the prescription information for one of the customers
24 she had sold a prescription to as observed by the inspector. B. A. gave the inspector the
25 prescription record, patient profile, and pick-up record for patient S. J. The records showed that
26 the prescription was for a new strength of Marinol and that there was a change in the directions
27 from the original prescription dispensed to the patient on October 10, 2012.

28

1 26. On or about June 3, 2015, the Board inspector requested a copy of the Power of
2 Attorney permitting other pharmacists to order Schedule II drugs and was informed that there was
3 no Power of Attorney in place.

4 27. On or about April 24, 2015, the Board received a complaint that a medication error
5 had occurred.,

6 28. Patient L. A. reported that on or about April 20, 2015, she had a prescription for
7 Lexpro filled at Quesenberry Waterford Pharmacy, prescription number 1284209, but was given
8 Vasotec. Upon taking the wrong medication, L.A. went to urgent care due to symptoms of
9 dizziness and heart palpitations.

10 29. On or about June 3, 2015, the Board conducted an inspection in which the inspector
11 determined that the prescription was filled by pharmacist Ronald C. Jennison.

12 30. During the Board inspection, a request was made for records pertaining to Quality
13 Assurance records for the medication error but no records were provided.

14 **FIRST CAUSE FOR DISCIPLINE**

15 **(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)**

16 31. Respondent Quesenberry Waterford Pharmacy's pharmacy permit and Respondent
17 Nelle's pharmacist license are subject to disciplinary action pursuant to Code section 4301,
18 subdivision (f), for unprofessional conduct, in that Respondents committed acts involving moral
19 turpitude, dishonesty, fraud, deceit, or corruption, as follows: Respondents failed to reverse the
20 claims or billings on the prescriptions identified below even though Respondents had not
21 dispensed the medications to the patients (the prescriptions had not been picked up by the patients
22 and had been returned to pharmacy stock), and had received payment for the drugs from the
23 patients' insurance companies:

24

RX No.	Fill Date	Drug
1217986	06/24/2013	Topiramate 15 mg capsules
1223141	07/17/2013	Trazodone 150 mg tablets
1225926	08/16/2013	Terbinafine 250 mg tablets
1205163	01/10/2013	Captopril 50 mg tablets
1197466	01/15/2013	Cyclobenzaprine 10 mg
1185178	05/21/2012	Singular 5 mg chewable tablets

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1221400	07/02/2013	Oxybutynin 5 mg
1189908	07/17/2012	Tribenzor 40-10-25 mg
1222059	07/08/2013	Trazodone 50 mg
1215049	06/03/2013	Montelukast 4 mg chewable tablets
1205960	01/18/2013	Cyclobenzaprine 10 mg

SECOND CAUSE FOR DISCIPLINE

(knowingly making or signing a certificate or document with false information)

32. Respondent Quesenberry Waterford Pharmacy's pharmacy permit and Respondent Nelle's pharmacist license are subject to disciplinary action pursuant to Code section 4301, subdivision (g), for unprofessional conduct, in that Respondents in that they billed insurance companies for prescriptions which were returned to stock as more specifically set forth above in paragraph 30.

THIRD CAUSE FOR DISCIPLINE

(Violations of State Regulations Governing Pharmacy)

33. Respondent Tower Pharmacy's permit and Respondent Nelle's pharmacist license are subject to disciplinary action pursuant to Code section 4301, subdivision (o), for unprofessional conduct, in that Respondents violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate state regulations governing pharmacy, as follows: On or about September 25, 2013, Respondents' pharmacy clerk, B. A., sold a prescription for patient S. J. without offering consultation by a pharmacist even though there had been a change in the dosing and directions of the prescription, in violation of Regulation 1707.2, subdivisions (b)(1)(B). Further, the Board Inspector did not observe or hear the clerk call the pharmacist to request a consultation at any time during the inspection.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Comply with CURES Reporting)

34. Respondent Tower Pharmacy's permit and Respondent Nelle's pharmacist license are subject to disciplinary action pursuant to Code section 4301, subdivision (o), in conjunction with Health and Safety Code section 11165 subdivision (d) and California Federal Regulations, Title 25 section 1305.05 for unprofessional conduct, in that Respondents violated or attempted to

1 violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate state
2 regulations governing pharmacy, as follows: For the period from February 15, 2015 to February
3 20, 2015, respondent's failed to comply with the reporting requirements for CURES.

4 **FIFTH CAUSE FOR DISCIPLINE**

5 **(Failure to Maintain a Power of Attorney)**

6 35. Respondent Tower Pharmacy's permit, and Respondent Nelle's pharmacist license
7 are subject to disciplinary action pursuant to Code section 4301 (o) in conjunction with Code of
8 Federal Regulation, Title 21, section 1305.05 in that during the inspection on June 3, 2015, it was
9 discovered that Respondents did not maintain a power of attorney permitting pharmacists to order
10 schedule prescriptions.

11 **SIXTH CAUSE FOR DISCIPLINE**

12 **(Deviation from Prescribed Medication)**

13 36. Respondent Tower Pharmacy's permit is subject to disciplinary action pursuant to
14 Code section 4301 (o) in conjunction with California Code of Regulation, Title 16 , section 1716,
15 for deviation from a prescription in that a prescription for Lexapro was filled with Vasotec as set
16 forth above in paragraphs 25 and 26.

17 **SEVENTH CAUSE FOR DISCIPLINE**

18 **(Failed to Investigate Medication Errors)**

19 37. Respondent Tower Pharmacy's permit and Respondent Nelle's pharmacist license are
20 subject to disciplinary action pursuant to Code section 4301 (o) in conjunction with California
21 Code of Regulation, Title 16 , section 1711, subdivision (d) (e), in that Respondents did not
22 investigate medication errors through a pharmacy quality assurance program as set forth above in
23 paragraphs 25 and 26.

