

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

In the Matter of the Accusation Against:

**MEDIRATTA RX INC.
DBA PEOPLE'S PHARMACY
31951 Dove Canyon Drive, Suite F
Rancho Santa Margarita, CA 92679**

**Pharmacy Permit No. PHY 47303
Sterile Compounding License No. LSC 99478**

and

**RASHIMI MEDIRATTA
31951 Dove Canyon Drive, Suite F
Rancho Santa Margarita, CA 92679**

Pharmacist License No. RPH 57047

Case No. 5942

OAH No. 2017040455

**STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER**

Respondents.

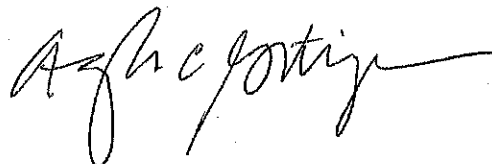
DECISION AND ORDER

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

This Decision shall become effective at 5:00 p.m. on November 29, 2017.

It is so ORDERED on October 30, 2017.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA



By _____

Amy Gutierrez, Pharm.D.
Board President

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

11 In the Matter of the Accusation Against:

Case No. 5942

12 **MEDIRATTA RX INC.**
13 **DBA PEOPLE'S PHARMACY**
14 **31951 Dove Canyon Drive, Suite F**
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15 **Pharmacy Permit No. PHY 47303**
16 **Sterile Compounding License No. LSC**
99478

STIPULATED SETTLEMENT AND
DISCIPLINARY ORDER

17 **and**

18 **RASHIMI MEDIRATTA**
19 **31951 Dove Canyon Drive, Suite F**
Rancho Santa Margarita, CA 92679

20 **Pharmacist License No. RPH 57047**

21 Respondents.

22
23 IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-
24 entitled proceedings that the following matters are true:

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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 Manuel Arambula, Deputy
5 Attorney General.

6 2. Respondent Mediratta Rx Inc. dba People's Pharmacy (Respondent People's
7 Pharmacy) and Rashimi Mediratta (Respondent Mediratta) are represented in this proceeding by
8 attorney Tony Park, whose address is California Pharmacy Lawyers, 49 Discovery, Ste. 240,
9 Irvine, CA 92618.

10 3. On or about June 6, 2005, the Board issued Pharmacist License No. RPH 57047 to
11 Respondent Mediratta. The Pharmacist License was in full force and effect at all times relevant to
12 the charges brought herein and will expire on September 30, 2018, unless renewed.

13 4. On or about October 7, 2005, the Board issued Pharmacy Permit No. PHY 47303 to
14 Respondent People's Pharmacy. The Pharmacy Permit was in full force and effect at all times
15 relevant to the charges brought in Accusation No. 5942, and will expire on October 1, 2017,
16 unless renewed.

17 5. On or about January 18, 2008, the Board issued Sterile Compounding Permit No.
18 LSC 99478 to Respondent People's Pharmacy. The Sterile Compounding Permit was in full force
19 and effect at all times relevant to the charges brought in Accusation No. 5942, and will expire on
20 October 1, 2017, unless renewed.

21 JURISDICTION

22 6. Accusation No. 5942 was filed before the Board, and is currently pending against
23 Respondents. The Accusation and all other statutorily required documents were properly served
24 on Respondents on February 1, 2017. Respondents timely filed their Notice of Defense contesting
25 the Accusation. A copy of Accusation No. 5942 is attached as exhibit A and incorporated herein
26 by reference.

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1 IT IS FURTHER ORDERED that Pharmacy Permit No. PHY 47303 issued to Mediratta
2 RX Inc., doing business as People's Pharmacy with Rashimi Mediratta as the President and
3 Pharmacist-in-Charge are revoked. However, the revocation is stayed and the Respondent
4 People's Pharmacy is placed on probation for three (3) years on the following terms and
5 conditions.

6 **1. Obey All Laws**

7 Respondent People's Pharmacy shall obey all state and federal laws and regulations.

8 Respondent People's Pharmacy shall report any of the following occurrences to the Board,
9 in writing, within seventy-two (72) hours of such occurrence:

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

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

21 **2. Report to the Board**

22 Respondent People's Pharmacy shall report to the Board quarterly, on a schedule as
23 directed by the Board or its designee. The report shall be made either in person or in writing, as
24 directed. Among other requirements, Respondent People's Pharmacy shall state in each report
25 under penalty of perjury whether there has been compliance with all the terms and conditions of
26 probation. Failure to submit timely reports in a form as directed shall be considered a violation of
27 probation. Any period(s) of delinquency in submission of reports as directed may be added to the
28 total period of probation. Moreover, if the final probation report is not made as directed,

1 probation shall be automatically extended until such time as the final report is made and accepted
2 by the Board.

