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7		RETHE
8	BOARD OF	PHARMACY CONSUMER AFFAIRS
9		CALIFORNIA
10	In the Matter of the Accusation Against:	Case No. 4125
11	DANIELS PHARMACY	
12	943 Geneva Avenue San Francisco, CA 94112	FIRST AMENDED ACCUSATION
13	Pharmacy License No. PHY 36740	
14	and	
15	IYAD I. NASRAH	
16 17	488 Gellert Drive San Francisco, CA 94132	
17	Pharmacist License No. RPH 40241	
10	Respondents.	
20	Complainant alleges:	
21	PAR	TIES
22	1. Virginia Herold (Complainant) bring	s this Accusation solely in her official capacity
23	as the Executive Officer of the Board of Pharma	cy, Department of Consumer Affairs.
24	2. On or about October 24, 1990, the B	oard of Pharmacy issued Pharmacy License No.
25	PHY 36740 to Daniels Pharmacy (Respondent D	vaniels). The License was in full force and effect
26	at all times relevant to the charges herein, and wi	Il expire on October 1, 2014, unless renewed.
27	3. On or about August 20, 1986, the Bo	ard of Pharmacy issued Pharmacist License No.
28	RPH 40241 to Iyad I. Nasrah (Respondent Nasra	h). The License was in full force and effect at all
{	1	First Amended Accusation

1	times relevant to the charges herein and will expire on October 31, 2014, unless renewed. Since
2	on or about October 24, 1990, Respondent Nasrah has served and/or has been reflected in Board
3	records as the Pharmacist in Charge (PIC) for Respondent Daniels.
4	JURISDICTION
5	4. This Accusation is brought before the Board of Pharmacy (Board), Department of
6	Consumer Affairs, under the authority of the following laws. All section references are to the
7	Business and Professions Code (Code) unless otherwise indicated.
8	5. Section 4011 of the Code provides that the Board shall administer and enforce both
9	the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
10	Act [Health & Safety Code, § 11000 et seq.].
11	6. Section 4300(a) of the Code provides that every license issued by the Board may be
12	suspended or revoked.
13	7. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or
14	suspension of a Board-issued license, the placement of a license on a retired status, or the
15	voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to
16	commence or proceed with any investigation of, or action or disciplinary proceeding against, the
17	licensee or to render a decision suspending or revoking the license.
18	STATUTORY AND REGULATORY PROVISIONS
19	Business and Professions Code:
20	8. Section 4043(a) of the Code states:
21	"Wholesaler" means and includes a person who acts as a wholesale merchant, broker,
22	jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for
23	resale, or negotiates for distribution, or takes possession of, any drug or device included in
24	Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or
25	authorize the storage or warehousing of drugs with any person or at any location not licensed by
26	the board.
27	9. Section 4059 of the Code, in pertinent part, prohibits furnishing of any dangerous
28	drug or dangerous device except upon the prescription of an authorized prescriber.
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10. Section 4059.5 of the Code, in pertinent part, permits ordering/delivery of dangerous drugs or devices only by and to entities licensed by the board and authorized prescribers, and requires that all deliveries to a licensed premises shall be signed for and received by a pharmacist.

11. Section **4061** of the Code provides, in pertinent part, that manufacturers' sales representatives may distribute complimentary samples of drugs only to and pursuant to a written request from an authorized prescriber that specifies the name and quantity of drug desired.

12. Section **4063** of the Code states:

8 No prescription for any dangerous drug or dangerous device may be refilled except upon
9 authorization of the prescriber. The authorization may be given orally or at the time of giving the
10 original prescription. No prescription for any dangerous drug that is a controlled substance may
11 be designated refillable as needed.

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13. Section 4064 of the Code states:

(a) A prescription for a dangerous drug or dangerous device may be refilled without the
prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the
pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's
ongoing care and have a significant adverse effect on the patient's well-being.

(b) The pharmacist shall inform the patient that the prescription was refilled pursuant to thissection.

(c) The pharmacist shall inform the prescriber within a reasonable period of time of any
refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every
 reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record,
 including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescriptionpursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug
or dangerous device furnished without prescription pursuant to this section.

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14. Section 4076, subdivision (a), of the Code provides, in pertinent part, that a

1	pharmacist shall not dispense any prescription except in a container meeting the requirements of
2	state and federal law that is correctly labeled with information including the following:
3	(1) Except where ordered otherwise by the prescriber, the manufacturer's trade name of the
4	drug or the generic name and the name of the manufacturer;
5	(2) The directions for use of the drug;
6	(3) The name of the patient or patients;
7	(4) The name(s) of the prescriber(s);
8	(5) The date of dispensing;
9	(6) The name and address of the pharmacy, and prescription number;
10	(7) The strength of the drug(s) dispensed;
11	(8) The quantity of the drug(s) dispensed;
12	(9) The expiration date of the drug(s) dispensed;
13	(10) If on the prescription, the condition or purpose for which the drug was prescribed;
14	(11) A physical description of the dispensed medication.
15	15. Section 4081 of the Code states, in pertinent part:
16	(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or
17	dangerous devices shall be at all times during business hours open to inspection by authorized
18	officers of the law, and shall be preserved for at least three years from the date of making. A
19	current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-
20	animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,
21	institution, or establishment holding a currently valid and unrevoked certificate, license, permit,
22	registration, or exemption under Division 2 (commencing with Section 1200) of the Health and
23	Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and
24	Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
25	(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal
26	drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated
27	representative-in-charge, for maintaining the records and inventory described in this section.
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1	16. Section 4105 of the Code requires, in pertinent part, that unless a waiver is granted by
2	the board, all records and other documentation of the acquisition and disposition of dangerous
3	drugs and devices by any entity licensed by the board be retained on the licensed premises, in a
4	readily retrievable form, for three years from the date of making.
5	17. Section 4113(c) of the Code states:
6	The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state
7	and federal laws and regulations pertaining to the practice of pharmacy.
8	18. Section 4115(e) of the Code states:
9	No person shall act as a pharmacy technician without first being licensed by the board as a
10	pharmacy technician.
11	19. Section 4125(a) of the Code states:
12	Every pharmacy shall establish a quality assurance program that shall, at a minimum,
13	document medication errors attributable, in whole or in part, to the pharmacy or its personnel.
14	The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy
15	in dispensing or furnishing prescription medications so that the pharmacy may take appropriate
16	action to prevent a recurrence.
17	20. Section 4160(a) of the Code states:
18	(a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless
19	he or she has obtained a license from the board.
20	21. Section 4301 of the Code states, in pertinent part:
21	The board shall take action against any holder of a license who is guilty of unprofessional
22	conduct or whose license has been procured by fraud or misrepresentation or issued by mistake.
23	Unprofessional conduct shall include, but is not limited to, any of the following:
24	•••
25	(f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or
26	corruption, whether the act is committed in the course of relations as a licensee or otherwise, and
27	whether the act is a felony or misdemeanor or not.
28	(g) Knowingly making or signing any certificate or other document that falsely represents
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the existence or nonexistence of a state of facts.

2 (j) The violation of any of the statutes of this state, of any other state, or of the United 3 States regulating controlled substances and dangerous drugs. 4 5 (m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 6 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code 8 relating to the Medi-Cal program. The record of the compromise is conclusive evidence of 9 unprofessional conduct. 10 11 (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the 12 violation of or conspiring to violate any provision or term of this chapter or of the applicable 13 federal and state laws and regulations governing pharmacy, including regulations established by 14 the board or by any other state or federal regulatory agency. 15 16 22. Section **4324** of the Code states: 17 (a) Every person who signs the name of another, or of a fictitious person, or falsely makes, 18 alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any 19 drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment 20 pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county 21 jail for not more than one year. 22 (b) Every person who has in his or her possession any drugs secured by a forged 23

prescription shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the
Penal Code, or by imprisonment in the county jail for not more than one year.

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23. Section **4332** of the Code states:

Any person who fails, neglects, or refuses to maintain the records required by Section 4081 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or

refuses to produce or provide the records within a reasonable time, or who willfully produces or furnishes records that are false, is guilty of a misdemeanor.

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24. Section **4342** of the Code states:

(a) 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).

(b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006
shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.

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Health and Safety Code:

13 25. Health and Safety Code section 11165 provides, in pertinent part, for establishment
14 and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES)
15 for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled
16 substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV
17 controlled substance, the dispensing pharmacy or clinic transmit a report with certain information
18 on the patient, prescriber, controlled substance, and prescription, to the California Department of
19 Justice, on a weekly basis in a format prescribed by the California Department of Justice. ¹

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26. Health and Safety Code section 111340 states:

21 Any drug or device is misbranded unless it bears a label containing all of the following 22 information:

(a) The name and place of business of the manufacturer, packer, or distributor.

(b) An accurate statement of the quantity of the contents in terms of weight, measure, ornumerical count.

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¹ Health and Safety Code section 11165 was first amended to impose CURES reporting requirements effective January 1, 2005; as of that date, prescriptions for Schedule II and III drugs had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.