24 **EIGHTH CAUSE FOR DISCIPLINE**

25 **(Failed to Keep Record Quality Assurance Review)**

26 38. Respondent Tower Pharmacy's permit and Respondent Nelle's pharmacist license are
27 subject to disciplinary action pursuant to Code section 4301 (o) in conjunction with California
28

1 Code of Regulation, Title 16 , section 1711, subdivision (e), in that Respondents did not keep a
2 record of the quality assurance review related to the medication errors as described above in
3 paragraphs 25 and 26.

4 **OTHER MATTERS**

5 39. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
6 PHY 50624 issued to Tower Pharmacy, Inc., doing business as Quesenberry's Waterford
7 Pharmacy, Tower Pharmacy, Inc. shall be prohibited from serving as a manager, administrator,
8 owner, member, officer, director, associate or partner of a licensee for five years if Pharmacy
9 Permit Number PHY 50624 is placed on probation, or until Pharmacy Permit Number PHY
10 50624 is reinstated if it is revoked.

11 40. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
12 PHY 50624 issued to Tower Pharmacy, Inc., doing business as Quesenberry's Waterford
13 Pharmacy, while Darin L. Nelle has been an officer and owner and had knowledge of or
14 knowingly participated in any conduct for which the licensee was disciplined, Darin L. Nelle
15 shall be prohibited from serving as a manager, administrator, owner, member, officer, director,
16 associate or partner of a licensee for five years if Pharmacy Permit Number PHY 50624 is placed
17 on probation, or until Pharmacy Permit Number PHY 50624 is reinstated if it is revoked.

18 **PRAYER**

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

- 21 1. Revoking or suspending Pharmacy Permit Number PHY 50624, issued to Tower
22 Pharmacy, Inc., doing business as Quesenberry's Waterford Pharmacy;
- 23 2. Revoking or suspending Pharmacist License Number RPH 44309, issued to Darin L.
24 Nelle;
- 25 3. Prohibiting Tower Pharmacy, Inc., from serving as a manager, administrator, owner,
26 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
27 Number PHY 50624 is placed on probation or until Pharmacy Permit Number PHY 50624 is
28

1 reinstated if Pharmacy Permit Number PHY 50624 issued to Quesenberry's Waterford Pharmacy
2 is revoked.

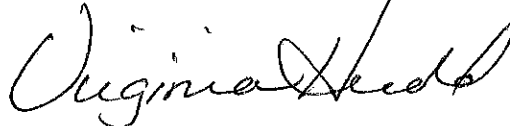
3 4. Prohibiting Darin L. Nelle from serving as a manager, administrator, owner, member,
4 officer, director, associate, or partner of a licensee for five years if Pharmacy Permit Number
5 PHY 50624 is placed on probation or until Pharmacy Permit Number PHY 50624 is reinstated if
6 Pharmacy Permit Number PHY 50624 issued to Quesenberry's Waterford Pharmacy is revoked.

7 5. Ordering Tower Pharmacy, Inc., doing business as Quesenberry's Waterford
8 Pharmacy, Darin L. Nelle to pay the Board of Pharmacy the reasonable costs of the investigation
9 and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

11
12 DATED: _____

8/15/16



VIRGINIA HEROLD

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

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EXHIBIT B

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2 KENT D. HARRIS
Supervising Deputy Attorney General
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Facsimile: (916) 327-8643
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. 5301

13 **TOWER PHARMACY**
14 **DARIN NELLE, OWNER AND PHARMACIST-IN-**
15 **CHARGE**

A C C U S A T I O N

16 **501 E. Olive Avenue**
17 **Turlock, California 95382**

18 **Pharmacy Permit Nos. PHY 47000 and PHY 54174**

19 **and**

20 **DARIN L. NELLE**
21 **1801 Colorado Avenue 100**
22 **Turlock, California 95382**

23 **Pharmacist License No. RPH 44309**

24 **Respondents.**

25 Complainant alleges:

26 **PARTIES**

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

29 2. On or about December 30, 2004, the Board issued Pharmacy Permit Number PHY
30 47000 to Darin L. Nelle, owner and pharmacist-in-charge of Tower Pharmacy (“Respondent
31 Tower”). On or about February 1, 2016, Pharmacy Permit No. PHY 54174 was issued to

1 Respondent Nelle as owner and pharmacist-in-charge of Tower Pharmacy due to a change in
2 location. The pharmacy permit was in full force and effect at all times relevant to the charges
3 brought herein and will expire on February 1, 2017 unless renewed.

4 3. On or about August 2, 1991, the Board issued Pharmacist License Number RPH
5 44309 to Respondent ("Respondent Nelle"). The pharmacist license was in full force and effect
6 at all times relevant to the charges brought herein and will expire on December 31, 2016, unless
7 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 4307 states:

12
13 "(a) Any person who has been denied a license or whose license has been revoked or
14 is under suspension, or who has failed to renew his or her license while it was under
15 suspension, or who has been a manager, administrator, owner, member, officer,
16 director, associate, or partner of any partnership, corporation, firm, or association
17 whose application for a license has been denied or revoked, is under suspension or
18 has been placed on probation, and while acting as the manager, administrator, owner,
19 member, officer, director, associate, or partner had knowledge of or knowingly
20 participated in any conduct for which the license was denied, revoked, suspended, or
21 placed on probation, shall be prohibited from serving as a manager, administrator,
22 owner, member, officer, director, associate, or partner of a licensee as follow:

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

25 (2) Where the license is denied or revoked, the prohibition shall continue until the
26 license is issued or reinstated...."