3 **3. Interview with the Board**

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

10 **4. Cooperate with Board Staff**

11 Respondent People's Pharmacy shall cooperate with the Board's inspection program and
12 with the Board's monitoring and investigation of Respondent People's Pharmacy's compliance
13 with the terms and conditions of its probation. Failure to cooperate shall be considered a violation
14 of probation.

15 **5. Reimbursement of Board Costs**

16 As a condition precedent to successful completion of probation, Respondent owner shall
17 pay to the board its costs of investigation and prosecution in the amount of \$13,500.00.
18 Respondent People's Pharmacy may submit a payment plan, within 30 days of the effective date,
19 for prior approval by the Board. Once approved, there shall be no deviation from the payment
20 plan absent prior written approval by the Board or its designee. Failure to pay costs by the
21 deadline(s) as directed shall be considered a violation of probation.

22 The filing of bankruptcy by Respondent People's Pharmacy shall not relieve respondent of
23 her responsibility to reimburse the board its costs of investigation and prosecution.

24 **6. Probation Monitoring Costs**

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

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7. Status of License

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

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

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8. License Surrender While on Probation/Suspension

Following the effective date of this decision, should Respondent People's Pharmacy discontinue business, Respondent People's Pharmacy may tender the premises license to the Board for surrender. The board or its designee shall have the discretion whether to grant the request for surrender or take any other action it deems appropriate and reasonable. Upon formal acceptance of the surrender of the license, Respondent will no longer be subject to the terms and conditions of probation.

Upon acceptance of the surrender, Respondent owner shall relinquish the premises wall and renewal license to the board within ten (10) days of notification by the board that the surrender is accepted. Respondent People's Pharmacy shall further submit a completed Discontinuance of Business form according to board guidelines and shall notify the board of the records inventory transfer. Respondent People's Pharmacy shall also, by the effective date of this decision, arrange for the continuation of care for ongoing patients of the pharmacy by, at minimum, providing a written notice to ongoing patients that specifies the anticipated closing date of the pharmacy and that identifies one or more area pharmacies capable of taking up the patients' care, and by cooperating as may be necessary in the transfer of records or prescriptions for ongoing patients. Within five days of its provision to the pharmacy's ongoing patients, Respondent People's

1 Pharmacy shall provide a copy of the written notice to the board. For the purposes of this
2 provision, "ongoing patients" means those patients for whom the pharmacy has on file a
3 prescription with one or more refills outstanding, or for whom the pharmacy has filled a
4 prescription within the preceding sixty (60) days.

5 Respondent People's Pharmacy may not apply for any new licensure from the board for
6 three (3) years from the effective date of the surrender. Respondent People's Pharmacy shall meet
7 all requirements applicable to the license sought as of the date the application for that license is
8 submitted to the board.

9 Respondent People's Pharmacy further stipulates that he or she shall reimburse the Board
10 for its costs of investigation and prosecution prior to the acceptance of the surrender.

11 9. Notice to Employees

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

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

25 10. Owners and Officers: Knowledge of the Law

26 Respondent shall provide, within thirty (30) days after the effective date of this decision,
27 signed and dated statements from its owners, including any owner or holder of ten percent (10%)
28 or more of the interest in Respondent or Respondent's stock, and any officer, stating under

1 penalty of perjury that said individuals have read and are familiar with state and federal laws and
2 regulations governing the practice of pharmacy. The failure to timely provide said statements
3 under penalty of perjury shall be considered a violation of probation.

4 **11. Posted Notice of Probation**

5 Respondent People's Pharmacy shall prominently post a probation notice provided by the
6 Board in a place conspicuous and readable to the public. The probation notice shall remain posted
7 during the entire period of probation.

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

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

13 **12. Violation of Probation**

14 If a Respondent People's Pharmacy has not complied with any term or condition of
15 probation, the Board shall have continuing jurisdiction over Respondent's license, and probation
16 shall be automatically extended until all terms and conditions have been satisfied or the Board has
17 taken other action as deemed appropriate to treat the failure to comply as a violation of probation,
18 to terminate probation, and to impose the penalty that was stayed.