Reasonable variations from the requirements of subdivision (b) shall be permitted. 1 Requirements for placement and prominence of the information and exemptions as to small 2 packages shall be established in accordance with regulations adopted pursuant to Section 110380. 3 Health and Safety Code section **111440** states: 27. 4 It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or 5 device that is misbranded. 6 **California Code of Regulations:** 7 28. California Code of Regulations, title 16, section 1707.2 states, in pertinent part: 8 (a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in 9 all care settings: 10 (1) upon request; or 11 (2) whenever the pharmacist deems it warranted in the exercise of his or her professional 12 judgment. 13 (b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall 14 provide oral consultation to his or her patient or the patient's agent in any care setting in which the 15 patient or agent is present: 16 (A) whenever the prescription drug has not previously been dispensed to a patient; or 17 (B) whenever a prescription drug not previously dispensed to a patient in the same dosage 18 form, strength or with the same written directions, is dispensed by the pharmacy. 19 (2) When the patient or agent is not present (including but not limited to a prescription drug 20 that was shipped by mail) a pharmacy shall ensure that the patient receives written notice: 21 (A) of his or her right to request consultation; and 22 (B) a telephone number from which the patient may obtain oral consultation from a 23 pharmacist who has ready access to the patient's record. 24 (3) A pharmacist is not required by this subsection to provide oral consultation to an 25 inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code, 26 or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the 27 patient's discharge. A pharmacist is not obligated to consult about discharge medications if a 28 8

health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250 has implemented a written policy about discharge medications which meets the requirements of Business and Professions Code Section 4074.

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29. California Code of Regulations, title 16, section 1707.3 states:

Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems.

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30. 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.

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(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.

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

paragraph (2) of this subdivision.

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

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

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1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and
documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

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

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

(g) The pharmacy's compliance with this section will be considered by the board as a
mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or
otherwise arranging for the provision of personnel or other resources, by a third party or
administrative offices, with such skill or expertise as the pharmacy believes to be necessary to
satisfy the requirements of this section.

California Code of Regulations, title 16, section 1714 states, in pertinent part: 31. 1 2 (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and 3 equipment so that drugs are safely and properly prepared, maintained, secured and distributed. 4 The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice 5 of pharmacy. 6 7 (e) The pharmacy owner, the building owner or manager, or a family member of a 8 pharmacist owner (but not more than one of the aforementioned) may possess a key to the 9 pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key 10 to a pharmacist or 2) providing access in case of emergency. An emergency would include fire, 11 flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that 12 the pharmacist may readily determine whether the key has been removed from the container. 13 14 California Code of Regulations, title 16, section 1716 states: 32. 15 Pharmacists shall not deviate from the requirements of a prescription except upon the prior 16 consent of the prescriber or to select the drug product in accordance with Section 4073 of the 17 Business and Professions Code. 18 Nothing in this regulation is intended to prohibit a pharmacist from exercising commonly-19 accepted pharmaceutical practice in the compounding or dispensing of a prescription. 20 33. California Code of Regulations, title 16, section 1717 states, in pertinent part: 21 (a) No medication shall be dispensed on prescription except in a new container which 22 conforms with standards established in the official compendia. 23 Notwithstanding the above, a pharmacist may dispense and refill a prescription for non-24 liquid oral products in a clean multiple-drug patient medication package (patient med pak), 25 provided: 26 (1) a patient med pak is reused only for the same patient; 27 (2) no more than a one-month supply is dispensed at one time; and 28 11

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."
 (b) In addition to the requirements of Business and Professions Code section 4040, the
 following information shall be maintained for each prescription on file and shall be readily
 retrievable: ______

5 (1) The date dispensed, and the name or initials of the dispensing pharmacist. All
6 prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising
7 pharmacist before they are dispensed.

8 (2) The brand name of the drug or device; or if a generic drug or device is dispensed, the
9 distributor's name which appears on the commercial package label; and

(3) If a prescription for a drug or device is refilled, a record of each refill, quantity
dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber
or directions for use, unless a complete record of all such changes is otherwise maintained.

(f) The pharmacy must have written procedures that identify each individual pharmacist
responsible for the filling of a prescription and a corresponding entry of information into an
automated data processing system, or a manual record system, and the pharmacist shall create in
his/her handwriting or through hand-initializing a record of such filling, not later than the
beginning of the pharmacy's next operating day. Such record shall be maintained for at least three
years.

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

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

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

35. California Code of Regulations, title 16, section 1793.7 states, in pertinent part:

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(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in 1 such a relationship that the supervising pharmacist is fully aware of all activities involved in the 2 preparation and dispensing of medications, including the maintenance of appropriate records. 3 4 (e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure 5 that all such activities are performed completely, safely and without risk of harm to patients. 6 7 Code of Federal Regulations: 8 Title 21, Code of Federal Regulations, section 1304.04(f) requires, in pertinent part, 36. 9 that inventories and records of Schedule I and II controlled substances shall be kept separate from 10 all other records, and that inventories and records of Schedule III-V controlled substances shall be 11 either kept separate from other records, or be immediately retrievable from the business records. 12 **Controlled Substances/Dangerous Drugs:** 13 Section 4021 of the Code provides that a "controlled substance" means any substance 37. 14 listed in Schedules I through V contained in Health and Safety Code section 11053 et seq. 15 38. Section **4022** of the Code states, in pertinent part: 16 "Dangerous drug: or "dangerous device" means any drug or device unsafe for self use, 17 except veterinary drugs that are labeled as such, and includes the following: 18 (a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without 19 prescription," "Rx only," or words of similar import.... 20(c) Any other drug or device that by federal or state law can be lawfully dispensed only on 21 prescription or furnished pursuant to Section 4006. 22 39. Klonopin is a brand name for clonazepam, a Schedule IV controlled substance as 23 designated by Health and Safety Code section 11057(d) and a dangerous drug as designated by 24 Business and Professions Code section 4022. It is used to treat mental health symptoms. 25 Celexa is a brand name for citalopram, a dangerous drug as designated by Business 40. 26 and Professions Code section 4022. It is used to treat mental health symptoms. 27 Zyprexa is a brand name for olanzapine, a dangerous drug as designated by Business 41. 28 13

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and Professions Code section 4022. It is used to treat mental health symptoms.

COST RECOVERY

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

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2011 INSPECTIONS AND INVESTIGATION

8 43. Between in or about January and April 2011, Respondents were the subject(s) of
9 investigation(s) by the Board of Pharmacy. The investigation(s) revealed record-keeping,
10 dispensing, and furnishing practices that failed to comply with the law.

44. During January 12 and January 27, 2011 inspections by Board Inspector(s), each of
the following deviations from pharmacy requirements was/were noted by the Inspector(s):

a. Included in the active drug inventory for the pharmacy were: (i) a prescription
bottle for patient SM, labeled by a Safeway Pharmacy, prescription number 6448294 dispensed
on January 4, 2009, that expired in October 2010, with some of the labeled drug quantity missing;
(ii) several boxes of prescription bottles containing professional drug samples; and (iii) one or
more bubble packs or strip packs containing drugs returned from board and care homes. There
were no records of acquisition maintained by Respondents with regard to any of these items.

b. Respondents used a prescription dispensing software and system to create prefilled bubble packs or strip packs for board and care homes, subdivided by patient and dose. The
software and system did not make note of the identity of the dispensing pharmacist, nor was this
information recorded anywhere on the label or in Respondents' records. Respondent Nasrah said
that he had no record of and/or it was not possible to identify the dispensing pharmacist for any of
the thousands of prescriptions dispensed using this system during the previous nine (9) years.

c. The software and system used to generate the bubble/strip packs for board and
care homes also did not include required information on the label(s) generated during this nine (9)
year period, including: dispense date; drug manufacturer; and/or address of the pharmacy.

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d.

In various places in the pharmacy, including in the active inventory, were

prescription bottles containing quantities of dangerous drugs, with either no labels or incomplete labels affixed. Respondent asserted that these were returned from assisted living facilities.

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e. Since at least October 21, 2009, Respondents had not successfully transmitted data regarding controlled substances dispensed by the pharmacy to the Controlled Substances Utilization Review (CURES) database maintained by the California Department of Justice.

f. Controlled substance invoices for at least the two months prior to the inspection were grouped and filed together, and there was no separation of Schedule II invoices.

g. On at least one occasion, including on or about July 17, 2010, a non-pharmacist
g. (store clerk) signed a wholesaler's proof of delivery form to accept delivery of dangerous drugs.

45. Between on or about July 10, 2009 and on or about January 10, 2011, Respondents
dispensed dangerous drugs and/or controlled substances to patient DC pursuant to unauthorized
prescriptions and/or refills, including:

a. On at least ten (10) occasions between on or about December 14, 2009 and on
or about January 10, 2011, Respondents filled new prescriptions for DC for controlled substances
and/or dangerous drugs without prescriber authorization, including: two (2) prescriptions for
controlled substance/dangerous drug clonazepam 0.5mg (Klonopin); six (6) prescriptions for the
dangerous drug Celexa 40mg; and two (2) prescriptions for the dangerous drug Zyprexa 20mg.

b. On at least twenty-nine (29) occasions between on or about August 2, 2009 and
on or about September 1, 2010, Respondents furnished refill prescriptions to DC for controlled
substances and/or dangerous drugs without prescriber authorization, including: five (5) refills for
controlled substance/dangerous drug clonazepam 0.5mg (Klonopin); fourteen (14) refills for the
dangerous drug Zyprexa 20mg; and ten (10) refills for the dangerous drug Celexa 40mg.

c. On at least seven (7) occasions between on or about July 10, 2009 and on or
about January 19, 2010, Respondents created and/or signed prescription documents for DC that
falsely stated authorization by the prescriber, including: one (1) prescription for controlled
substance/dangerous drug clonazepam 0.5mg (Klonopin); five (5) prescriptions for the
dangerous drug Celexa 40mg; and one (1) prescription for the dangerous drug Zyprexa 20mg.
///