27 STATUTORY AND REGULATORY PROVISIONS

28 (Statutory Provisions)

6. Section 4300 states, in pertinent part:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the
board, whose default has been entered or whose case has been heard by the board and
found guilty, by any of the following methods:

(1) Suspending judgment.

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(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper . . .

7. Section 4300.1 states:

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

///

8. Section 4301 states, in pertinent part:

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.

...

(g) Knowingly making or signing any certificate or other document that falsely represents the existence or nonexistence of a state of facts.

.....

(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.

....

(q) Engaging in any conduct that subverts or attempts to subvert an investigation of the board . . .

9. Section 4040.5 states:

1 "Reverse distributor" means every person who acts as an agent for
2 pharmacies, drug wholesalers, third-party logistics providers, manufacturers, and
3 other entities by receiving, inventorying, warehousing, and managing the disposition
4 of outdated or nonsaleable dangerous drugs.

5 10. Section 4043 states:

6 "Wholesaler" means and includes a person who acts as a wholesale
7 merchant, broker, jobber, customs broker, reverse distributor, agent, or a nonresident
8 wholesaler, who sells for resale, or negotiates for distribution, or takes possession of,
9 any drug or device included in Section 4022. Unless otherwise authorized by law, a
10 wholesaler may not store, warehouse, or authorize the storage or warehousing of
11 drugs with any person or at any location not licensed by the board.

12 11. Section 4081, subdivision (a), states, in pertinent part:

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

24 12. Section 4113, subdivision (c), states that "[t]he pharmacist-in-charge shall be
25 responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining
26 to the practice of pharmacy.

27 13. Section 4160, subdivision (a), states that "[a] person may not act as a wholesaler of
28 any dangerous drug or dangerous device unless he or she has obtained a license from the board."

//

14. Section 4342, subdivision (a), states:

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

15. Health and Safety Code section 110290 states:

In determining whether the labeling or advertisement of a food, drug,
device, or cosmetic is misleading, all representations made or suggested by statement,

1 word, design, device, sound, or any combination of these, shall be taken into account.
2 The extent that the labeling or advertising fails to reveal facts concerning the food,
3 drug, device, or cosmetic or consequences of customary use of the food, drug, device,
4 or cosmetic shall also be considered.

5 16. Health and Safety Code section 111335 states that "[a]ny drug or device is
6 misbranded if its labeling or packaging does not conform to the requirements of Chapter 4
7 (commencing with Section 110290)."

8 17. Health and Safety Code section 111340 states, in pertinent part:

9 Any drug or device is misbranded unless it bears a label containing all of
10 the following information:

11

12 (b) An accurate statement of the quantity of the contents in terms of
13 weight, measure, or numerical count . . .

14 **(Regulatory Provisions)**

15 18. California Code of Regulations, title 16, section ("Regulation") 1735.2 states, in
16 pertinent part:

17

18 (g) All chemicals, bulk drug substances, drug products, and other
19 components used for drug compounding shall be stored and used according to
20 compendial and other applicable requirements to maintain their integrity, potency,
21 quality, and labeled strength.

22 (h) Every compounded drug product shall be given an expiration date
23 representing the date beyond which, in the professional judgment of the pharmacist
24 performing or supervising the compounding, it should not be used. This "beyond use
25 date" of the compounded drug product shall not exceed 180 days from preparation or
26 the shortest expiration date of any component in the compounded drug product,
27 unless a longer date is supported by stability studies of finished drugs or compounded
28 drug products using the same components and packaging. Shorter dating than set
forth in this subsection may be used if it is deemed appropriate in the professional
judgment of the responsible pharmacist.

(i) The pharmacist performing or supervising compounding is responsible
for the proper preparation, labeling, storage, and delivery of the compounded drug
product . . .

19. Regulation 1735.3 states, in pertinent part:

(a) For each compounded drug product, the pharmacy records shall
include:

- (1) The master formula record.

- 1 (2) The date the drug product was compounded.
- 2 product.
- 3 (3) The identity of the pharmacy personnel who compounded the drug
- 4 product.
- 5 (4) The identity of the pharmacist reviewing the final drug product.
- 6 (5) The quantity of each component used in compounding the drug
- 7 product.
- 8 (6) The manufacturer, expiration date and lot number of each component .
- 9 If the manufacturer name is demonstrably unavailable, the name of the supplier may
- 10 be substituted . . .
- 11 (7) A pharmacy assigned reference or lot number for the compounded
- 12 drug product.
- 13 (8) The expiration date of the final compounded drug product.
- 14 (9) The quantity or amount of drug product compounded.
- 15 (b) Pharmacies shall maintain records of the proper acquisition, storage,
- 16 and destruction of chemicals, bulk drug substances, drug products, and components
- 17 used in compounding.
- 18 (c) Chemicals, bulk drug substances, drug products, and components used
- 19 to compound drug products shall be obtained from reliable suppliers. The pharmacy
- 20 shall acquire and retain any available certificates of purity or analysis for chemicals,
- 21 bulk drug substances, drug products, and components used in compounding.
- 22 Certificates of purity or analysis are not required for drug products that are approved
- 23 by the Food and Drug Administration.
- 24 (d) Pharmacies shall maintain and retain all records required by this
- 25 article in the pharmacy in a readily retrievable form for at least three years from the
- 26 date the record was created.