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

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13. **Completion of Probation**

1 Upon written notice by the board or its designee indicating successful completion of
2 probation, Respondent People's Pharmacy license will be fully restored.
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4 14. **Consultant Pharmacist Review of Pharmacy Operations**

5 During the period of probation, Respondent People's Pharmacy shall retain an independent
6 consultant at its own expense who shall be responsible for reviewing pharmacy operations on a
7 monthly basis for compliance by Respondent with state and federal laws and regulations
8 governing the practice of pharmacy. The consultant shall be a pharmacist licensed by and not on
9 probation with the board and whose name shall be submitted to the Board or its designee, for
10 prior approval, within thirty (30) days of the effective date of this decision. During the period of
11 probation, the Board or its designee retains the discretion to reduce the frequency of the
12 pharmacist consultant's review of Respondent pharmacy's operations. Failure to timely retain,
13 seek approval of, or ensure timely reporting by the consultant shall be considered a violation of
14 probation

15 IT IS FURTHER ORDERED that Pharmacist License No. RPH 57047 issued to Rashimi
16 Mediratta is revoked. However, the revocation is stayed and the Respondent is placed on
17 probation for three (3) years on the following terms and conditions.

18 1. **Obey All Laws**

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

20 Respondent shall report any of the following occurrences to the Board, in writing, within
21 seventy-two (72) hours of such occurrence:

- 22
- 23 • an arrest or issuance of a criminal complaint for violation of any provision of the
24 Pharmacy Law, state and federal food and drug laws, or state and federal controlled
25 substances laws
 - 26 • a plea of guilty or nolo contendere in any state or federal criminal proceeding to any
27 criminal complaint, information or indictment
 - 28 • a conviction of any crime

- 1 • discipline, citation, or other administrative action filed by any state or federal agency
2 which involves Respondent's licenses or which is related to the practice of pharmacy
3 or the manufacturing, obtaining, handling, distributing, billing, or charging for any
4 drug, device or controlled substance.

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

6 **2. Report to the Board**

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

15 **3. Interview with the Board**

16 Upon receipt of reasonable prior notice, Respondent shall appear in person for interviews
17 with the Board or its designee, at such intervals and locations as are determined by the Board or
18 its designee. Failure to appear for any scheduled interview without prior notification to Board
19 staff, or failure to appear for two (2) or more scheduled interviews with the Board or its designee
20 during the period of probation, shall be considered a violation of probation.

21 **4. Cooperate with Board Staff**

22 Respondent shall cooperate with the Board's inspection program and with the Board's
23 monitoring and investigation of Respondent's compliance with the terms and conditions of her
24 probation. Failure to cooperate shall be considered a violation of probation.

25 **5. Continuing Education**

26 Respondent shall provide evidence of efforts to maintain skill and knowledge as a
27 pharmacist as directed by the Board or its designee.

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1 6. **Notice to Employers**

2 During the period of probation, Respondent shall notify all present and prospective
3 employers of the decision in case number 5942 and the terms, conditions and restrictions imposed
4 on Respondent by the decision, as follows:

5 Within thirty (30) days of the effective date of this decision, and within fifteen (15) days of
6 Respondent undertaking any new employment, Respondent shall cause her direct supervisor,
7 pharmacist-in-charge (including each new pharmacist-in-charge employed during Respondent's
8 tenure of employment) and owner to report to the Board in writing acknowledging that the listed
9 individual(s) has/have read the decision in case number 5942, and terms and conditions imposed
10 thereby. It shall be Respondent's responsibility to ensure that her employer(s) and/or
11 supervisor(s) submit timely acknowledgment(s) to the Board.

12 If Respondent works for or is employed by or through a pharmacy employment service,
13 Respondent must notify her direct supervisor, pharmacist-in-charge, and owner at every entity
14 licensed by the Board of the terms and conditions of the decision in case number 5942 in advance
15 of the Respondent commencing work at each licensed entity. A record of this notification must be
16 provided to the Board upon request.

17 Furthermore, within thirty (30) days of the effective date of this decision, and within fifteen
18 (15) days of Respondent undertaking any new employment by or through a pharmacy
19 employment service, Respondent shall cause her direct supervisor with the pharmacy
20 employment service to report to the Board in writing acknowledging that they have read the
21 decision in case number 5942 and the terms and conditions imposed thereby. It shall be
22 Respondent's responsibility to ensure that her employer(s) and/or supervisor(s) submit timely
23 acknowledgment(s) to the Board.

24 Failure to timely notify present or prospective employer(s) or to cause that/those
25 employer(s) to submit timely acknowledgments to the Board shall be considered a violation of
26 probation.

