

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

In the Matter of the Accusation Against:

**AMER RX, INC. DBA AGE WELL, AMRO
SHAKKER AMER, PRESIDENT AND
OWNER**

**191 W. Burton Blvd, Ste. A
Lompoc, CA 93436
Pharmacy License No. PHY 49116,**

**AMRO SHAKKER AMER,
PHARMACIST-IN-CHARGE
147 Century
Arroyo Grande, CA 93420
Pharmacist License No. RPH 56570**

And

**SAMI BORAIE
237 Town Center West #123
Santa Maria, CA 93458
Pharmacist License No. RPH 69985**

Respondents.

Case No. 5972

OAH No. 2017110236

**STIPULATED SURRENDER OF LICENSE
AND ORDER [AS TO RESPONDENT
AMER RX, INC. DBA AGE WELL, AMRO
SHAKKER AMER, PRESIDENT AND
OWNER, PERMIT NO. PHY 49116, ONLY]**

DECISION AND ORDER

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

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

It is so ORDERED on July 3, 2018.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By

Victor Law, R.Ph.
Board President

1 XAVIER BECERRA
Attorney General of California
2 THOMAS L. RINALDI
Supervising Deputy Attorney General
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Attorneys for Complainant
7

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

10 In the Matter of the Accusation Against:
11 **AMER RX, INC. DBA AGE WELL, AMRO**
12 **SHAKKER AMER, PRESIDENT AND**
13 **OWNER**
14 **191 W. Burton Blvd, Ste. A**
Lompoc, CA 93436
15 **Permit No. PHY 49116,**
16 **AMRO SHAKKER AMER,**
17 **PHARMACIST-IN-CHARGE**
147 Century
Arroyo Grande, CA 93420
18 **Pharmacist License No. RPH 56570,**
19 **And**
20 **SAMI BORAIE**
21 **237 Town Center West #123**
Santa Maria, CA 93458
22 **Pharmacist License No. RPH 69985**
23 Respondents.
24

Case No. 5972

OAH No. 2017110236

**STIPULATED SURRENDER OF
LICENSE AND ORDER [AS TO
RESPONDENT AMER RX, INC. DBA
AGE WELL, AMRO SHAKKER AMER,
PRESIDENT AND OWNER, PERMIT
NO. PHY 49116, ONLY]**

25
26 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
27 entitled proceedings that the following matters are true:

28 ///

1 PARTIES

2 1. Virginia Herold (Complainant) is the Executive Officer of the Board of Pharmacy
3 (Board). She brought this action solely in her official capacity and is represented in this matter by
4 Xavier Becerra, Attorney General of the State of California, by M. Travis Peery, Deputy Attorney
5 General.

6 2. Amer Rx, Inc. dba Age Well, Amro Shakker Amer, President and Owner, is
7 represented in this proceeding by attorney Ivan Petrzela, whose address is 49 Discovery, Suite
8 240, Irvine, CA 92618.

9 3. On or about September 12, 2008, the Board issued Permit No. PHY 49116 to Amer
10 Rx, Inc. dba Age Well, Amro Shakker Amer, President and Owner (Respondent). The Permit
11 expired on July 14, 2016, and has not been renewed.

12 JURISDICTION

13 4. Accusation No. 5972 was filed before the Board, and is currently pending against
14 Respondent. The Accusation and all other statutorily required documents were properly served
15 on Respondent on July 21, 2017. Respondent timely filed its Notice of Defense contesting the
16 Accusation. A copy of Accusation No. 5972 is attached as Exhibit A and incorporated by
17 reference.

18 ADVISEMENT AND WAIVERS

19 5. Respondent has carefully read, fully discussed with counsel, and understands the
20 charges and allegations in Accusation No. 5972. Respondent also has carefully read, fully
21 discussed with counsel, and understands the effects of this Stipulated Surrender of License and
22 Order.

23 6. Respondent is fully aware of its legal rights in this matter, including the right to a
24 hearing on the charges and allegations in the Accusation; the right to confront and cross-examine
25 the witnesses against them; the right to present evidence and to testify on its own behalf; the right
26 to the issuance of subpoenas to compel the attendance of witnesses and the production of
27 documents; the right to reconsideration and court review of an adverse decision; and all other
28 rights accorded by the California Administrative Procedure Act and other applicable laws.