20. Regulation 1735.5 states, in pertinent part:

- 21 (a) Any pharmacy engaged in compounding shall maintain a written
- 22 policy and procedure manual for compounding that establishes procurement
- 23 procedures, methodologies for the formulation and compounding of drugs, facilities
- 24 and equipment cleaning, maintenance, operation, and other standard operating
- 25 procedures related to compounding.
- 26 (b) The policy and procedure manual shall be reviewed on an annual
- 27 basis by the pharmacist-in-charge and shall be updated whenever changes in
- 28 processes are implemented . . .

21. Regulation 1735.6 states, in pertinent part:

- 26
- 27 (b) Any equipment used to compound drug products shall be stored, used,
- 28 and maintained in accordance with manufacturers' specifications.

1 (c) Any equipment used to compound drug products for which calibration
2 or adjustment is appropriate shall be calibrated prior to use to ensure accuracy.
3 Documentation of each such calibration shall be recorded in writing and these records
4 of calibration shall be maintained and retained in the pharmacy.

5 22. Regulation 1735.7 states, in pertinent part:

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

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

14 23. Regulation 1735.8 states, in pertinent:

15 (a) Any pharmacy engaged in compounding shall maintain, as part of its
16 written policies and procedures, a written quality assurance plan designed to monitor
17 and ensure the integrity, potency, quality, and labeled strength of compounded drug
18 products.

19

20 (d) The quality assurance plan shall include a written procedure for
21 scheduled action in the event any compounded drug product is ever discovered to be
22 below minimum standards for integrity, potency, quality, or labeled strength.

23 COST RECOVERY

24 24. Section 125.3 provides, in pertinent part, that a Board may request the administrative
25 law judge to direct a licentiate found to have committed a violation or violations of the licensing
26 act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the
27 case.

28 BOARD INSPECTIONS OF SEPTEMBER AND OCTOBER 2013

29 Inspection of September 26, 2013

30 25. On or about August 9, 2013, the Board received an anonymous complaint from a
31 "concerned consumer", alleging that Tower Pharmacy was engaging in illegal business practices.

32 26. On or about September 26, 2013, an inspector of the Board went to Tower Pharmacy
33 to conduct an inspection and was assisted by Respondent. Respondent had a separate
34 compounding room and a small room designated for bubble packing in addition to the larger retail
35 pharmacy area and drug inventory.

1 27. While the inspector was in the bubble packing room, she observed numerous open
2 paper cups with unlabeled prescription drugs in them, some with a stock bottle placed inside the
3 cup. There were also numerous empty bubble pack cards in the trash and unlabeled plastic bags
4 containing drugs sitting on the shelf or rubber-banded to a stock bottle. The inspector opened
5 various stock bottles and found that some were over-filled. The inspector also saw stacks of
6 boxes containing full bubble pack cards that appeared to have been filled several months earlier.

7 28. The inspector asked pharmacy technician B. M. about the bubble pack cards. B. M.
8 stated that some of the cards were returned for destruction by the assisted living facilities they
9 serviced. The inspector left the area to retrieve her camera. Later, when the inspector returned to
10 the bubble packing room, she noticed that all of the paper cups and drugs in the plastic bags were
11 missing. The inspector looked in the trash cans and boxes under the counter and found empty and
12 discarded bubble pack cards with prescription labels still affixed to them. The inspector collected
13 the cards, then continued looking through the trash. The inspector found the paper cups stacked
14 together, with the drugs still inside them, below the layers of papers. The inspector asked B. M.
15 why the paper cups were in the trash. B. M. stated that she "knew it would look bad", so she
16 removed the cups from the drug shelves.

17 29. The inspector had B. M. and Respondent retrieve the prescription information for one
18 of the empty bubble pack cards she removed from the trash. The computer record showed that
19 the prescription had been filled and the claim had been transmitted to a third party; however, the
20 patient never received the medication as evidenced by the empty bubble pack.

21 30. The inspector asked one of Respondent's other pharmacy technicians to explain the
22 return to stock process for prescriptions that were not picked up by patients. The technician
23 brought the inspector a binder and showed her a document titled "New Office Policy RTS
24 Prescriptions". The policy stated that when returning prescriptions in the pharmacy system not
25 picked up by customers, staff was not to reverse the claim to the insurance company.

26 31. The inspector selected random prescription numbers from the binder and asked
27 Respondent to bring up the transaction information related to each in the computer. The
28 transaction records indicated that all of the prescriptions were "RTS'd". Respondent told the

1 inspector that if a prescription was received by a patient, the Script Pickup Status report would
2 indicate "picked up" along with the date. None of the Script Pickup reports had a pick-up date.
3 The inspector found that none of the prescriptions had been reversed even though Respondent had
4 received payment for the claims from the insurance companies. The inspector told Respondent to
5 copy the entire contents of the binder, review all of the reports, and reverse the insurance billings
6 for all prescriptions that were not received by the patients and were returned to stock.

7 32. The inspector showed Respondent the bubble pack cards she found in the current
8 inventory. Respondent claimed that the cards were returned to stock because the prescriptions
9 were canceled. The inspector requested and received from Respondent the prescription
10 transaction reports and Script Pickup Status reports for each of the bubble pack cards she
11 removed from the drug shelves. The inspector found that the billings were not reversed to the
12 insurance companies and that the prescriptions had each been delivered or dispensed. The
13 inspector determined based on the presence of the bubble packs in the pharmacy and the
14 computer records that Respondent was reusing medications which had been returned for
15 destruction by the assisted living facilities. The inspector warned Respondent that he was not
16 authorized to accept returned medications from the facilities for destruction.

17 33. The inspector went to the compounding room with Respondent and observed
18 numerous expired compounding ingredients and syringes filled with compounded products
19 labeled with odd numbers and expiration dates (some syringes had no dates) in the compounding
20 area. Respondent stated that he used the syringes to draw up compounded medications from the
21 containers, reused the syringes after filling an order, and labeled each syringe once and did not
22 update the label. The inspector asked Respondent to show her which patients received the
23 product from a batch he compounded. Respondent claimed that he knew which patients were
24 getting medications compounded, so he would make multiple orders to meet their needs.