27 "Employment" within the meaning of this provision shall include any full-time,
28 part-time, temporary, relief or pharmacy management service as a pharmacist or any

1 position for which a pharmacist license is a requirement or criterion for employment,
2 whether the Respondent is an employee, independent contractor or volunteer.

3 **7. No Supervision of Interns, Serving as Designated Representative-in-**
4 **Charge, or Serving as a Consultant**

5 During the period of probation, Respondent shall not supervise any intern pharmacist, be
6 the pharmacist-in-charge or designated representative-in-charge of any entity not designated in
7 this settlement, or serve as a consultant. Assumption of any such unauthorized supervision
8 responsibilities shall be considered a violation of probation. Respondent Mediratta may continue
9 to be the pharmacist-in-charge only at People's Pharmacy.

10 **8. Reimbursement of Board Costs**

11 As a condition precedent to successful completion of probation, Respondent Mediratta shall
12 pay to the Board its costs of investigation and prosecution in the amount of \$13,500.00.
13 Respondent Mediratta may submit a payment plan, within 30 days of the effective date, for prior
14 approval by the Board. Once approved, there shall be no deviation from the payment plan absent
15 prior written approval by the Board or its designee. Failure to pay costs by the deadline(s) as
16 directed shall be considered a violation of probation.

17 The filing of bankruptcy by Respondent shall not relieve Respondent of the responsibility
18 to reimburse the Board its costs of investigation and prosecution.

19 **9. Probation Monitoring Costs**

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

24 **10. Status of License**

25 Respondent shall, at all times while on probation, maintain an active, current license with
26 the Board. Failure to maintain an active, current license shall be considered a violation of
27 probation.

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1 If Respondent's licenses expire or are cancelled by operation of law or otherwise at any
2 time during the period of probation, including any extensions thereof due to tolling or otherwise,
3 upon renewal or reapplication Respondent's licenses shall be subject to all terms and conditions
4 of this probation not previously satisfied.

5 **11. License Surrender While on Probation/Suspension**

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

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

19 **12. Notification of a Change in Name, Residence Address, Mailing**
20 **Address or Employment**

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

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

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1 13. **Tolling of Probation**

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

8 Should Respondent, regardless of residency, for any reason (including vacation) cease
9 practicing as a pharmacist for a minimum of 40 hours per calendar month in California,
10 Respondent must notify the Board in writing within ten (10) days of the cessation of practice, and
11 must further notify the Board in writing within ten (10) days of the resumption of practice. Any
12 failure to provide such notification(s) shall be considered a violation of probation.

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

16 "Cessation of practice" means any calendar month during which Respondent
17 Mediratta is not practicing as a pharmacist for at least 40 hours, as defined by
18 Business and Professions Code section 4000 et seq. "Resumption of practice" means
19 any calendar month during which Respondent Mediratta is practicing as a pharmacist
20 for at least 40 hours as a pharmacist as defined by Business and Professions Code
21 section 4000 et seq.

22 Respondent Mediratta is required to practice as a pharmacist in a licensed pharmacy
23 setting that dispenses medication for a minimum of one year prior to the completion of probation.
24 After the first year of probation, the Board or its designee may consider a modification of this
25 requirement. If Respondent Mediratta fails to comply with this requirement or a subsequent
26 modification thereto, such failure shall be considered a violation of probation.

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14. Violation of Probation

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

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

15. Completion of Probation

Upon written notice by the Board or its designee indicating successful completion of probation, Respondent's license will be fully restored.

16. Restricted Practice

Respondent's practice of pharmacy shall be restricted as follows: Respondent must complete 30 hours of remedial education in sterile compounding and at least 50% of those hours must be in-person training. Respondent may not compound sterile products until this term has been met. Respondent shall submit proof satisfactory to the Board of compliance with this term of probation and Respondent's probation shall not be successfully completed until this term has been met.

17. No New Ownership of Licensed Premises

Respondent shall not acquire any new ownership, legal or beneficial interest nor serve as a manager, administrator, member, officer, director, trustee, associate, or partner of any additional business, firm, partnership, or corporation licensed by the Board. If Respondent currently owns or has any legal or beneficial interest in, or serve as a manager, administrator, member, officer,

1 director, trustee, associate, or partner of any business, firm, partnership, or corporation currently
2 or hereinafter licensed by the Board, Respondent may continue to serve in such capacity or hold
3 that interest, but only to the extent of that position or interest as of the effective date of this
4 decision. Violation of this restriction shall be considered a violation of probation.