1 negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order
2 may not be altered, amended, modified, supplemented, or otherwise changed except by a writing
3 executed by an authorized representative of each of the parties.

4 14. In consideration of the foregoing admissions and stipulations, the parties agree that
5 the Board may, without further notice or formal proceeding, issue and enter the following Order:

6 **ORDER**

7 IT IS HEREBY ORDERED that Permit No. PHY 49116, issued to Respondent Amer Rx,
8 Inc. dba Age Well, Amro Shakker Amer, President and Owner, is surrendered and accepted by
9 the Board of Pharmacy.

10 1. The surrender of Respondent's Permit and the acceptance of the surrendered license
11 by the Board shall constitute the imposition of discipline against Respondent. This stipulation
12 constitutes a record of the discipline and shall become a part of Respondent's license history with
13 the Board of Pharmacy.

14 2. Respondent shall lose all rights and privileges as a pharmacy in California as of the
15 effective date of the Board's Decision and Order.

16 3. Respondent shall cause to be delivered to the Board its pocket license and, if one was
17 issued, its wall certificate on or before the effective date of the Decision and Order.

18 4. If Respondent ever applies for licensure or petitions for reinstatement in the State of
19 California, the Board shall treat it as a new application for licensure. Respondent must comply
20 with all the laws, regulations and procedures for licensure in effect at the time the application or
21 petition is filed, and all of the charges and allegations contained in Accusation No. 5972 shall be
22 deemed to be true, correct and admitted by Respondent when the Board determines whether to
23 grant or deny the application or petition.

24 5. If Respondent should ever apply or reapply for a new license or certification, or
25 petition for reinstatement of a license, by any other health care licensing agency in the State of
26 California, all of the charges and allegations contained in Accusation, No. 5972 shall be deemed
27 to be true, correct, and admitted by Respondent for the purpose of any Statement of Issues or any
28 other proceeding seeking to deny or restrict licensure.

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ENDORSEMENT

The foregoing Stipulated Surrender of License and Order is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5-10-18

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
THOMAS L. RINALDI
Supervising Deputy Attorney General



M. TRAVIS PEERY
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

Accusation No. 5972

1 XAVIER BECERRA
Attorney General of California
2 THOMAS L. RINALDI
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6 *Attorneys for Complainant*

7 **BEFORE THE**
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10 In the Matter of the Accusation Against:

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12 **SHAKKER AMER, PRESIDENT AND**
13 **OWNER**
191 W. Burton Mesa Blvd., Ste. A
Lompoc, CA 93436

A C C U S A T I O N

14 Permit No. PHY 49116,

15 **AMRO SHAKKER AMER,**
16 **PHARMACIST-IN-CHARGE**
147 Century
Arroyo Grande, CA 93420

17 Pharmacist License No. RPH 56570,

18 and

19 **SAMI BORAIE**
20 237 Town Center West #123
Santa Maria, CA 93458

21 Pharmacist License No. RPH 69985

22 Respondent.

23
24
25 Complainant alleges:

26 **PARTIES**

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

1 “(b) Any device that bears the statement: "Caution: federal law restricts this device to sale
2 by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled
3 in with the designation of the practitioner licensed to use or order use of the device.

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

6 8. Section 4169 of the Code states in pertinent part:

7 “(a) A person or entity shall not do any of the following:

8 “... ”

9 “(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably
10 should have known were misbranded, as defined in Section 111335 of the Health and Safety
11 Code.”

12 9. Section 4300 of the Code states:

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

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

17 “(1) Suspending judgment.

18 “(2) Placing him or her upon probation.

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

20 “(4) Revoking his or her license.

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

23 “... ”

24 “(e) The proceedings under this article shall be conducted in accordance with Chapter 5
25 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code, and the board
26 shall have all the powers granted therein. The action shall be final, except that the propriety of the
27 action is subject to review by the superior court pursuant to Section 1094.5 of the Code of Civil
28 Procedure.”

1 10. Section 4301 of the Code states:

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

5 "...

6 "(j) The violation of any of the statutes of this state, of any other state, or of the United
7 States regulating controlled substances and dangerous drugs.