25 34. The inspector asked Respondent for his compounding policies and procedures,
26 training records, and quality assurance monitoring policy and procedures. Respondent was
27 unable to provide the inspector with the documents. The inspector also asked Respondent for his
28 compounding records, and he showed her a log book. The inspector found in reviewing the log

1 that there were no master formulas for the compounded products in the pharmacy. The inspector
2 instructed Respondent to suspend all compounding activities until he removed all of the outdated
3 products, discarded the used syringes he utilized for drawing up compounded products, removed
4 the batch compounds that were not made pursuant to a patient specific order, and produced all
5 policies and procedures for compounding, quality assurance, and training. The inspector also
6 instructed Respondent to quarantine all expired inventory in his pharmacy, including the returned
7 bubble pack cards and unlabeled cups and plastic bags containing drugs.

8 **Re-inspection of October 4, 2013**

9 35. On or about October 4, 2013, the inspector returned to the pharmacy for a re-
10 inspection and found expired drug products in the current inventory, more loose pills and
11 unlabeled drugs in small plastic bags in the bubble packing area, and large plastic bags (many
12 unlabeled) with compounding bulk ingredients in the cabinets of the compounding area.

13 36. The inspector requested and obtained Respondent's compounding policies and
14 procedures as well as his pharmacy and compounding self-assessments. The inspector told
15 Respondent that his recordkeeping and compounding policies were not in compliance with the
16 Board's regulations.

17 37. The inspector asked Respondent if he had reversed the billings for all of the
18 prescriptions that had been returned to stock and had not been reversed as determined during the
19 prior inspection. Respondent provided the inspector with various documents, including a report
20 titled "3rd Party Recon Scripts List", showing all of the reversals Respondent had processed from
21 the RTS binder. The inspector compared the prescription numbers on the Scripts List with the
22 prescription numbers on the will call reports from the RTS binder, and found that Respondent had
23 reversed approximately 146 prescriptions.

24 **FIRST CAUSE FOR DISCIPLINE**

25 **(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)**

26 38. Respondent's pharmacy permit and pharmacist license are subject to disciplinary
27 action pursuant to section 4301, subdivisions (f) and (g), for unprofessional conduct, in that

28

1 Respondent committed acts involving moral turpitude, dishonesty, fraud, deceit, or corruption, as
2 follows:

3 a. Respondent failed to reverse the claims/billings on the prescriptions identified below,
4 as determined during the Board inspection of September 26, 2013, even though Respondent had
5 not dispensed the medications to the patients and had received payment for the drugs from the
6 patients' insurance companies; or had previously dispensed the medications to the patients, had
7 received the drugs back from the patients' assisted living facilities for destruction, and had reused
8 and/or attempted to reuse the drugs. Further, the Board's inspector identified over 140 additional
9 prescriptions requiring reversal as determined during the re-inspection of October 4, 2013.

Rx No.	Rx. Fill Date	Patient Name	Transmission Status & Rx Pick up Status
180940	07/24/2013	Marisa G.	Transmitted "t"; no pick up date
179961	07/10/2013	Carol M.	Transmitted "t"; no pick up date
180406	07/16/2013	Eunice J.	Transmitted "n"; no pick up date
180215	07/13/2013	Francisco S.	Transmitted "n"; no pick up date
183854	08/30/2013	Virginia A.	Transmitted "t"; no pick up date
178062	08/24/2013	Louise H.	Transmitted "t"; no pick up date
175713	08/26/2013	Greg A.	Transmitted "t"; no pick up date
134124	12/19/2011	Chris L.	Transmitted "t"; no pick up date
182662	08/14/2013	Jacqueline M.	Transmitted "n"; no pick up date
177854	06/12/2013	Sophia S.	Transmitted "n"; no pick up date
177339	06/05/2013	Greg P.	Transmitted "t"; no pick up date
177417	06/06/2013	Jerrie T.	Transmitted "t"; no pick up date
181385	07/30/2013	Brandon S.	Transmitted "t"; pick up date 07/30/2013; delivery log confirmed delivery to patient
185660	09/19/2013	Aaron J.	Transmitted "t"; pick up date 09/20/2013; delivery log confirmed delivery to patient on 09/20/2013
C175622	05/21/2013	Joyce W.	Transmitted "t"; pick up date 05/22/2013; delivery log confirmed delivery to patient
178297	07/15/2013	Uriel C.	Transmitted "n"; pick up date 07/16/2013; delivery log confirmed drug delivered on 07/16/2013
180014	07/11/2013	Cornel J.	Transmitted "t"; pick up date 07/11/2013; delivery log was for the wrong date
C178416	06/27/2013	Evelyn V.	Transmitted "n"; pick up date 06/28/2013; signature log showed pick up on 06/28/2013
162349	02/18/2013	Guy P.	Transmitted "t"; pick up date 02/25/2013; delivery log confirmed delivery to patient on 02/22/2013
184370	09/05/2013	Charlie F.	Transmitted "n"; pick up date 09/16/2013; delivery log confirmed delivery to patient on 09/05/2013
168875	07/26/2013	Alexis W.	Transmitted "t"; pick up date 07/31/2013; delivery log confirmed delivery to patient on 07/26/2013
178049	06/14/2013	Joseph S.	Transmitted "n"; pick up date 06/14/2013
169353	07/31/2013	Trung L.	Transmitted "t"; pick up shows no date
169353	04/22/2013	Trung L.	Transmitted "t"; pick up date 04/24/2013

179926	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179927	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179928	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179930	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179931	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
179932	07/10/2013	Raymoki E.	Transmitted "t"; pick up date 07/10/2013
175725	05/13/2013	Robert C.	Transmitted "t"; pick up date 05/15/2013
179429	07/03/2013	Robert C.	Transmitted "t"; no pick up date

b. On or before September 26, 2013, Respondent reused and/or attempted to reuse bubble pack cards containing prescription medications that had previously been dispensed to patients and had been returned to Tower Pharmacy by the patients' assisted living facilities for destruction, in order to re-dispense the drugs to different patients.