1	FIRST CAUSE FOR DISCIPLINE
2	(Incomplete Inventory and/or Records of Acquisition and/or Disposition)
3	46. Respondents are each and severally subject to discipline under section 4301(j) and/or
4	(o) and/or section 4113(c) of the Code, by reference to section(s) 4081, 4105, 4332 and/or 4342
5	of the Code, and/or California Code of Regulations, title 16, section 1718, for violating statutes
6	regulating controlled substances or dangerous drugs, and/or directly or indirectly violating,
7	attempting to violate, or assisting in or abetting a violation of laws or regulations governing the
8	practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents failed to
9	maintain an accurate, complete, and readily retrievable inventory and/or records of acquisition
10	and disposition of all dangerous drugs in the pharmacy inventory.
11	SECOND CAUSE FOR DISCIPLINE
12	(Possessing and/or Dispensing/Furnishing Drug Samples)
13	47. Respondents are each and severally subject to discipline under section 4301(j) and/or
14	(o) and/or section 4113(c) of the Code, by reference to section 4061 of the Code, for violating
15	statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly
16	violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
17	governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents
18	had in their inventory, and/or had previously dispensed or furnished, manufacturer drug samples.
19	THIRD CAUSE FOR DISCIPLINE
20	(Failure to Identify Dispensing Pharmacist)
21	48. Respondents are each and severally subject to discipline under section 4301(j) and/or
22	(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16,
23	section 1717, for violating statutes regulating controlled substances or dangerous drugs, and/or
24	directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws
25	or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44
26	above, Respondents dispensed medications without a means of identifying the dispensing
27	pharmacist.
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FOURTH CAUSE FOR DISCIPLINE

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2	(Inadequately Labeled Prescription Containers)
3	49. Respondents are each and severally subject to discipline under section 4301(j) and/or
4	(o) and/or section 4113(c) of the Code, by reference to section 4076 of the Code, for violating
5	statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly
6	violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
7	governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, Respondents
8	dispensed medications in prescription containers which failed to include required information.
9	FIFTH CAUSE FOR DISCIPLINE
10	(Possession of Misbranded Drug Containers)
11	50. Respondents are each and severally subject to discipline under section 4301(j) and/or
12	(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340
13	and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or
14	directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws
15	or regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44
16	above, Respondents possessed drug containers that were misbranded inasmuch as they had
17	affixed to them no or incomplete labels describing the contents, the manufacturer, and other
18	required data.
19	SIXTH CAUSE FOR DISCIPLINE
20	(Failure to Report Controlled Substance Prescriptions to CURES)
21	51. Respondents are each and severally subject to discipline under section 4301(j) and/or
22	(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 11165, for
23	violating statutes regulating controlled substances or dangerous drugs, and/or directly or
24	indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or
25	regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above,
26	in the period prior to January 12, 2011, the pharmacy had not successfully transmitted any
27	dispensing data to CURES for controlled substances that were dispensed since at least October
28	21, 2009.
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SEVENTH CAUSE FOR DISCIPLINE 1 2 (Failure to Segregate Schedule II Records) 52. Respondents are each and severally subject to discipline under section 4301(i) and/or 3 (o) and/or section 4113(c) of the Code, by reference to Title 21, Code of Federal Regulations, 4 section 1304.04(f), for violating statutes regulating controlled substances or dangerous drugs, 5 and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a 6 violation of laws or regulations governing the practice of pharmacy, in that, as described in 7 paragraphs 43-44 above, on or about January 12, 2011, Schedule II records were not segregated. 8 EIGHTH CAUSE FOR DISCIPLINE 9 (Receipt and Acknowledgment of Delivery by Non-Pharmacist) 10 53. Respondents are each and severally subject to discipline under section 4301(j) and/or 11 (o) and/or section 4113(c) of the Code, by reference to section(s) 4059 and/or 4059.5 of the Code, 12 for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or 13 indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or 14 regulations governing the practice of pharmacy, in that, as described in paragraphs 43-44 above, a 15 non-pharmacist received and/or signed for a delivery of a dangerous drug or device. 16 NINTH CAUSE FOR DISCIPLINE 17 (Furnishing/Dispensing Prescriptions Without Prescriber Authorization) 18 Respondents are each and severally subject to discipline under section 4301(j) and/or 54. 19 (o) and/or section 4113(c) of the Code, by reference to section 4059 of the Code, for violating 20statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly 21 violating, attempting to violate, or assisting in or abetting a violation of laws or regulations 22 governing the practice of pharmacy, in that, as described in paragraph 45 above, Respondents 23 furnished ten (10) new prescriptions to patient DC that were not authorized by a prescriber. 24 TENTH CAUSE FOR DISCIPLINE 25 (Furnishing/Dispensing Refills Without Prescriber Authorization) 26 55. Respondents are each and severally subject to discipline under section 4301(j) and/or 27 (o) and/or section 4113(c) of the Code, by reference to section 4063 of the Code, for violating 28 18

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1	statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly
2	violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
3	governing the practice of pharmacy, in that, as described in paragraph 45 above, Respondents
4	furnished twenty nine (29) refills to patient DC that were not authorized by a prescriber.
5	ELEVENTH CAUSE FOR DISCIPLINE
6	(Dishonesty/Creation of False Prescription Document(s))
7	56. Respondents are each and severally subject to discipline under section 4301(f) and/or
8	(g) and/or section 4113(c) and/or section 4324 of the Code, for acts involving moral turpitude,
9	dishonesty, fraud, deceit, corruption and forgery, and/or for knowingly making or signing any
10	certificate or other document that falsely represents the existence or nonexistence of a state of
11	facts in that, as described in paragraph 45 above, Respondents created seven (7) false
12	prescriptions for patient DC.
13	TWELFTH CAUSE FOR DISCIPLINE
14	(Failure to Maintain Records of Acquisition of Drugs)
15	57. Respondents are each and severally subject to discipline under section 4301(j) and/or
16	(o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes
17	regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating,
18	attempting to violate, or assisting in or abetting a violation of laws or regulations governing the
19	practice of pharmacy, in that on or about January 12, 2011, Respondents' facility contained a
20	prescription bottle containing 180 Premarin 1.25 tablets, Safeway prescription number 6448294,
21	issue to patient SM on January 4, 2009. Respondents had no record of the acquisition of this
22	item.
23	THIRTEENTH CAUSE FOR DISCIPLINE
24	(Unprofessional Conduct)
25	58. are each and severally subject to discipline under section 4301 of the Code in that
26	Respondents, as described in paragraphs 43-45 above, engaged in unprofessional conduct.
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1	CASH COMPROMISE OF MEDI-CAL CHARGES
2	59. On or about June, 2010, the California Department of Health Care Services
3	(hereinafter "Department") audited Respondents' premises and records pertaining to the period of
4	March 1, 2009 through March 31, 2010.
5	60. Based on this audit, on or about July 16, 2010, the Department took formal action
6	against Respondents by withholding all Medi-Cal payments to Respondents and by suspending
7	and deactivating Respondents' Medi-Cal provider number and National Provider Identifier
8	number. The Department charged Respondents with having violated California Welfare and
9	Institutions Code section 14107(b) (false and fraudulent claims) and California Code of
10	Regulations, Title 22, sections 51470(a) (false billing) and 51485 (submission of false
11	information), based on to the following misconduct:
12	a) Overbilling for medications;
13	b) Billing for prescriptions that had not actually been provided to beneficiaries;
14	c) Falsification of a telephone prescription; and
15	d) Failure to purchase sufficient quantities of drugs to fill claims made for orders filled.
16	61. On or about October 13, 2010, Respondents entered into a cash compromise of the
17	above-described charges by signing a document entitled "Stipulation And Settlement Agreement
18	Between The California Department of Health Care Services And Daniel's Pharmacy." The
19	agreement provided for settlement of the charges in exchange for Respondents' agreement to pay
20	approximately \$1,000,000.00 to the Department.
21	FOURTEENTH CAUSE FOR DISCIPLINE
22	(Cash Compromise of Medi-Cal Charges)
23	62. Respondents are each and severally subject to discipline under section 4301(m)
24	and/or section 4113(c) of the Code, in that they engaged in a cash compromise of a charge of
25	violation of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare
26	and Institutions Code relating to the Medi-Cal program, as described above in paragraphs 59-61.
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1	2013 INSPECTION
2	63. On or about August 1, 2013, Pharmacy Board inspectors inspected Respondents'
3	pharmacy in order to ascertain whether Respondents continued to be in violation of law. The
4	Inspectors observed numerous violations, as set forth below in the following Causes for
5	Discipline.
6	FIFTEENTH CAUSE FOR DISCIPLINE
7	(Failure to Consult with On-Premises Patient)
8	64. Respondents are each and severally subject to discipline under section 4301(j) and/or
9	(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
10	section 1707.2(b)(1)(A), for violating statutes regulating controlled substances or dangerous
11	drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a
12	violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013,
13	Respondents dispensed a prescription to patient DV, which had not previously been dispensed to
14	patient DV, without providing a consultation by a pharmacist. Respondents failed to have a
15	policy or procedure identifying medications for which a consultation should be provided.
16	SIXTEENTH CAUSE FOR DISCIPLINE
17	(Failure to Consult with Off-Premises Patient)
18	65. Respondents are each and severally subject to discipline under section 4301(j) and/or
19	(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
20	section 1707.2(b)(2), for violating statutes regulating controlled substances or dangerous drugs,
21	and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a
22	violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013,
23	Respondents prepared prescription medication for delivery to a patient, which medication had not
24	previously been dispensed to said patient, without providing any notification to the patient
25	regarding the patient's right to request a consultation.
26	SEVENTEENTH CAUSE FOR DISCIPLINE
27	(Possession of Misbranded Drug Containers)
28	66. Respondents are each and severally subject to discipline under section 4301(j) and/or
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1	(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340
2	and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or
3	directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws
4	or regulations governing the practice of pharmacy, in that on or about August 1, 2013,
5	Respondents possessed numerous misbranded/unlabeled prescription vials with dangerous drugs
6	and outdated products in current inventory. Respondents also had in its possession previously-
7	dispensed bubble packs of medications which had been returned by board-and-care homes.
8	EIGHTEENTH CAUSE FOR DISCIPLINE
9	(Failure to Initiate Quality Assurance Review)
10	67. Respondents are each and severally subject to discipline under section 4301(j) and/or
11	(o) and/or section 4113(c) of the Code, by reference to Code section 4125(a) and California Code
12	of Regulations, Title 16, section 1711, for violating statutes regulating controlled substances or
13	dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or
14	abetting a violation of laws or regulations governing the practice of pharmacy, in that on August
15	1, 2013, Respondents admitted to Board Inspectors that they had failed to complete quality
16	assurance reviews, procedures and related forms in the aftermath of dispensing errors.
17	NINETEENTH CAUSE FOR DISCIPLINE
18	(Variation from Prescription)
19	68. Respondents are each and severally subject to discipline under section 4301(j) and/or
20	(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
21	section 1716, for violating statutes regulating controlled substances or dangerous drugs, and/or
22	for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of
23	laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Board
24	Inspectors identified two prescriptions, RX numbers N9878911 and N9879201, which contained
25	erroneous directions for use and/or identified the wrong prescriber.
26	TWENTIETH CAUSE FOR DISCIPLINE
27	(Improper Supervision of Pharmacy Technician)
28	69. Respondents are each and severally subject to discipline under section 4301(j) and/or
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(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
section 1793.7, for violating statutes regulating controlled substances or dangerous drugs, and/or
for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of
laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents'
pharmacy technician worked unsupervised in the basement of the facility, and had the ability to
override the automated dispensing unit SynMed's scan features when replenishing the dispensing
unit.