8 "...

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

13 11. Health and Safety Code section 111335 states:

14 "Any drug or device is misbranded if its labeling or packaging does not conform to the
15 requirements of Chapter 4 (commencing with Section 110290)."

16 12. Health and Safety Code section 111375 states:

17 "Any drug or device is misbranded unless its labeling bears all of the following information:

18 "(a) Adequate directions for use.

19 "(b) Such adequate warnings against use in pathological conditions or by children where its
20 use may be dangerous to health.

21 "(c) Adequate warning against unsafe dosage or methods or duration of administration or
22 application.

23 "Warnings shall be in a manner and form as are necessary for the protection of users.

24 "If the department determines that any requirement of subdivision (a), as applied to any
25 drug or device, is not necessary for the protection of the public health, the department may adopt
26 regulations exempting the drug or device from these requirements.

27 "Any drug or device exempted under Section 502(f) of the federal act (21 U.S.C. Sec.
28 352(f)) is exempt from the requirement of this section. The department, however, may adopt any

1 regulation including a drug or device within, or excluding a drug or device from the requirements
2 of this section, whether or not the inclusion or exclusion of the drug or device is in accord with
3 the federal act.”

4 13. Health and Safety Code section 111400 states:

5 “Any drug or device is misbranded if it is dangerous to health when used in the dosage, or
6 with the frequency or duration prescribed, recommended, or suggested in its labeling.”

7 14. Health and Safety Code section 111440 states:

8 “It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug
9 or device that is misbranded.”

10 COST RECOVERY

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

15 FACTUAL BACKGROUND

16 16. Domperidone is an anti-dopaminergic drug which acts as an antiemetic and a
17 prokinetic agent. It is used in some countries for the treatment of gastroparesis; however,
18 domperidone is not FDA-approved for use in humans in the United States due to significant
19 health and safety concerns including the potential for sudden death, cardiac arrest, and cardiac
20 arrhythmias. The FDA has warned breastfeeding women in particular not to use products
21 containing domperidone due to its associated risks and propensity to be excreted in breast milk.
22 Domperidone can only be obtained in the United States through an Expanded Access Program by
23 submitting an investigational new drug application for the treatment of gastroesophageal reflux
24 disease with upper gastrointestinal symptoms or gastroparesis in patients greater than 12 years old
25 who have failed standard therapies. Currently, no pharmacies are authorized to compound
26 domperidone.

27 17. Despite these prohibitions on the use of domperidone and products containing
28 domperidone, between March 19, 2015 and May 18, 2015, Respondent Age Well compounded

1 domperidone 10mg capsules from the unapproved drug domperidone and dispensed seven (7)
2 domperidone prescriptions, totaling 885 capsules, to two (2) patients. Six (6) of the prescriptions
3 were dispensed by Respondent Amer and one (1) was dispensed by Respondent Boraie. In
4 illegally dispensing these capsules, Respondents failed to notify consumers of the risks associated
5 with the drug or of its unapproved status with the FDA. Respondent Age Well continued to
6 dispense domperidone after issuance of a warning by the Board on April 14, 2015.

7 **FIRST CAUSE FOR DISCIPLINE**

8 **(Unlawful Manufacturing and Sale of Misbranded Drugs)**

9 18. Respondent Age Well is subject to disciplinary action under section 4301, subdivision
10 (j), of the Code in conjunction with sections 111440, 111400, and 111375 of the Health and
11 Safety Code in that Respondent violated state law regulating dangerous drugs by manufacturing,
12 selling, delivering, holding, and/or offering for sale misbranded drugs. Complainant refers to, and
13 by this reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive,
14 as though set forth fully herein.

15 **SECOND CAUSE FOR DISCIPLINE**

16 **(Prohibited Acts: Selling Misbranded Drugs)**

17 19. Respondent Age Well is subject to disciplinary action under section 4301, subdivision
18 (o), of the Code in conjunction with section 4169, subdivision (a)(3), of the Code in that
19 Respondent violated the California Pharmacy Law by purchasing, trading, selling and/or
20 transferring drugs that Respondent knew or reasonably should have known were misbranded.
21 Complainant refers to, and by this reference incorporates, the allegations set forth above in
22 paragraphs 16 and 17, inclusive, as though set forth fully herein.