5 **18. Remedial Education**

6 Within thirty (30) days of the effective date of this decision, Respondent Mediratta shall
7 submit to the Board or its designee, for prior approval, an appropriate program of remedial
8 education related to pharmacy operations and the role of the PIC. The program of remedial
9 education shall consist of 12 hours, which shall be completed at the rate of four hours a year at
10 Respondent Mediratta's own expense. All remedial education shall be in addition to, and shall not
11 be credited toward, continuing education (CE) courses used for license renewal purposes.

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

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

22 **19. Ethics Course**

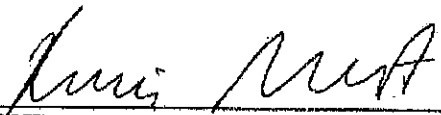
23 Within sixty (60) calendar days of the effective date of this decision, Respondent Mediratta
24 shall enroll in a course in ethics, at Respondent Mediratta expense, approved in advance by the
25 Board or its designee. Failure to initiate the course during the first year of probation, and
26 complete it within the second year of probation, is a violation of probation.

27 Respondent Mediratta shall submit a certificate of completion to the Board or its designee
28 within five days after completing the course.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony Park. I understand the stipulation and surrender and the effect it will have on my Pharmacy Permit, Pharmacist License, and Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order and Stipulated Surrender voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: 09/06/2017


RASHIMI MEDIRATTA as an individual and as
authorized agent on behalf of MEDIRATTA RX INC.
DBA PEOPLE'S PHARMACY
Respondents

I have read and fully discussed with Respondents Rashimi Mediratta and Mediratta Rx Inc. dba People's Pharmacy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order and Stipulated Surrender. I approve its form and content.

DATED: _____

TONY PARK
Attorney for Respondents

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ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order and have fully discussed it with my attorney, Tony Park. I understand the stipulation and surrender and the effect it will have on my Pharmacy Permit, Pharmacist License, and Sterile Compounding Permit. I enter into this Stipulated Settlement and Disciplinary Order and Stipulated Surrender voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

RASHIMI MEDIRATTA as an individual and as
authorized agent on behalf of MEDIRATTA RX INC.
DBA PEOPLE'S PHARMACY
Respondents

I have read and fully discussed with Respondents Rashimi Mediratta and Mediratta Rx Inc. dba People's Pharmacy the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order and Stipulated Surrender. I approve its form and content.

DATED: 09/06/2017


TONY PARK
Attorney for Respondents

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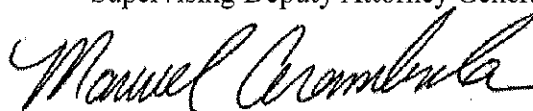
ENDORSEMENT

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

Dated: 09/06/2017

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
ANTOINETTE B. CINCOTTA
Supervising Deputy Attorney General



MANUEL ARAMBULA
Deputy Attorney General
Attorneys for Complainant

SD2016702116

Exhibit A

Accusation No. 5942

1 XAVIER BECERRA
Attorney General of California
2 ANTOINETTE B. CINCOTTA
Supervising Deputy Attorney General
3 MANUEL ARAMBULA
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Attorneys for Complainant

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

11 In the Matter of the Accusation Against:

Case No. 5942

12 **MEDIRATTA RX INC.**
13 **DBA PEOPLE'S PHARMACY**
14 **31951 Dove Canyon Drive, Suite F**
Rancho Santa Margarita, CA 92679

A C C U S A T I O N

15 **Pharmacy Permit No. PHY 47303**
16 **Sterile Compounding License No. LSC**
99478

17 **and**

18 **RASHIMI MEDIRATTA**
19 **31951 Dove Canyon Drive, Suite F**
Rancho Santa Margarita, CA 92679

20 **Pharmacist License No. RPH 57047**

21 Respondents.

22
23 Complainant alleges:

24 **PARTIES**

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

27 2. On or about June 6, 2005, the Board issued Pharmacist License No. RPH 57047 to
28 Rashimi Mediratta (Respondent Mediratta). The Pharmacist License was in full force and effect

1 at all times relevant to the charges brought herein and will expire on September 30, 2018, unless
2 renewed.

3 3. On or about October 7, 2005, the Board issued Pharmacy Permit Number PHY 47303
4 to Mediratta RX Inc., doing business as People's Pharmacy (Respondent People's Pharmacy)
5 with Rashimi Mediratta as the President and Pharmacist-in-Charge. The Pharmacy Permit was in
6 full force and effect at all times relevant to the charges brought herein and will expire on October
7 1, 2017, unless renewed.