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TWENTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards -- Drugs)

70. Respondents are each and severally subject to discipline under section 4301(j) and/or 10 (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, 11 section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or 12 for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of 13 laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' 14 pharmacy premises contained dangerous drugs on stock shelves in unlabeled containers without 15 drug name, strength, lot numbers and expiration dates. The premises also contained automated 16 dispensing units without accurate lot numbers and expiration dates. Loose pills were sitting in on 17 various counters in various locations. 18

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TWENTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition of Drugs)

Respondents are each and severally subject to discipline under section 4301(j) and/or 71. 21 (o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes 22 regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, 23 attempting to violate, or assisting in or abetting a violation of laws or regulations governing the 24 practice of pharmacy, in that on or about August 1, 2013, Respondents' facility contained 25 numerous full bubble packs which had been acquired from board-and-care homes, the 26 receipt/acquisition of which had not been memorialized in any record. Similarly, Respondents 27 were in possession of a Walgreens prescription bottle containing amlodipine-benzapril capsules 28

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which had evidently previously been issued to patient PL. Respondents had no record of the
 acquisition of this item.

TWENTY-THIRD CAUSE FOR DISCIPLINE

(Unlicensed Wholesale Activity)

72. Respondents are each and severally subject to discipline under section 4301(f) and/or 5 (i) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4060, for violating 6 statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly 7 violating, attempting to violate, or assisting in or abetting a violation of laws or regulations 8 governing the practice of pharmacy, in that on or about August 13, 2013, Respondents were 9 found to be in possession of medications which had been returned to them by board-and-care 10 homes, thus constituting wholesaling activity, when Respondents were not licensed as 11 wholesalers. Respondents evidently intended to reuse the medications. 12

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TWENTY-FOURTH CAUSE FOR DISCIPLINE

(False Statements on Certificates or Documents)

73. Respondents are each and severally subject to discipline under section 4301(g) and/or 15 (i) and/or (o) and/or section 4113(c) of the Code, for making a false statement on a certificate or 16 document and for violating statutes regulating controlled substances or dangerous drugs, and/or 17 for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of 18 laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Board 19 Inspectors located documents showing that Respondents had filled a prescription for divalproex 20 by Wockhardt by utilizing Mylan divalproex, but billed insurance as if they had provided 21 divalproex by Wockhardt. 22

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TWENTY-FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards -- Key)

74. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or
for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of

1	laws or regulations governing the practice of pharmacy, in that on or about August 2, 2013,
2	Respondents admitted that the key to the pharmacy was in the possession of a family member,
3	and was not in a tamper-proof container.
4	2014 INSPECTION
5	75. On or about August 5, 2014, Pharmacy Board inspectors inspected Respondents'
6	pharmacy. At that time, the inspectors observed an individual, Lydia Dean, acting as a pharmacy
7	technician, and filling prescriptions, when that individual was not licensed as a pharmacy
8	technician.
9	TWENTY-SIXTH CAUSE FOR DISCIPLINE
10	(Employment of Unlicensed Pharmacy Technician)
11	76. Respondents are each and severally subject to discipline under Code section 4301,
12	subsections (j) and/or (o), and under Code sections 4113, subsection (c), and 4115, subsection (e),
13	in that Respondents employed an unlicensed individual, Lydia Dean, to act as a pharmacy
14	technician, as set forth above in paragraph 75.
15	DISCIPLINE CONSIDERATIONS
16	77. To determine the level of discipline, if any, to be imposed on Respondent Daniels
17	and/or Respondent Nasrah (collectively, Respondents), Complainant further alleges that:
18	a. On or about October 21, 2009, Citation No. CI 2008 38553, with a fine of \$4,000.00,
19	was issued to Respondent Daniels for failure(s) to comply with its obligation(s) under Health and
20	Safety Code section 11165 to report all Schedule II, III, and IV controlled substance prescriptions
21	dispensed by the pharmacy to the Controlled Substance Utilization Review and Evaluation
22	System (CURES), in and/or between December 2004 and December 2008. That citation is now
23	final and is incorporated by reference as if fully set forth herein.
24	b. On or about October 21, 2009, Citation No. CI 2008 41785, with a fine of \$4,000.00,
25	was issued to Respondent Nasrah, as PIC, for Daniels Pharmacy's failure(s) to comply with its
26	obligation(s) under Health and Safety Code section 11165 to report all Schedule II, III, and IV
27	controlled substance prescriptions dispensed to the Controlled Substance Utilization Review and
28	Evaluation System (CURES), in and/or between December 2004 and December 2008. That
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1	citation is now final and is incorporated by reference as if fully set forth herein.
2	PRAYER
3	WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged,
4	and that following the hearing, the Board of Pharmacy issue a decision:
5	1. Revoking or suspending Pharmacy License No. PHY 36740, issued to Daniels
6	Pharmacy (Respondent Daniels);
7	2. Revoking or suspending Pharmacist License No. RPH 40241, issued to Iyad Nasrah
8	(Respondent Nasrah);
9	3. Ordering Respondent Daniels and Respondent Nasrah to jointly and severally be
10	responsible to pay the Board of Pharmacy the reasonable costs of the investigation and
11	enforcement of this case, pursuant to Business and Professions Code section 125.3;
12	4. Taking such other and further action as is deemed necessary and proper.
13	DATED: 1/23/15 (tigrine the old
14	VIRGINIA HEROLD Executive Officer
15	Board of Pharmacy Department of Consumer Affairs
16	State of California Complainant
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1 2 3	KAMALA D. HARRIS Attorney General of California FRANK H. PACOE Supervising Deputy Attorney General JONATHAN D. COOPER
4	Deputy Attorney General State Bar No. 141461
5	455 Golden Gate Avenue, Suite 11000 San Francisco, CA 94102-7004
6	Telephone: (415) 703-1404 Facsimile: (415) 703-5480
7	Attorneys for Complainant
8	BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS
9	STATE OF CALIFORNIA
10 11	In the Matter of the Accusation Against: Case No. 4125
12	DANIELS PHARMACY 943 Geneva Avenue
12	San Francisco, CA 94112 A C C U S A T I O N
14	Pharmacy License No. PHY 36740
15	and
16	IYAD I. NASRAH 488 Gellert Drive San Francisco, CA 94132
17	Pharmacist License No. RPH 40241
10	Respondents.
20	Complainant alleges:
21	PARTIES
22	1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
23	as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
24	2. On or about October 24, 1990, the Board of Pharmacy issued Pharmacy License No.
25	PHY 36740 to Daniels Pharmacy (Respondent Daniels). The License was in full force and effect
26	at all times relevant to the charges herein, and will expire on October 1, 2014, unless renewed.
27	3. On or about August 20, 1986, the Board of Pharmacy issued Pharmacist License No.
28	RPH 40241 to Iyad I. Nasrah (Respondent Nasrah). The License was in full force and effect at all
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1	times relevant to the charges herein and will expire on October 31, 2014, unless renewed. Since
2	on or about October 24, 1990, Respondent Nasrah has served and/or has been reflected in Board
3	records as the Pharmacist in Charge (PIC) for Respondent Daniels.
4	JURISDICTION
5	4. This Accusation is brought before the Board of Pharmacy (Board), Department of
6	Consumer Affairs, under the authority of the following laws. All section references are to the
7	Business and Professions Code (Code) unless otherwise indicated.
8	5. Section 4011 of the Code provides that the Board'shall administer and enforce both
9	the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
10	Act [Health & Safety Code, § 11000 et seq.].
11	6. Section 4300(a) of the Code provides that every license issued by the Board may be
12	suspended or revoked.
13	7. Section 4300.1 of the Code provides that the expiration, cancellation, forfeiture, or
14	suspension of a Board-issued license, the placement of a license on a retired status, or the
15	voluntary surrender of a license by a licensee, shall not deprive the Board of jurisdiction to
16	commence or proceed with any investigation of, or action or disciplinary proceeding against, the
17	licensee or to render a decision suspending or revoking the license.
18	STATUTORY AND REGULATORY PROVISIONS
19	Business and Professions Code:
20	8. Section 4043(a) of the Code states:
21	"Wholesaler" means and includes a person who acts as a wholesale merchant, broker,
22	jobber, customs broker, reverse distributor, agent, or a nonresident wholesaler, who sells for
23	resale, or negotiates for distribution, or takes possession of, any drug or device included in
24	Section 4022. Unless otherwise authorized by law, a wholesaler may not store, warehouse, or
25	authorize the storage or warehousing of drugs with any person or at any location not licensed by
26	the board.
27	9. Section 4059 of the Code, in pertinent part, prohibits furnishing of any dangerous
28	drug or dangerous device except upon the prescription of an authorized prescriber.
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ì . 10. Section 4059.5 of the Code, in pertinent part, permits ordering/delivery of dangerous
 drugs or devices only by and to entities licensed by the board and authorized prescribers, and
 requires that all deliveries to a licensed premises shall be signed for and received by a pharmacist.