23 **THIRD CAUSE FOR DISCIPLINE**

24 **(Unlawful Manufacturing and Sale of Misbranded Drugs)**

25 20. Respondent Amer is subject to disciplinary action under section 4301, subdivision (j),
26 of the Code in conjunction with sections 111440, 111400, and 111375 of the Health and Safety
27 Code in that Respondent violated state law regulating dangerous drugs by manufacturing, selling,
28 delivering, holding, and/or offering for sale misbranded drugs. Complainant refers to, and by this

1 reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive, as
2 though set forth fully herein.

3 **FOURTH CAUSE FOR DISCIPLINE**

4 **(Prohibited Acts: Selling Misbranded Drugs)**

5 21. Respondent Amer is subject to disciplinary action under section 4301, subdivision
6 (o), of the Code in conjunction with section 4169, subdivision (a)(3), of the Code in that
7 Respondent violated the California Pharmacy Law by purchasing, trading, selling and/or
8 transferring drugs that Respondent knew or reasonably should have known were misbranded.
9 Complainant refers to, and by this reference incorporates, the allegations set forth above in
10 paragraphs 16 and 17, inclusive, as though set forth fully herein.

11 **FIFTH CAUSE FOR DISCIPLINE**

12 **(Unlawful Manufacturing and Sale of Misbranded Drugs)**

13 22. Respondent Boraie is subject to disciplinary action under section 4301, subdivision
14 (j), of the Code in conjunction with sections 111440, 111400, and 111375 of the Health and
15 Safety Code in that Respondent violated state law regulating dangerous drugs by manufacturing,
16 selling, delivering, holding, and/or offering for sale misbranded drugs. Complainant refers to, and
17 by this reference incorporates, the allegations set forth above in paragraphs 16 and 17, inclusive,
18 as though set forth fully herein.

19 **SIXTH CAUSE FOR DISCIPLINE**

20 **(Prohibited Acts: Selling Misbranded Drugs)**

21 23. Respondent Boraie is subject to disciplinary action under section 4301, subdivision
22 (o), of the Code in conjunction with section 4169, subdivision (a)(3), of the Code in that
23 Respondent violated the California Pharmacy Law by purchasing, trading, selling and/or
24 transferring drugs that Respondent knew or reasonably should have known were misbranded.
25 Complainant refers to, and by this reference incorporates, the allegations set forth above in
26 paragraphs 16 and 17, inclusive, as though set forth fully herein.

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28 ///

1 DISCIPLINE CONSIDERATIONS

2 24. To determine the degree of discipline, if any, to be imposed on Respondent Age Well,
3 Complainant alleges that on or about April 26, 2016, in a prior action, the Board of Pharmacy
4 issued Citation Number CI 2015 66762 and ordered Respondent Age Well to pay a fine of
5 \$1,000.00. That Citation is now final and is incorporated by reference as if fully set forth.

6 25. To determine the degree of discipline, if any, to be imposed on Respondent Amer,
7 Complainant alleges that on or about April 26, 2016, in a prior action, the Board of Pharmacy
8 issued Citation Number CI 2015 70092 and ordered Respondent Amer to pay a fine of \$2,000.00.
9 That Citation is now final and is incorporated by reference as if fully set forth.

10 PRAYER

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

13 1. Revoking or suspending Permit Number PHY 49116, issued to Amer Rx, Inc. dba
14 Age Well, Amro Shakker Amer, President and Owner;

15 2. Revoking or suspending Pharmacist License Number RPH 56570, issued to Amro
16 Shakker Amer, Pharmacist-in-Charge;

17 3. Revoking or suspending Pharmacist License Number RPH 69985, issued to Sami
18 Boraie;

19 4. Ordering Amer Rx, Inc. dba Age Well, Amro Shakker Amer, President and Owner,
20 Amro Shakker Amer, Pharmacist-in-Charge, and Sami Boraie to pay the Board of Pharmacy the
21 reasonable costs of the investigation and enforcement of this case, pursuant to Business and
22 Professions Code section 125.3; and,

23 5. Taking such other and further action as deemed necessary and proper.

24 DATED: 6/30/17

Virginia Herold

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

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