8 4. On or about January 18, 2008, the Board issued Sterile Compounding License
9 Number LSC 99478 to Mediratta RX Inc., doing business as People's Pharmacy (Respondent
10 People's Pharmacy). The Sterile Compounding License was in full force and effect at all times
11 relevant to the charges brought herein and will expire on October 1, 2017, unless renewed.

12 JURISDICTION

13 5. This Accusation is brought before the Board, Department of Consumer Affairs, under
14 the authority of the following laws. All section references are to the Business and Professions
15 Code (Code) unless otherwise indicated.

16 6. Section 4011 of the Code provides that the Board shall administer and enforce both
17 the Pharmacy Law [Bus. & Prof. Code, § 4000 et seq.] and the Uniform Controlled Substances
18 Act [Health & Safety Code, § 11000 et seq.].

19 7. Section 4300(a) of the Code provides that every license issued by the Board may be
20 suspended or revoked.

21 8. Section 4300.1 of the Code states:

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

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1 **STATUTORY PROVISIONS**

2 9. Section 4022 of the Code states:

3 "Dangerous drug" or "dangerous device" means any drug or device unsafe
4 for self-use in humans or animals, and includes the following:

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

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

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

13 10. Section 4033, subsection (a)(1) of the Code defines the term "manufacturer" as
14 "every person who prepares, derives, produces, compounds, or repackages any drug or device
15 except a pharmacy that manufactures on the immediate premises where the drug or device is sold
16 to the ultimate consumer."

17 11. Section 4113, subsection (c) of the Code states: "The pharmacist-in-charge shall be
18 responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining
19 to the practice of pharmacy."

20 12. 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
22 unprofessional conduct or whose license has been procured by fraud or
23 misrepresentation or issued by mistake. Unprofessional conduct shall include, but
24 is not limited to, any of the following:

25

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

28

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

. . . .

1 13. Health and Safety Code section 11030 defines an “Ultimate user” as “a person who
2 lawfully possesses a controlled substance for his own use or for the use of a member of his
3 household or for administering to an animal owned by him or by a member of his household.”

4 14. Health and Safety Code section 111330 provides that any drug or device is
5 misbranded if its labeling is false or misleading in any particular.

6 15. Health and Safety Code section 111425 provides that a drug or device is misbranded
7 if it was manufactured in this state in an establishment not duly licensed by the Department of
8 Public Health.

9 16. Health and Safety Code section 111430 provides that a drug or device is misbranded
10 if it was manufactured in an establishment not duly registered with the Secretary of Health,
11 Education, and Welfare of the United States.

12 17. Health and Safety Code section 111440 provides that it is unlawful for any person to
13 manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded.

14 18. Health and Safety Code section 111450 provides that it is unlawful for any person to
15 receive in commerce any drug or device that is misbranded or to deliver or proffer for delivery
16 any drug or device.

17 19. Health and Safety Code section 111615 provides that no person shall manufacture
18 any drug or device in this state unless he or she has a valid license from the Department of Public
19 Health.

20 **REGULATORY PROVISIONS**

21 20. California Code of Regulations, title 16, section 1735, subsection (a):
22 states in pertinent part:

23 “Compounding” means any of the following activates occurring in a
24 licensed pharmacy, by or under the supervision of a licensed pharmacist, pursuant
to a prescription:

- 25 (1) Altering the dosage form or delivery system of a drug
26 (2) Altering the strength of a drug
27 (3) Combining components or active ingredients
28 (4) Preparing a drug product from chemicals or bulk drug substances

...
28

1 21. California Code of Regulations, title 16, section 1735.2,:

2 states in pertinent part:

3 ...
4 (c) Pursuant to Business and Professions Code section 4052(a)(1), a
5 “reasonable quantity” of compounded drug product may be furnished to a
6 prescriber for office use upon prescriber order, where “reasonable quantity” is that
7 amount of compounded drug product that:

8 (1) is sufficient for administration or application to patients in the prescriber’s
9 office, or for distribution of not more than a 72-hour supply to the prescriber’s
10 patients, as estimated by the prescriber; and

11 (2) is reasonable considering the intended use of the compounded medication
12 and the nature of the prescriber’s practice; and

13 (3) for any individual prescriber and for all prescribers taken as a whole, is an
14 amount which the pharmacy is capable of compounding in compliance with
15 pharmaceutical standards for integrity, potency, quality and strength of the
16 compounded drug product.