- 11. Section 4061 of the Code provides, in pertinent part, that manufacturers' sales
 representatives may distribute complimentary samples of drugs only to and pursuant to a written
 request from an authorized prescriber that specifies the name and quantity of drug desired.
 - 12. Section 4063 of the Code states:

8 No prescription for any dangerous drug or dangerous device may be refilled except upon 9 authorization of the prescriber. The authorization may be given orally or at the time of giving the 10 original prescription. No prescription for any dangerous drug that is a controlled substance may 11 be designated refillable as needed.

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13. Section 4064 of the Code states:

(a) A prescription for a dangerous drug or dangerous device may be refilled without the
prescriber's authorization if the prescriber is unavailable to authorize the refill and if, in the
pharmacist's professional judgment, failure to refill the prescription might interrupt the patient's
ongoing care and have a significant adverse effect on the patient's well-being.

- (b) The pharmacist shall inform the patient that the prescription was refilled pursuant to thissection.
- (c) The pharmacist shall inform the prescriber within a reasonable period of time of any
 refills dispensed pursuant to this section.

(d) Prior to refilling a prescription pursuant to this section, the pharmacist shall make every
 reasonable effort to contact the prescriber. The pharmacist shall make an appropriate record,
 including the basis for proceeding under this section.

(e) The prescriber shall not incur any liability as the result of a refilling of a prescription
pursuant to this section.

(f) Notwithstanding Section 4060 or any other law, a person may possess a dangerous drug
or dangerous device furnished without prescription pursuant to this section.

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14. Section 4076, subdivision (a), of the Code provides, in pertinent part, that a

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1	pharmacist shall not dispense any prescription except in a container meeting the requirements of
2	state and federal law that is correctly labeled with information including the following:
3	(1) Except where ordered otherwise by the prescriber, the manufacturer's trade name of the
4	drug or the generic name and the name of the manufacturer;
5	(2) The directions for use of the drug;
6	(3) The name of the patient or patients;
7	(4) The name(s) of the prescriber(s);
8	(5) The date of dispensing;
9	(6) The name and address of the pharmacy, and prescription number;
10	(7) The strength of the drug(s) dispensed;
11	(8) The quantity of the drug(s) dispensed;
12	(9) The expiration date of the drug(s) dispensed;
13	(10) If on the prescription, the condition or purpose for which the drug was prescribed;
14	(11) A physical description of the dispensed medication.
15	15. Section 4081 of the Code states, in pertinent part:
16	(a) All records of manufacture and of sale, acquisition, or disposition of dangerous drugs or
17	dangerous devices shall be at all times during business hours open to inspection by authorized
18	officers of the law, and shall be preserved for at least three years from the date of making. A
19	current inventory shall be kept by every manufacturer, wholesaler, pharmacy, veterinary food-
20	animal drug retailer, physician, dentist, podiatrist, veterinarian, laboratory, clinic, hospital,
21	institution, or establishment holding a currently valid and unrevoked certificate, license, permit,
22	registration, or exemption under Division 2 (commencing with Section 1200) of the Health and
23	Safety Code or under Part 4 (commencing with Section 16000) of Division 9 of the Welfare and
24	Institutions Code who maintains a stock of dangerous drugs or dangerous devices.
25	(b) The owner, officer, and partner of a pharmacy, wholesaler, or veterinary food-animal
26	drug retailer shall be jointly responsible, with the pharmacist-in-charge or designated
27	representative-in-charge, for maintaining the records and inventory described in this section.
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Section 4105 of the Code requires, in pertinent part, that unless a waiver is granted by 16. 1 the board, all records and other documentation of the acquisition and disposition of dangerous 2 drugs and devices by any entity licensed by the board be retained on the licensed premises, in a 3 readily retrievable form, for three years from the date of making. 4 17. Section **4113(c)** of the Code states: 5 The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state 6 and federal laws and regulations pertaining to the practice of pharmacy. 7 18. Section 4125(a) of the Code states: 8 9 Every pharmacy shall establish a quality assurance program that shall, at a minimum, document medication errors attributable, in whole or in part, to the pharmacy or its personnel. 10 The purpose of the quality assurance program shall be to assess errors that occur in the pharmacy 11 in dispensing or furnishing prescription medications so that the pharmacy may take appropriate 12 action to prevent a recurrence. 13 19. Section 4160(a) of the Code states: 14 (a) A person may not act as a wholesaler of any dangerous drug or dangerous device unless 15 he or she has obtained a license from the board. 16 20. Section 4301 of the Code states, in pertinent part: 17 The board shall take action against any holder of a license who is guilty of unprofessional 18 conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. 19 Unprofessional conduct shall include, but is not limited to, any of the following: 20 21 (f) The commission of any act involving moral turpitude, dishonesty, fraud, deceit, or 22corruption, whether the act is committed in the course of relations as a licensee or otherwise, and 23 whether the act is a felony or misdemeanor or not. 24 (g) Knowingly making or signing any certificate or other document that falsely represents 25the existence or nonexistence of a state of facts. 2627(i) The violation of any of the statutes of this state, of any other state, or of the United 28 5 Accusation States regulating controlled substances and dangerous drugs.

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2 (m) The cash compromise of a charge of violation of Chapter 13 (commencing with Section 3 801) of Title 21 of the United States Code regulating controlled substances or of Chapter 7 4 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare and Institutions Code 5 relating to the Medi-Cal program. The record of the compromise is conclusive evidence of 6 unprofessional conduct. 7 8 (o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the 9 violation of or conspiring to violate any provision or term of this chapter or of the applicable 10 federal and state laws and regulations governing pharmacy, including regulations established by 11 the board or by any other state or federal regulatory agency. 12 13 Section 4324 of the Code states: 21. 14 (a) Every person who signs the name of another, or of a fictitious person, or falsely makes, 15 alters, forges, utters, publishes, passes, or attempts to pass, as genuine, any prescription for any 16 drugs is guilty of forgery and upon conviction thereof shall be punished by imprisonment 17 pursuant to subdivision (h) of Section 1170 of the Penal Code, or by imprisonment in a county 18 jail for not more than one year. 19 (b) Every person who has in his or her possession any drugs secured by a forged 20 prescription shall be punished by imprisonment pursuant to subdivision (h) of Section 1170 of the 21 Penal Code, or by imprisonment in the county jail for not more than one year. 22 22. Section **4332** of the Code states: 23 Any person who fails, neglects, or refuses to maintain the records required by Section 4081 24 or who, when called upon by an authorized officer or a member of the board, fails, neglects, or 25 refuses to produce or provide the records within a reasonable time, or who willfully produces or 26 furnishes records that are false, is guilty of a misdemeanor. 27 |||28 6

Accusation

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- 23. Section 4342 of the Code states:

(a) 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).

8 (b) Any knowing or willful violation of any regulation adopted pursuant to Section 4006
9 shall be subject to punishment in the same manner as is provided in Sections 4336 and 4321.

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Health and Safety Code:

11 24. Health and Safety Code section **11165** provides, in pertinent part, for establishment 12 and maintenance of a Controlled Substance Utilization Review and Evaluation System (CURES) 13 for the electronic monitoring of prescribing and dispensing of Schedule II, III, and IV controlled 14 substances, and requires, in pertinent part, that for each prescription for a Schedule II, III, or IV 15 controlled substance, the dispensing pharmacy or clinic transmit a report with certain information 16 on the patient, prescriber, controlled substance, and prescription, to the California Department of 17 Justice, on a weekly basis in a format prescribed by the California Department of Justice.¹

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- 25. Health and Safety Code section 111340 states:
- 19 Any drug or device is misbranded unless it bears a label containing all of the following20 information:
 - (a) The name and place of business of the manufacturer, packer, or distributor.
- (b) An accurate statement of the quantity of the contents in terms of weight, measure, ornumerical count.
- 24 Reasonable variations from the requirements of subdivision (b) shall be permitted.
- 25 Requirements for placement and prominence of the information and exemptions as to small
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Health and Safety Code section 11165 was first amended to impose CURES reporting requirements effective January 1, 2005; as of that date, prescriptions for Schedule II and III drugs had to be reported. Effective January 1, 2007, Schedule IV prescriptions also had to be reported.