SECOND CAUSE FOR DISCIPLINE

(Violations of the Pharmacy Law and State

Laws and Regulations Governing Pharmacy)

39. Respondent's pharmacy permit and pharmacist license are subject to disciplinary action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondent violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.) and state laws and regulations governing pharmacy, as follows:

a. On or about September 26, 2013, Respondent had in his current inventory numerous expired compounding ingredients, numerous containers (paper cups and plastic bags) filled with medications without a label affixed to the container or any drug information, including lot number and/or expiration date, and overfilled stock bottles of drugs, in violation of section 4342. Consequently, the drugs were misbranded.

b. On or about September 26, 2013, Respondent failed to maintain or have available for inspection records of acquisition or disposition for the bubble pack cards he acquired from various assisted living facilities for destruction, in violation of section 4081, subdivision (a).

c. On or about September 26, 2013, Respondent acted as a reverse distributor by accepting or acquiring numerous bubble pack cards containing prescription medications from

1 various assisted living facilities for destruction when, in fact, he did not have a wholesaler's
2 license issued by the Board, in violation of section 4160, subdivision (a).

3 d. On or about September 26, 2013, Respondent failed to prepare and/or maintain
4 written policies and procedures reflecting the compounding activities of the pharmacy, including
5 procurement procedures, methodologies for the formulation and compounding of drugs, facilities
6 and equipment cleaning, maintenance, operation, and/or other standard operating procedures
7 related to compounding, in violation of Regulation 1735.5, subdivision (a).

8 e. On or about September 26, 2013, Respondent failed to prepare and/or maintain
9 training records, written policies and procedures, or competency evaluations for pharmacy
10 personnel involved in compounding, in violation of Regulation 1735.7, subdivisions (a) and (b).

11 f. On or about September 26, 2013, Respondent failed to maintain the master formula
12 records for each compounded drug product in the pharmacy, certificates of analysis for bulk
13 ingredients used in compounding, and records pertaining to the acquisition and disposition of
14 chemicals, bulk drug substances, drug products, and/or components used in compounding, in
15 violation of Regulation 1735.3.

16 g. On or about September 26, 2013, Respondent failed to prepare and/or maintain any
17 written quality assurance plans for compounded prescriptions, in violation of Regulation 1735.8,
18 subdivision (a).

19
20
21 **FOLLOW-UP INSPECTIONS OF JULY AND AUGUST 2014**

22 **Inspection of July 31, 2014**

23 40. On or about July 31, 2014, Board Inspector S. conducted a follow-up inspection at the
24 pharmacy and was assisted by Respondent. The inspector checked the pharmacy bathroom and
25 located seven boxes containing various expired drugs and bubble pack cards.

26 41. The inspector asked Respondent if the pharmacy was still taking back drugs and
27 bubble packs from assisted living facilities. Respondent claimed they informed the facilities that
28 they were no longer taking back medications, but then admitted that they had recently started

1 taking back drugs from one facility, Excell Center, for destruction. Respondent also claimed that
2 they were storing the drugs in the bathroom quarantined for destruction. The inspector asked
3 Respondent if he had obtained records of acquisition or disposition for the returned drugs.
4 Respondent stated that he did not have the records, but could get them later (Respondent obtained
5 the disposition records from Excell Center and produced them at the end of the inspection). The
6 inspector asked Respondent when he started taking back drugs. Respondent called pharmacy
7 clerk K. F. over to the inspector. K. F. told the inspector that she received five sealed boxes from
8 Excell Center about one week ago and that each of the boxes was labeled with the facility's name.
9 The inspector noticed that only one of the boxes was labeled Excell Center.

10 42. Later, the inspector looked through the compounding area of the pharmacy and found
11 several expired compounds along with compounded drugs with beyond use dates in excess of 180
12 days. The inspector saw a master formula compounding record with a lot number of
13 0415201403. The record indicated that the final compounded drug had been sent for end-product
14 testing on July 10, 2014. The inspector asked Respondent to show her the test results. While
15 looking the information up on the Dynalab website, the inspector saw several test results for the
16 pharmacy that were outside of the acceptable range. The inspector asked Respondent if he
17 executed his recall procedure for the compounded drugs. Respondent told the inspector that
18 K. C., the pharmacy technician for the compounding area, had reviewed the results. The
19 inspector asked K. C. if they had taken any recall steps or any action to determine the cause of the
20 out-of-range results. K. C. indicated that she had not executed a recall for the drugs or made any
21 specific changes to the pharmacy's compounding process to improve the results. The inspector
22 showed Respondent and K. C. the pharmacy's policy for recalls¹, and neither of them could

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24
25 ¹ Respondent's recall policy, "Plan for Recalled Products and Chemicals Used in Lab",
26 dated October 2, 2013, states that "[w]hen any chemical or product used in dispensed
27 prescriptions is recalled the pharmacist-in-charge shall remove the recalled item(s) from the lab
28 and place in bathroom storage area,, box and dispose or return as required. The customer shall be
contacted and informed of the recall after the pharmacist-in-charge consults with the customer's
physician or prescriber and determines the course of action dictated by the customer's physician.
In all cases the customer will be informed within the same business day of recalled products."

