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

10 In the Matter of the Accusation Against:

Case No. 4349

11 **HALF MOON BAY PHARMACY**
12 **40 Stone Pine Road, Suite 1**
13 **Half Moon Bay, CA 94019**

ACCUSATION

14 **Pharmacy License No. PHY 44400**

15 **and**

16 **HARISH ODEDRA**
17 **130 Turnberry Road**
Half Moon Bay, CA 94019

18 **Pharmacist License No. RPH 43972**

19 Respondents.

20 Complainant alleges:

21
22 PARTIES

- 23 1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity
24 as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 25 2. On or about February 4, 2000, the Board of Pharmacy issued Pharmacy License No.
26 PHY 44400 to Odedra Pharmacy Inc., Harish Odedra, President, dba Half Moon Bay Pharmacy
27 (Respondent Half Moon Bay) The License was in full force and effect at all times relevant to the
28 charges brought herein and will expire on February 1, 2014, unless renewed.

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

5 9. Section 4113, subdivision (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 10. Section 4104 of the Code requires, in pertinent part, that every pharmacy shall have in
9 place procedures for taking action to protect the public when a licensed individual employed by
10 or with the pharmacy is discovered or known to be chemically, mentally, or physically impaired
11 to the extent it affects his or her ability to practice the profession or occupation authorized by his
12 or her license, or is discovered or known to have engaged in the theft, diversion, or self use of
13 dangerous drugs, and that every pharmacy shall have written policies and procedures for
14 addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of
15 dangerous drugs, among licensed individuals employed by or with the pharmacy.

16 11. Health and Safety Code section 11158 et seq., including but not limited to Health and
17 Safety Code section 11162.1, require in pertinent part that any prescription for a Schedule II, III,
18 or IV controlled substance (as designated by Health and Safety Code sections 11055, 11056, and
19 11057) shall be written on a controlled substance prescription form (security form) meeting the
20 requirements of Health and Safety Code section(s) 11161.5 and/or 11162.1.

21 12. Health and Safety Code section(s) 11159.2, in pertinent part, sets out out a limited
22 exception to the controlled substance prescription form (security form) requirements applicable to
23 terminally ill patients under circumstances and according to requirements specified therein.

24 13. Health and Safety Code section(s) 11167.5, in pertinent part, sets out out a limited
25 exception to the controlled substance prescription form (security form) requirements applicable to
26 patients in certain settings (patients of a licensed skilled nursing facility, licensed intermediate
27 care facility, licensed home health agency, or licensed hospice), under circumstances and
28 according to requirements specified therein.

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

5 15. Section 125.3 of the Code provides, in pertinent part, that the Board may request the
6 administrative law judge to direct a licentiate found to have committed a violation of the licensing
7 act to pay a sum not to exceed its reasonable costs of investigation and enforcement.

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9 CONTROLLED SUBSTANCES / DANGEROUS DRUGS

10 16. Section 4021 of the Code provides that a “controlled substance” means any substance
11 listed in Schedules I through V contained in Health and Safety Code section 11053 et seq.

12 17. Section 4022 of the Code states, in pertinent part:

13 “‘Dangerous drug’ or ‘dangerous device’ means any drug or device unsafe for self use,
14 except veterinary drugs that are labeled as such, and includes the following:

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

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

19 18. **OxyContin** is a brand name for **oxycodone**, a Schedule II controlled substance as
20 designated by Health and Safety Code section 11055(b)(1)(M) and a dangerous drug as
21 designated by Business and Professions Code section 4022. It is an opioid analgesic.

22 19. **Fentanyl** is a Schedule II controlled substance as designated by Health and Safety
23 Code section 11055(c)(8) and a dangerous drug as designated by Business and Professions Code
24 section 4022. It is an opioid analgesic.

25 20. **Morphine** is a Schedule II controlled substance as designated by Health and Safety
26 Code section 11055(b)(1)(L) and a dangerous drug as designated by Business and Professions
27 Code section 4022. It is an opioid analgesic.

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1 21. **Methadone** is a Schedule II controlled substance as designated by Health and Safety
2 Code section 11055(c)(14) and a dangerous drug as designated by Business and Professions Code
3 section 4022. It is an opioid analgesic.

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5 **CAUSES FOR DISCIPLINE, AS TO BOTH RESPONDENTS**

6 FIRST CAUSE FOR DISCIPLINE

7 (Lack of Procedures to Protect Against/Address Employee Impairment)

8 22. 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 section 4104 of the Code, for violating
10 statutes regulating controlled substances or dangerous drugs, and/or directly or indirectly
11 violating, attempting to violate, or assisting in or abetting a violation of laws or regulations
12 governing the practice of pharmacy, in that, during an inspection conducted by the Board on or
13 about December 2, 2011, Board Inspector(s) discovered that Respondents had no procedures in
14 place for taking action to protect the public from a chemically, mentally, or physically impaired,
15 or diverting or self-using, licensed employee, and/or had no written policies or procedures for
16 addressing chemical, mental, or physical impairment, as well as theft, diversion, or self-use of
17 dangerous drugs, among licensed individuals employed by or with the pharmacy.

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19 SECOND CAUSE FOR DISCIPLINE

20 (Failure to Segregate Schedule II Records)

21 23. 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 Title 21, Code of Federal Regulations,
23 section 1304.04(f), for violating statutes regulating controlled substances or dangerous drugs,
24 and/or for directly or indirectly violating, attempting to violate, or assisting in or abetting a
25 violation of laws or regulations governing the practice of pharmacy, in that, during an inspection
26 conducted by the Board on or about December 2, 2011, Board Inspector(s) discovered that
27 Respondents had not segregated Schedule II records from other drug records.

1 THIRD CAUSE FOR DISCIPLINE

2 (Invalid Controlled Substance Prescriptions)

3 24. 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 Health and Safety Code section(s) 11158
5 et seq., 11162.1, 11159.2, and/or 11167.5, for violating statutes regulating controlled substances
6 or dangerous drugs, and/or for directly or indirectly violating, attempting to violate, or assisting in
7 or abetting a violation of laws or regulations governing the practice of pharmacy, in that, between
8 on or about December 28, 2009 and on or about August 30, 2011, Respondents dispensed at least
9 fifty (50) prescriptions for Schedule II controlled substances, including **oxycodone, fentanyl,**
10 **morphine,** and **methadone,** that were not written on required controlled substance prescription
11 forms (security forms), and which were not otherwise valid controlled substance prescriptions.

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13 FOURTH CAUSE FOR DISCIPLINE

14 (Unprofessional Conduct)

15 25. Respondents are subject to discipline under section 4301 of the Code in that
16 Respondents, as described in paragraphs 22 to 24 above, engaged in unprofessional conduct
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20 PRAYER

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

- 23 1. Revoking or suspending Pharmacy License No. PHY 44400, issued to to Odedra
24 Pharmacy Inc., Harish Odedra, President, dba Half Moon Bay Pharmacy;
- 25 2. Revoking or suspending Pharmacist License No. RPH 43972, issued to Harish D.
26 Odedra;
- 27 3. Ordering Respondents to pay the Board the reasonable costs of the investigation and
28 enforcement of this case, pursuant to Business and Professions Code section 125.3;

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4. Taking such other and further action as is deemed necessary and proper.

DATED: 5/9/13



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

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