1	packages shall be established in accordance with regulations adopted pursuant to Section 110380.
2	26. Health and Safety Code section 111440 states:
3	It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or
4	device that is misbranded.
5	California Code of Regulations:
6	27. California Code of Regulations, title 16, section 1707.2 states, in pertinent part:
7	(a) A pharmacist shall provide oral consultation to his or her patient or the patient's agent in
8	all care settings:
9	(1) upon request; or
10	(2) whenever the pharmacist deems it warranted in the exercise of his or her professional
11	judgment.
12	(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall
13	provide oral consultation to his or her patient or the patient's agent in any care setting in which the
14	patient or agent is present:
15	(A) whenever the prescription drug has not previously been dispensed to a patient; or
16	(B) whenever a prescription drug not previously dispensed to a patient in the same dosage
17	form, strength or with the same written directions, is dispensed by the pharmacy.
18	(2) When the patient or agent is not present (including but not limited to a prescription drug
19	that was shipped by mail) a pharmacy shall ensure that the patient receives written notice:
20	(A) of his or her right to request consultation; and
21	(B) a telephone number from which the patient may obtain oral consultation from a
22	pharmacist who has ready access to the patient's record.
23	(3) A pharmacist is not required by this subsection to provide oral consultation to an
24	inpatient of a health care facility licensed pursuant to section 1250 of the Health and Safety Code,
25	or to an inmate of an adult correctional facility or a juvenile detention facility, except upon the
26	patient's discharge. A pharmacist is not obligated to consult about discharge medications if a
27	health facility licensed pursuant to subdivision (a) or (b) of Health and Safety Code Section 1250
28	has implemented a written policy about discharge medications which meets the requirements of
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	Accusation

1	Business and Professions Code Section 4074.
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3	28. California Code of Regulations, title 16, section 1707.3 states:
4	Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's
5	drug therapy and medication record before each prescription drug is delivered. The review shall
6	include screening for severe potential drug therapy problems.
7	29. California Code of Regulations, title 16, section 1711 states:
8	(a) Each pharmacy shall establish or participate in an established quality assurance program
9	which documents and assesses medication errors to determine cause and an appropriate response
10	as part of a mission to improve the quality of pharmacy service and prevent errors.
11	(b) For purposes of this section, "medication error" means any variation from a prescription
12	or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as
13	defined in the section, does not include any variation that is corrected prior to furnishing the drug
14	to the patient or patient's agent or any variation allowed by law.
15	(c)(1) Each quality assurance program shall be managed in accordance with written policies
16	and procedures maintained in the pharmacy in an immediately retrievable form.
17	(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall
18	as soon as possible:
19	(A) Communicate to the patient or the patient's agent the fact that a medication error has
20	occurred and the steps required to avoid injury or mitigate the error.
21	(B) Communicate to the prescriber the fact that a medication error has occurred.
22	(3) The communication requirement in paragraph (2) of this subdivision shall only apply to
23	medication errors if the drug was administered to or by the patient, or if the medication error
24	resulted in a clinically significant delay in therapy.
25	(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a
26	prescriber, the pharmacist is not required to communicate with that individual as required in
27	paragraph (2) of this subdivision.
28	(d) Each pharmacy shall use the findings of its quality assurance program to develop
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ľ	Accusation

pharmacy systems and workflow processes designed to prevent medication errors. An
 investigation of each medication error shall commence as soon as is reasonably possible, but no
 later than 2 business days from the date the medication error is discovered. All medication errors
 discovered shall be subject to a quality assurance review.

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

1. the date, location, and participants in the quality assurance review;

2. the pertinent data and other information relating to the medication error(s) reviewed and
 documentation of any patient contact required by subdivision (c);

3. the findings and determinations generated by the quality assurance review; and,

4. recommend changes to pharmacy policy, procedure, systems, or processes, if any.

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

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

(g) The pharmacy's compliance with this section will be considered by the board as a
mitigating factor in the investigation and evaluation of a medication error.

(h) Nothing in this section shall be construed to prevent a pharmacy from contracting or
otherwise arranging for the provision of personnel or other resources, by a third party or
administrative offices, with such skill or expertise as the pharmacy believes to be necessary to
satisfy the requirements of this section.



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30. California Code of Regulations, title 16, section 1714 states, in pertinent part:

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

6 (e) The pharmacy owner, the building owner or manager, or a family member of a
7 pharmacist owner (but not more than one of the aforementioned) may possess a key to the
8 pharmacy that is maintained in a tamper evident container for the purpose of 1) delivering the key
9 to a pharmacist or 2) providing access in case of emergency. An emergency would include fire,
10 flood or earthquake. The signature of the pharmacist-in-charge shall be present in such a way that
11 the pharmacist may readily determine whether the key has been removed from the container.

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31. California Code of Regulations, title 16, section 1716 states:

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.

Nothing in this regulation is intended to prohibit a pharmacist from exercising commonlyaccepted pharmaceutical practice in the compounding or dispensing of a prescription.

32. California Code of Regulations, title 16, section 1717 states, in pertinent part:

(a) No medication shall be dispensed on prescription except in a new container which
conforms with standards established in the official compendia.

Notwithstanding the above, a pharmacist may dispense and refill a prescription for nonliquid oral products in a clean multiple-drug patient medication package (patient med pak),
provided:

(1) a patient med pak is reused only for the same patient;

(2) no more than a one-month supply is dispensed at one time; and

(3) each patient med pak bears an auxiliary label which reads, "store in a cool, dry place."

(b) In addition to the requirements of Business and Professions Code section 4040, the

following information shall be maintained for each prescription on file and shall be readily
 retrievable:

3 (1) The date dispensed, and the name or initials of the dispensing pharmacist. All
4 prescriptions filled or refilled by an intern pharmacist must also be initialed by the supervising
5 pharmacist before they are dispensed.

6 (2) The brand name of the drug or device; or if a generic drug or device is dispensed, the
7 distributor's name which appears on the commercial package label; and

8 (3) If a prescription for a drug or device is refilled, a record of each refill, quantity
9 dispensed, if different, and the initials or name of the dispensing pharmacist.

(4) A new prescription must be created if there is a change in the drug, strength, prescriber
or directions for use, unless a complete record of all such changes is otherwise maintained.

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(f) The pharmacy must have written procedures that identify each individual pharmacist
responsible for the filling of a prescription and a corresponding entry of information into an
automated data processing system, or a manual record system, and the pharmacist shall create in
his/her handwriting or through hand-initializing a record of such filling, not later than the
beginning of the pharmacy's next operating day. Such record shall be maintained for at least three
years.

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

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

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

25 26 34.

(b) Pharmacy technicians must work under the direct supervision of a pharmacist and in
such a relationship that the supervising pharmacist is fully aware of all activities involved in the

California Code of Regulations, title 16, section 1793.7 states, in pertinent part:

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preparation and dispensing of medications, including the maintenance of appropriate records.

(e) A pharmacist shall be responsible for all activities of pharmacy technicians to ensure that all such activities are performed completely, safely and without risk of harm to patients.

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Code of Federal Regulations:

Title 21, Code of Federal Regulations, section 1304.04(f) requires, in pertinent part, 7 35. that inventories and records of Schedule I and II controlled substances shall be kept separate from 8 9 all other records, and that inventories and records of Schedule III-V controlled substances shall be either kept separate from other records, or be immediately retrievable from the business records. 10

Controlled Substances/Dangerous Drugs:

Section 4021 of the Code provides that a "controlled substance" means any substance 36. 12 listed in Schedules I through V contained in Health and Safety Code section 11053 et seq. 13

> 37. Section **4022** of the Code states, in pertinent part:

"Dangerous drug: or "dangerous device" means any drug or device unsafe for self use, 15 except veterinary drugs that are labeled as such, and includes the following: 16

(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without 17 prescription," "Rx only," or words of similar import. ... 18

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on 19 prescription or furnished pursuant to Section 4006. 20

38. Klonopin is a brand name for clonazepam, a Schedule IV controlled substance as 21 22 designated by Health and Safety Code section 11057(d) and a dangerous drug as designated by Business and Professions Code section 4022. It is used to treat mental health symptoms. 23

39. Celexa is a brand name for citalopram, a dangerous drug as designated by Business 24 and Professions Code section 4022. It is used to treat mental health symptoms. 25

40. **Zyprexa** is a brand name for **olanzapine**, a dangerous drug as designated by Business 26and Professions Code section 4022. It is used to treat mental health symptoms. 27

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1	COST RECOVERY
2	41. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
3	administrative law judge to direct a licentiate found to have committed a violation or violations of
4	the licensing act to pay a sum not to exceed the reasonable costs of the investigation and
5	enforcement of the case.
6	2011 INSPECTIONS AND INVESTIGATION
7	42. Between in or about January and April 2011, Respondents were the subject(s) of
8	investigation(s) by the Board of Pharmacy. The investigation(s) revealed record-keeping,
9	dispensing, and furnishing practices that failed to comply with the law.
10	43. During January 12 and January 27, 2011 inspections by Board Inspector(s), each of
11	the following deviations from pharmacy requirements was/were noted by the Inspector(s):
12	a. Included in the active drug inventory for the pharmacy were: (i) a prescription
13	bottle for patient SM, labeled by a Safeway Pharmacy, prescription number 6448294 dispensed
14	on January 4, 2009, that expired in October 2010, with some of the labeled drug quantity missing;
15	(ii) several boxes of prescription bottles containing professional drug samples; and (iii) one or
16	more bubble packs or strip packs containing drugs returned from board and care homes. There
17	were no records of acquisition maintained by Respondents with regard to any of these items.
18	b. Respondents used a prescription dispensing software and system to create pre-
19	filled bubble packs or strip packs for board and care homes, subdivided by patient and dose. The
20	software and system did not make note of the identity of the dispensing pharmacist, nor was this
21	information recorded anywhere on the label or in Respondents' records. Respondent Nasrah said
22	that he had no record of and/or it was not possible to identify the dispensing pharmacist for any of
23	the thousands of prescriptions dispensed using this system during the previous nine (9) years.
24	c. The software and system used to generate the bubble/strip packs for board and
25	care homes also did not include required information on the label(s) generated during this nine (9)
26	year period, including: dispense date; drug manufacturer; and/or address of the pharmacy.
27	d. In various places in the pharmacy, including in the active inventory, were
28	prescription bottles containing quantities of dangerous drugs, with either no labels or incomplete
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labels affixed. Respondent asserted that these were returned from assisted living facilities.

e. Since at least October 21, 2009, Respondents had not successfully transmitted
data regarding controlled substances dispensed by the pharmacy to the Controlled Substances
Utilization Review (CURES) database maintained by the California Department of Justice.

f. Controlled substance invoices for at least the two months prior to the inspection
were grouped and filed together, and there was no separation of Schedule II invoices.

g. On at least one occasion, including on or about July 17, 2010, a non-pharmacist
8 (store clerk) signed a wholesaler's proof of delivery form to accept delivery of dangerous drugs.