1 explain why they failed to follow their own procedures. The inspector told Respondent she
2 would be returning the following day to complete the inspection since the pharmacy was closing.

3 **Inspection of August 1, 2014**

4 43. On or about August 1, 2014, Inspector S. returned to the pharmacy accompanied by
5 Board Inspector I. Respondent assisted them with the inspection. Inspector S. began checking
6 the boxes of returned drugs that were allegedly awaiting destruction. Inspector S. noticed that
7 there were four more boxes labeled "Excell Center" and asked Respondent about the additional
8 boxes. Respondent claimed that they found the boxes in the trunk of their delivery driver's car.
9 Inspector S. noticed that only one of the four boxes was sealed. Inspector S. inventoried the
10 contents of the five boxes labeled Excell Center as well as the other six boxes of returned drugs,
11 and found numerous bubble pack cards for various patients from several different assisted living
12 facilities, including Excell Center. Inspector S. also found numerous prescription vials from other
13 pharmacies.

14 44. The inspectors went to the compounding area. Inspector I. found that Respondent's
15 calibration records for the weight scale were not in compliance with state regulations, that there
16 were numerous wetting agents and ingredients stored in unlabeled containers covered with
17 cardboard around and inside the powder safe hood, and that the TopiClick delivery system was
18 being used improperly. The inspectors reviewed some of Respondent's master formula records
19 and noticed that PCCA was the source of his formulas. Some of the formulas lacked information
20 regarding the storage requirements of the compounded drugs, the capsule size of the drug, lot
21 number, expiration date, etc. The inspectors asked Respondent for the source data or original
22 master formulas from PCCA. Respondent admitted that he did not have the records available.

23 45. K. C. showed Inspector S. the Dynalab result for the compounded drug sample
24 identified during the inspection of July 31, 2014. When reviewing the records with K. C.,
25 Inspector S. noticed that some of the Dynalab results were outside of the acceptable range.
26 Inspector I. reviewed the results for potency testing for the compounded drugs indicated. Four of
27 the 18 samples provided by the pharmacy in 2013 and 2014 had results outside of the acceptable
28 potency range. The inspectors asked Respondent for the compounding master formula records

1 pertaining to the four failed results. Respondent was able to locate only two of the records and
2 provided them to the inspectors.

3 46. The inspectors reviewed the records and identified several prescriptions that had been
4 dispensed using the two compounded drugs. Inspector I. asked Respondent whether he took any
5 action regarding the out-of-range results for the drugs that had been dispensed to the patients.
6 Respondent admitted that he took no action and had failed to execute his policies and procedures
7 for compounding recalls. At the conclusion of the inspection, Inspector S. asked Respondent to
8 provide her with various documents within 14 days, including the compounding records and
9 dispensed prescriptions relating to the two failed results he was unable to provide. About two
10 weeks later, Inspector S. received the compounding records for the two failed results from
11 Respondent's legal representative; however, the dispensing records were provided for only one of
12 them.

13 **THIRD CAUSE FOR DISCIPLINE**

14 **(Acts Involving Moral Turpitude, Dishonesty, Fraud, Deceit, or Corruption)**

15 47. Respondent's pharmacy permit and pharmacist license are subject to disciplinary
16 action pursuant to section 4301, subdivision (f), for unprofessional conduct, in that Respondent
17 committed an act involving moral turpitude, dishonesty, fraud, deceit, or corruption, as follows:
18 On or about July 31, 2014, Respondent falsely represented to Board Inspector S. that the
19 pharmacy was taking back drugs for destruction from only one assisted living facility (Excell
20 Center). In fact, Respondent had accepted or acquired numerous prescription medications from
21 several different facilities, including Excell Center.

22 **FOURTH CAUSE FOR DISCIPLINE**

23 **(Violations of the Pharmacy Law and State** 24 **Laws and Regulations Governing Pharmacy)**

25 48. Respondent's pharmacy permit and pharmacist license are subject to disciplinary
26 action pursuant to section 4301, subdivision (o), for unprofessional conduct, in that Respondent
27 violated or attempted to violate, directly or indirectly, assisted in or abetted the violation of, or

28

1 conspired to violate provisions or terms of the Pharmacy Law (Bus. & Prof. Code § 4300, et seq.)
2 and state laws and regulations governing pharmacy, as follows:

3 a. On or about July 31, 2014 and August 1, 2014, Respondent acted as a reverse
4 distributor by accepting or acquiring bubble pack cards containing prescription medications from
5 various assisted living facilities for destruction and prescription drugs from other pharmacies
6 when, in fact, he did not have a wholesaler's license issued by the Board, in violation of section
7 4160, subdivision (a). Further, Respondent continued taking back drugs for destruction even
8 though he had been warned during the inspection of September 26, 2013, that he was not
9 authorized to accept returned medications from the facilities for destruction.

10 b. On or about July 31, 2014 and August 1, 2014, Respondent failed to maintain or have
11 available for inspection records of acquisition or disposition for the bubble pack cards he acquired
12 from the assisted living facilities for destruction and the prescription drugs he received from other
13 pharmacies, in violation of section 4081, subdivision (a).

14 c. On or about July 31, 2014 and August 1, 2014, Respondent had in his current
15 inventory numerous batch compounded drug products that were expired, in violation of section
16 4342.

17 d. In and between October 2013 and June 2014, Respondent failed to follow the
18 pharmacy's written policies and procedures for recalling compounded drugs which were below
19 the minimum standards for integrity, potency, quality or labeled strength, in violation of
20 Regulation 1735.8, as follows: Respondent failed to recall 4 compounded drugs which were
21 below the minimum standards for potency, including the 3 drugs identified below, even though he
22 knew, or should have known, that the drugs were dispensed to at least 16 patients.