17 ...
18 (h) Every compounded drug product shall be given an expiration date
19 representing the date beyond which, in the professional judgment of the
20 pharmacist performing or supervising the compounding, it should not be used.
21 This “beyond use date” of the compounded drug product shall not exceed 180 days
22 from preparation or the shortest expiration date of any component in the
23 compounded drug product, unless a longer date is supported by stability studies of
24 finished drugs or compounded drug products using the same components and
25 packaging. Shorter dating than set forth in this subsection may be used if it is
26 deemed appropriate in the professional judgment of the responsible pharmacist.

27 ...
28 22. California Code of Regulations, title 16, section 1735.5, Compounding Policies
and Procedures, states in pertinent part:

29 (a) Any pharmacy engaged in compounding shall maintain a written policy
30 and procedure manual for compounding that establishes procurement procedures,
31 methodologies for the formulation and compounding of drugs, facilities and
32 equipment cleaning, maintenance, operation, and other standard operating
33 procedures related to compounding.

34 (b) The policy and procedure manual shall be reviewed on an annual basis
35 by the pharmacist-in-charge and shall be updated whenever changes in processes
36 are implemented.

37 (c) The policy and procedure manual shall include the following:

38 ...
39 (3) The procedures for maintaining, storing, calibrating, cleaning, and
40 disinfecting equipment used in compounding, and for training on these procedures
41 as part of the staff training and competency evaluation process.

1 (4) Documentation of the methodology used to test integrity, potency,
2 quality, and labeled strength of compounded drug products.

3 (5) Documentation of the methodology used to determine appropriate
4 expiration dates for compounded drug products.

5 23. California Code of Regulations, title 16, section 1735.8, Compounding Quality
6 Assurance, states that:

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

11 (b) The quality assurance plan shall include written procedures for verification,
12 monitoring, and review of the adequacy of the compounding processes and shall
13 also include written documentation of review of those processes by qualified
14 pharmacy personnel.

15 (c) The quality assurance plan shall include written standards for qualitative and
16 quantitative integrity, potency, quality, and labeled strength analysis of
17 compounded drug products. All qualitative and quantitative analysis reports for
18 compounded drug products shall be retained by the pharmacy and collated with the
19 compounding record and master formula.

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

23 DRUGS

24 24. Tacrolimus is a dangerous drug pursuant to Code section 4022.

25 25. Cyclosporine is a dangerous drug pursuant to Code section 4022.

26 26. Idoxuridine is a dangerous drug pursuant to Code section 4022.

27 27. Demecarium is a dangerous drug pursuant to Code section 4022.

28 COST RECOVERY

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

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1 **FACTUAL ALLEGATIONS**

2 29. From January 18, 2008, to the present, Respondent Rashimi Mediratta has been and is
3 the Pharmacist-in-Charge (PIC) of Respondent People’s Pharmacy. Respondent People’s
4 Pharmacy is not, and has never been, an establishment duly registered as a manufacturer with the
5 Secretary of Health, Education and Welfare of the United States or licensed with the California
6 Department of Public Health as a manufacturer.

7 30. On or about March 6, 2015, the Board conducted an annual inspection of Respondent
8 People’s Pharmacy. The inspector found the following medications in large quantities:
9 tacrolimus, EDTA, dexamethasone, and cyclosporine.¹ Respondent Mediratta stated to the
10 inspector that she compounds these large quantities of eye drops in anticipation of sending them
11 to doctor’s offices. These eye drops were, however, compounded without a patient specific
12 prescriptions and outside of the compounding limits permitted under pharmacy law. The
13 investigator also reviewed the Respondent’s policies and procedures for compounding.
14 Pharmacists are required, under California Code of Regulations, title 16 (CCR), section 1735.5, to
15 keep “a written quality assurance plan designed to monitor and ensure the integrity, potency,
16 quality, and labeled strength of compounded drug products.” After reviewing Respondents’
17 policies and procedures, the investigator noted that Respondents did not have a written quality
18 assurance plan for compounding. The investigator also requested copies of Respondents’
19 compounding logs, dispensing records, master formulas, other and documents related to
20 Respondents’ compounding practices.

21 31. After reviewing the documents provided by Respondents, several other violations by
22 Respondents were noted in these records. Respondents’ compounding records stated that
23 Respondent Mediratta used sterile water for irrigation, as opposed to sterile water for injection, in
24 compounding tacrolimus ophthalmic solution on five separate occasions. The United States
25 Pharmacopeial Convention (USP) — a scientific nonprofit organization that sets standards for the
26 identity, strength, quality, and purity of medicines manufactured, distributed, and consumed

27 ¹ The named ophthalmic solutions are commonly used in veterinary medicine for the
28 treatment of Keratoconjunctivitis Sicca (dry eye) and other diseases of the eye in dogs.