9 44. Between on or about July 10, 2009 and on or about January 10, 2011, Respondents
10 dispensed dangerous drugs and/or controlled substances to patient DC pursuant to unauthorized
11 prescriptions and/or refills, including:

On at least ten (10) occasions between on or about December 14, 2009 and on 12 a. or about January 10, 2011, Respondents filled new prescriptions for DC for controlled substances 13 and/or dangerous drugs without prescriber authorization, including: two (2) prescriptions for 14 controlled substance/dangerous drug clonazepam 0.5mg (Klonopin); six (6) prescriptions for the 15 dangerous drug Celexa 40mg; and two (2) prescriptions for the dangerous drug Zyprexa 20mg. 16 On at least twenty-nine (29) occasions between on or about August 2, 2009 and Ь. 17 on or about September 1, 2010, Respondents furnished refill prescriptions to DC for controlled 18 substances and/or dangerous drugs without prescriber authorization, including: five (5) refills for 19 controlled substance/dangerous drug clonazepam 0.5mg (Klonopin); fourteen (14) refills for the 20 dangerous drug Zyprexa 20mg; and ten (10) refills for the dangerous drug Celexa 40mg. 21

c. On at least seven (7) occasions between on or about July 10, 2009 and on or
about January 19, 2010, Respondents created and/or signed prescription documents for DC that
falsely stated authorization by the prescriber, including: one (1) prescription for controlled
substance/dangerous drug clonazepam 0.5mg (Klonopin); five (5) prescriptions for the
dangerous drug Celexa 40mg; and one (1) prescription for the dangerous drug Zyprexa 20mg.
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FIRST CAUSE FOR DISCIPLINE
(Incomplete Inventory and/or Records of Acquisition and/or Disposition)
45. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to section(s) 4081, 4105, 4332 and/or 4342
of the Code, and/or California Code of Regulations, title 16, section 1718, for violating statutes
regulating controlled substances or dangerous drugs, and/or directly or indirectly violating,
attempting to violate, or assisting in or abetting a violation of laws or regulations governing the
practice of pharmacy, in that, as described in paragraph 43 above, Respondents failed to maintain
an accurate, complete, and readily retrievable inventory and/or records of acquisition and
disposition of all dangerous drugs in the pharmacy inventory.
SECOND CAUSE FOR DISCIPLINE
(Possessing and/or Dispensing/Furnishing Drug Samples)
46. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to section 4061 of the Code, for violating
statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly
violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
governing the practice of pharmacy, in that, as described in paragraph 43 above, Respondents had
in their inventory, and/or had previously dispensed or furnished, manufacturer drug samples.
THIRD CAUSE FOR DISCIPLINE
(Failure to Identify Dispensing Pharmacist)
47. Respondents are each and severally subject to discipline under section 4301(j) and/or
(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, title 16,
section 1717, for violating statutes regulating controlled substances or dangerous drugs, and/or
directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws
or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above,
Respondents dispensed medications without a means of identifying the dispensing pharmacist.
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16 Accusation

1	FOURTH CAUSE FOR DISCIPLINE
2	(Inadequately Labeled Prescription Containers)
3	48. Respondents are each and severally subject to discipline under section 4301(j) and/or
4	(o) and/or section 4113(c) of the Code, by reference to section 4076 of the Code, for violating
5	statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly
6	violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
7	governing the practice of pharmacy, in that, as described in paragraph 43 above, Respondents
8	dispensed medications in prescription containers which failed to include required information.
9	FIFTH CAUSE FOR DISCIPLINE
10	(Possession of Misbranded Drug Containers)
11	49. Respondents are each and severally subject to discipline under section 4301(j) and/or
12	(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 111340
13	and/or 111440, for violating statutes regulating controlled substances or dangerous drugs, and/or
14	directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws
15	or regulations governing the practice of pharmacy, in that, as described in paragraph 43 above,
16	Respondents possessed drug containers that were misbranded inasmuch as they had affixed to
17	them no or incomplete labels describing the contents, the manufacturer, and other required data.
18	SIXTH CAUSE FOR DISCIPLINE
19	(Failure to Report Controlled Substance Prescriptions to CURES)
20	50. Respondents are each and severally subject to discipline under section 4301(j) and/or
21	(o) and/or section 4113(c) of the Code, by reference to Health and Safety Code section 11165, for
22	violating statutes regulating controlled substances or dangerous drugs, and/or directly or
23	indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or
24	regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, in the
25	period prior to January 12, 2011, the pharmacy had not successfully transmitted any dispensing
26	data to CURES for controlled substances that were dispensed since at least October 21, 2009.
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1	SEVENTH CAUSE FOR DISCIPLINE
2	(Failure to Segregate Schedule II Records)
3	51. Respondents are each and severally subject to discipline under section 4301(j) and/or
4	(o) and/or section 4113(c) of the Code, by reference to Title 21, Code of Federal Regulations,
5	section 1304.04(f), for violating statutes regulating controlled substances or dangerous drugs,
6	and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a
7	violation of laws or regulations governing the practice of pharmacy, in that, as described in
8	paragraph 43 above, on or about January 12, 2011, Schedule II records were not segregated.
9	EIGHTH CAUSE FOR DISCIPLINE
10	(Receipt and Acknowledgment of Delivery by Non-Pharmacist)
11	52. Respondents are each and severally subject to discipline under section 4301(j) and/or
12	(o) and/or section 4113(c) of the Code, by reference to section(s) 4059 and/or 4059.5 of the Code,
13	for violating statutes regulating controlled substances or dangerous drugs, and/or for directly or
14	indirectly violating, attempting to violate, or assisting in or abetting a violation of laws or
15	regulations governing the practice of pharmacy, in that, as described in paragraph 43 above, a
16	non-pharmacist received and/or signed for a delivery of a dangerous drug or device.
17	NINTH CAUSE FOR DISCIPLINE
18	(Furnishing/Dispensing Prescriptions Without Prescriber Authorization)
19	53. Respondents are each and severally subject to discipline under section 4301(j) and/or
20	(o) and/or section 4113(c) of the Code, by reference to section 4059 of the Code, for violating
21	statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly
22	violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
23	governing the practice of pharmacy, in that, as described in paragraph 44 above, Respondents
24	furnished ten (10) new prescriptions to patient DC that were not authorized by a prescriber.
25	TENTH CAUSE FOR DISCIPLINE
26	(Furnishing/Dispensing Refills Without Prescriber Authorization)
27	54. Respondents are each and severally subject to discipline under section 4301(j) and/or
28	(o) and/or section 4113(c) of the Code, by reference to section 4063 of the Code, for violating
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	Accusation