23	Compounded Drug/Lot No.	Dynalabs Results	Rx Number	Date Dispensed
24	Testosterone 50 mg/gm gel; Lot #10172013-8	124.43% (acceptable range: 90-110%); results signed by Dynalabs on 11/08/2013	188008	10/17/2013
25			187881	10/16/2013
26			181294	10/16/2013
27				
28			162826	10/16/2013

1			183232	10/18/2013
2			181576	10/18/2013
3			189070	10/31/2013
4	Naltrexone 4.5 mg capsules Lot #01272014-02	69.3% (acceptable range: 90-110%); results signed by Dynalabs on 03/02/2014	196459	01/23/2014
5			190874	02/10/2014
6	Naltrexone 4.5 mg capsules Lot #01272014-02	69.3% (acceptable range: 90-110%); results signed by Dynalabs on 03/02/2014	195722	02/14/2014
7			198850	02/20/2014
8	Naltrexone 4.5 mg capsules Lot #02282014-04	67.96% (acceptable range: 90-110%); results signed by Dynalabs on 05/01/2014	199356	02/26/2014
9			202032	03/28/2014
10			199356	04/23/2014
11			205015	04/30/2014
12			207927	06/03/2014

14 e. On or about July 31, 2014 and August 1, 2014, Respondent failed to document in the
15 calibration records for the compounding (weight) scale the calibration readings of the scale or the
16 method used to calibrate the equipment, in violation of Regulation 1735.6, subdivisions (b) and
17 (c).

18 f. On or about July 31, 2014 and August 1, 2014, Respondent stored the bulk
19 compounding ingredients around and inside the powder safe hood in glass containers without lot
20 numbers or expiration dates, and failed to store the ingredients in the manufacturers' original
21 containers, in violation of Regulation 1735.2, subdivision (g). Further, Respondent covered the
22 glass containers with cardboard, increasing the risk of contamination of the ingredients.

23 g. On or about July 31, 2014 and August 1, 2014, Respondent failed to use the Topi-
24 Click delivery system properly in preparing compounded drugs, in violation of Regulation
25 1735.2, subdivision (i), in that Respondent measured the compound ingredients using weight
26 measurement when, in fact, the device is only approved for volume measurement.

1 h. On or about July 31, 2014 and August 1, 2014, Respondent failed to maintain and/or
2 have available for inspection the source data for the master formulas from PCCA, and failed to
3 ensure that the master formulas had all of the required information, including the storage
4 requirements of the compounded drugs, the capsule size, lot number, and expiration date, in
5 violation of Regulation 1735.3, subdivisions (a)(1), (b), and (c).

6 i. On or about July 31, 2014 and August 1, 2014, Respondent had in his current
7 inventory compounded drugs with beyond use dates exceeding 180 days, in violation of
8 Regulation 1735.2, subdivision (h).

9 **FIFTH CAUSE FOR DISCIPLINE**

10 **(Subverting or Attempting to Subvert an Investigation of the Board)**

11 49. Respondent's pharmacy permit and pharmacist license are subject to disciplinary
12 action pursuant to section 4301, subdivision (q), for unprofessional conduct, in that on or about
13 September 26, 2013 and July 31, 2014, Respondent subverted or attempted to subvert an
14 investigation of the Board, as set forth respectively in paragraphs 28 and 46 above.

15 **OTHER MATTERS**

16 50. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
17 PHY 54174, issued to Tower Pharmacy, Tower Pharmacy shall be prohibited from serving as a
18 manager, administrator, owner, member, officer, director, associate, or partner of a licensee for
19 five years if Pharmacy Permit Number PHY 54174 is placed on probation or until Pharmacy
20 Permit Number PHY 54174 is reinstated if it is revoked.

21 51. Pursuant to Code section 4307, if discipline is imposed on Pharmacy Permit Number
22 PHY 54174, issued to Tower Pharmacy while Darin L. Nelle has been an officer and owner and
23 had knowledge of or knowingly participated, in any conduct for which the licensee was
24 disciplined, Darin L. Nelle shall be prohibited from serving as a manager, administrator, owner,
25 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
26 Number PHY 54174 is placed on probation or until Pharmacy Permit Number PHY 54174 is
27 reinstated if it is revoked.

1 PRAYER

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

4 1. Revoking or suspending Pharmacy Permit Number PHY 54174, issued to Darin
5 Nelle, owner of Tower Pharmacy;

6 2. Revoking or suspending Pharmacist License Number RPH 44309, issued to Darin L.
7 Nelle;

8 3. Prohibiting Tower Pharmacy from serving as a manager, administrator, owner,
9 member, officer, director, associate, or partner of a licensee for five years if Pharmacy Permit
10 Number PHY 54174 is placed on probation or until Pharmacy Permit Number PHY 54174 is
11 reinstated if it is revoked;

12 4. Prohibiting Darin L. Nelle, Pharmacist License Number RPH 44309, from serving as
13 a manager, administrator, owner, member, officer, director, associate, or partner of or partner of a
14 licensee for five years if Pharmacy Permit Number PHY 54174 is placed on probation or until
15 Pharmacy Permit Number PHY 54174 is reinstated if it is revoked;

16 5. Ordering Darin L. Nelle, individually, and as owner of Tower Pharmacy, to pay the
17 Board of Pharmacy the reasonable costs of the investigation and enforcement of this case,
18 pursuant to Business and Professions Code section 125.3; and

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

20
21 DATED: _____

11/3/16



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

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