1	statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly
2	violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
3	governing the practice of pharmacy, in that, as described in paragraph 44 above, Respondents
4	furnished twenty nine (29) refills to patient DC that were not authorized by a prescriber.
5	ELEVENTH CAUSE FOR DISCIPLINE
6	(Dishonesty/Creation of False Prescription Document(s))
7	55. Respondents are each and severally subject to discipline under section 4301(f) and/or
8	(g) and/or section 4113(c) and/or section 4324 of the Code, for acts involving moral turpitude,
9	dishonesty, fraud, deceit, corruption and forgery, and/or for knowingly making or signing any
10	certificate or other document that falsely represents the existence or nonexistence of a state of
11	facts in that, as described in paragraph 44 above, Respondents created seven (7) false
12	prescriptions for patient DC.
13	TWELFTH CAUSE FOR DISCIPLINE
14	(Failure to Maintain Records of Acquisition of Drugs)
15	56. Respondents are each and severally subject to discipline under section 4301(j) and/or
16	(o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes
17	regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating,
18	attempting to violate, or assisting in or abetting a violation of laws or regulations governing the
19	practice of pharmacy, in that on or about January 12, 2011, Respondents' facility contained a
20	prescription bottle containing 180 Premarin 1.25 tablets, Safeway prescription number 6448294,
21	issue to patient SM on January 4, 2009. Respondents had no record of the acquisition of this
22	item.
23	THIRTEENTH CAUSE FOR DISCIPLINE
24	(Unprofessional Conduct)
25	57. Respondent is subject to discipline under section 4301 of the Code in that
26	Respondents, as described in paragraphs 42-44 above, engaged in unprofessional conduct.
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1	CASH COMPROMISE OF MEDI-CAL CHARGES
2	58. On or about June, 2010, the California Department of Health Care Services
3	(hereinafter "Department") audited Respondents' premises and records pertaining to the period of
4	March 1, 2009 through March 31, 2010.
5	59. Based on this audit, on or about July 16, 2010, the Department took formal action
6	against Respondents by withholding all Medi-Cal payments to Respondents and by suspending
7	and deactivating Respondents' Medi-Cal provider number and National Provider Identifier
8	number. The Department charged Respondents with having violated California Welfare and
9	Institutions Code section 14107(b) (false and fraudulent claims) and California Code of
10	Regulations, Title 22, sections 51470(a) (false billing) and 51485 (submission of false
11	information), based on to the following misconduct:
12	a) Overbilling for medications;
13	b) Billing for prescriptions that had not actually been provided to beneficiaries;
14	c) Falsification of a telephone prescription; and
15	d) Failure to purchase sufficient quantities of drugs to fill claims made for orders filled.
16	60. On or about October 13, 2010, Respondents entered into a cash compromise of the
17	above-described charges by signing a document entitled "Stipulation And Settlement Agreement
18	Between The California Department of Health Care Services And Daniel's Pharmacy." The
19	agreement provided for settlement of the charges in exchange for Respondents' agreement to pay
20	approximately \$1,000,000.00 to the Department.
21	FOURTEENTH CAUSE FOR DISCIPLINE
22	(Cash Compromise of Medi-Cal Charges)
23	61. Respondents are each and severally subject to discipline under section 4301(m)
24	and/or section 4113(c) of the Code, in that they engaged in a cash compromise of a charge of
25	violation of Chapter 7 (commencing with Section 14000) of Part 3 of Division 9 of the Welfare
26	and Institutions Code relating to the Medi-Cal program, as described above in paragraphs 55-57.
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1	2013 INSPECTION
2	62. On or about August 1, 2013, Pharmacy Board inspectors inspected Respondents'
3	pharmacy in order to ascertain whether Respondents continued to be in violation of law. The
4	Inspectors observed numerous violations, as set forth below in the following Causes for
5	Discipline.
6	FIFTEENTH CAUSE FOR DISCIPLINE
7	(Failure to Consult with On-Premises Patient)
8	63. Respondents are each and severally subject to discipline under section 4301(j) and/or
9	(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
10	section 1707.2(b)(1)(A), for violating statutes regulating controlled substances or dangerous
11	drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a
12	violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013,
13	Respondents dispensed a prescription to patient DV, which had not previously been dispensed to
14	patient DV, without providing a consultation by a pharmacist. Respondents failed to have a
15	policy or procedure identifying medications for which a consultation should be provided.
16	SIXTEENTH CAUSE FOR DISCIPLINE
17	(Failure to Consult with Off-Premises Patient)
18	64. Respondents are each and severally subject to discipline under section 4301(j) and/or
19	(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
20	section 1707.2(b)(2), for violating statutes regulating controlled substances or dangerous drugs,
21	and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a
22	violation of laws or regulations governing the practice of pharmacy, in that on August 1, 2013,
23	Respondents prepared prescription medication for delivery to a patient, which medication had not
24	previously been dispensed to said patient, without providing any notification to the patient
25	regarding the patient's right to request a consultation.
26	SEVENTEENTH CAUSE FOR DISCIPLINE
27	(Possession of Misbranded Drug Containers)
28	65. Respondents are each and severally subject to discipline under section 4301(j) and/or
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r section 4113(c) of the Code, by reference to Health and Safety Code section 111340
1440, for violating statutes regulating controlled substances or dangerous drugs, and/or
or indirectly violating, attempting to violate, or assisting in or abetting a violation of laws
tions governing the practice of pharmacy, in that on or about August 1, 2013,
ents possessed numerous misbranded/unlabeled prescription vials with dangerous drugs
ated products in current inventory. Respondents also had in its possession previously-
bubble packs of medications which had been returned by board-and-care homes.
EIGHTEENTH CAUSE FOR DISCIPLINE
(Failure to Initiate Quality Assurance Review)
Respondents are each and severally subject to discipline under section 4301(j) and/or
r section 4113(c) of the Code, by reference to Code section 4125(a) and California Code
ations, Title 16, section 1711, for violating statutes regulating controlled substances or
s drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in or
violation of laws or regulations governing the practice of pharmacy, in that on August
Respondents admitted to Board Inspectors that they had failed to complete quality
e reviews, procedures and related forms in the aftermath of dispensing errors.
NINETEENTH CAUSE FOR DISCIPLINE
(Variation from Prescription)
Respondents are each and severally subject to discipline under section 4301(j) and/or
r section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
716, for violating statutes regulating controlled substances or dangerous drugs, and/or
ly or indirectly violating, attempting to violate, or assisting in or abetting a violation of
egulations governing the practice of pharmacy, in that on August 1, 2013, Board
s identified two prescriptions, RX numbers N9878911 and N9879201, which contained
s directions for use and/or identified the wrong prescriber.
TWENTIETH CAUSE FOR DISCIPLINE
(Improper Supervision of Pharmacy Technician)
Respondents are each and severally subject to discipline under section 4301(j) and/or
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(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
section 1793.7, for violating statutes regulating controlled substances or dangerous drugs, and/or
for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of
laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents'
pharmacy technician worked unsupervised in the basement of the facility, and had the ability to
override the automated dispensing unit SynMed's scan features when replenishing the dispensing
unit.

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TWENTY-FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Operational Standards -- Drugs)

Respondents are each and severally subject to discipline under section 4301(j) and/or 69. 10 (o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16, 11 section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or 12 for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of 13 laws or regulations governing the practice of pharmacy, in that on August 1, 2013, Respondents' 14 pharmacy premises contained dangerous drugs on stock shelves in unlabeled containers without 15 drug name, strength, lot numbers and expiration dates. The premises also contained automated 16 dispensing units without accurate lot numbers and expiration dates. Loose pills were sitting in on 17 various counters in various locations. 18

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TWENTY-SECOND CAUSE FOR DISCIPLINE

(Failure to Maintain Records of Acquisition of Drugs)

Respondents are each and severally subject to discipline under section 4301(j) and/or 70. 21 (o) and/or section 4113(c) of the Code, by reference to Code section 4081, for violating statutes 22 regulating controlled substances or dangerous drugs, and/or for directly or indirectly violating, 23 attempting to violate, or assisting in or abetting a violation of laws or regulations governing the 24 practice of pharmacy, in that on or about August 1, 2013, Respondents' facility contained 25 numerous full bubble packs which had been acquired from board-and-care homes, the 26 receipt/acquisition of which had not been memorialized in any record. Similarly, Respondents 27 were in possession of a Walgreens prescription bottle containing amlodipine-benzapril capsules 28

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1	which had evidently previously been issued to patient PL. Respondents had no record of the
2	acquisition of this item.
3	TWENTY-THIRD CAUSE FOR DISCIPLINE
4	(Unlicensed Wholesale Activity)
5	71. Respondents are each and severally subject to discipline under section 4301(f) and/or
6	(j) and/or (o) and/or section 4113(c) of the Code, by reference to Code section 4060, for violating
7	statutes regulating controlled substances or dangerous drugs, and/or for directly or indirectly
8	violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
9	governing the practice of pharmacy, in that on or about August 13, 2013, Respondents were
10	found to be in possession of medications which had been returned to them by board-and-care
11	homes, thus constituting wholesaling activity, when Respondents were not licensed as
12	wholesalers. Respondents evidently intended to reuse the medications.
13	TWENTY-FOURTH CAUSE FOR DISCIPLINE
14	(False Statements on Certificates or Documents)
15	72. Respondents are each and severally subject to discipline under section 4301(g) and/or
16	(j) and/or (o) and/or section 4113(c) of the Code, for making a false statement on a certificate or
17	document and for violating statutes regulating controlled substances or dangerous drugs, and/or
18	for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of
19	laws or regulations governing the practice of pharmacy, in that on or about August 1, 2013, Board
20	Inspectors located documents showing that Respondents had filled a prescription for divalproex
21	by Wockhardt by utilizing Mylan divalproex, but billed insurance as if they had provided
22	divalproex by Wockhardt.
23	TWENTY-FIFTH CAUSE FOR DISCIPLINE
24	(Failure to Maintain Operational Standards Key)
25	73. Respondents are each and severally subject to discipline under section 4301(j) and/or
26	(o) and/or section 4113(c) of the Code, by reference to California Code of Regulations, Title 16,
27	section 1714, for violating statutes regulating controlled substances or dangerous drugs, and/or
28	for directly or indirectly violating, attempting to violate, or assisting in or abetting a violation of
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laws or regulations governing the practice of pharmacy, in that on or about August 2, 2013, Respondents admitted that the key to the pharmacy was in the possession of a family member, 2 and was not in a tamper-proof container. 3

DISCIPLINE CONSIDERATIONS

To determine the level of discipline, if any, to be imposed on Respondent Daniels 74. and/or Respondent Nasrah (collectively, Respondents), Complainant further alleges that:

On or about October 21, 2009, Citation No. CI 2008 38553, with a fine of \$4,000.00, a. 7 was issued to Respondent Daniels for failure(s) to comply with its obligation(s) under Health and 8 Safety Code section 11165 to report all Schedule II, III, and IV controlled substance prescriptions 9 dispensed by the pharmacy to the Controlled Substance Utilization Review and Evaluation 10 System (CURES), in and/or between December 2004 and December 2008. That citation is now 11 final and is incorporated by reference as if fully set forth herein. 12

b. On or about October 21, 2009, Citation No. CI 2008 41785, with a fine of \$4,000.00, 13 was issued to Respondent Nasrah, as PIC, for Daniels Pharmacy's failure(s) to comply with its 14 obligation(s) under Health and Safety Code section 11165 to report all Schedule II, III, and IV 15 controlled substance prescriptions dispensed to the Controlled Substance Utilization Review and 16 Evaluation System (CURES), in and/or between December 2004 and December 2008. That 17 citation is now final and is incorporated by reference as if fully set forth herein. 18

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PRAYER

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

Revoking or suspending Pharmacy License No. PHY 36740, issued to Daniels 1. 22 Pharmacy (Respondent Daniels); 23

2. Revoking or suspending Pharmacist License No. RPH 40241, issued to Iyad Nasrah 24 (Respondent Nasrah); 25

Ordering Respondent Daniels and Respondent Nasrah to jointly and severally be 3. 26 responsible to pay the Board of Pharmacy the reasonable costs of the investigation and 27 enforcement of this case, pursuant to Business and Professions Code section 125.3; 28

Taking such other and further action as is deemed necessary and proper. 4. end 5/8/14 DATED: VIRGINIA Executive Officer Board of Pharmacy Department of Consumer Affairs State of California Complainant

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