1 worldwide — has standardized the use of sterile water in drug compounding so that sterile water
2 for irrigation is below the acceptable standard for use in the compounding of ophthalmic solutions
3 and sterile water for injection is accepted. Respondents’ compounding records from six separate
4 dates show that Respondent Mediratta used sterile water for irrigation for compounding
5 tacrolimus ophthalmic solution. These dates are: December 9, 2014; December 22, 2014; January
6 19, 2015; February 4, 2015; February 24, 2015; and March 4, 2015.

7 32. Respondent People’s Pharmacy compounding records show that on March 4, 2015,
8 Respondent Mediratta compounded 200 bottles of tacrolimus ophthalmic solution with a beyond
9 use date — a date after which a compounded drug product should not be used — that was after
10 the expiration date of one of its components. Under CCR section 1735.2, subsection (h),
11 Respondent Mediratta cannot label a drug product with a beyond use date that exceeds an
12 “expiration date of any component in the compounded drug product.” The expiration date of the
13 benalkonium chloride used in compounding the tacrolimus ophthalmic solution was August 25,
14 2015. The beyond use date used by Respondent Mediratta for the 200 compounded tacrolimus
15 ophthalmic solution bottles was August 31, 2015, six days after the expiration date of the
16 benalkonium chloride.

17 33. From December 1, 2014, through February 28, 2015, Respondents’ compounding
18 records show that Respondent Meditratta compounded and sold approximately 5,700 ophthalmic
19 drops or ointments which were not sold to an ultimate user. Such compounding is considered
20 manufacturing under Code section 4033, subsection (a)(1). Respondents, who are not licensed to
21 manufacture in California, sold these 5,700 ophthalmic drops or ointments to veterinary clinics
22 without an existing prescription and outside of the “reasonable quantity” exceptions found in
23 CCR 1735.2, subsection (c). Furthermore, the 5,700 ophthalmic drops or ointments manufactured
24 by Respondents are misbranded as a result of being manufactured in an unlicensed facility, as
25 defined in Health and Safety Code section 111425. As an unlicensed manufacturer, Respondents
26 were also prohibited from manufacturing or selling these misbranded ophthalmic drops and
27 ointments under Health and Safety Code section 111440.

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FIRST CAUSE FOR DISCIPLINE

(Failure to Maintain Quality Assurance)

34. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating regulations requiring pharmacies to maintain a written policy and procedure manual for compounding that establishes methodologies for the formulation and compounding of drugs and other standard operating procedures related to compounding, as defined under CCR section 1735, subsection (a). Respondents failed to maintain documentation of the methodology used to test the integrity, potency, quality, and labeled strength of compounded drug products, as set forth in paragraphs 29 through 33, which are incorporated herein by reference.

SECOND CAUSE FOR DISCIPLINE

(Sale of Adulterated Drugs)

35. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating statutes regulating the adulteration of drugs as stated in the Sherman Food, Drug, and Cosmetic Act, and as defined under Health and Safety Code sections 111255 and 111260. Respondents offered for sale adulterated drugs in violation of Health and Safety Code section 111295, as set forth in paragraphs 29 through 33, which are incorporated herein by reference.

THIRD CAUSE FOR DISCIPLINE

(Compounding Limitation Requirements)

36. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating regulations regulating the expiration date of compounded drug products in that they compounded or manufactured drugs with a beyond use date exceeding the expiration date of a component of a the compounded drug product in violation of CCR section 1735.2, subsection (h), as set forth in paragraphs 29 through 33, which are incorporated herein by reference.

FOURTH CAUSE FOR DISCIPLINE

(Manufacturing Compounded Drugs)

37. Respondents are subject to disciplinary action under Code sections 4301(j) and (o), for violating statutes regulating controlled substances and dangerous drugs and state laws governing pharmacy, in that they compounded or manufactured drugs as defined by Code section

1 4033(a)(1), non-patient specific drugs without being licensed by the California Department of
2 Public Health, in violation of Health and Safety Code section 111615, as set forth in paragraphs
3 29 through 33, which are incorporated herein by reference.

4 **FIFTH CAUSE FOR DISCIPLINE**

5 **(Sold Misbranded Drugs)**

6 38. Respondents are subject to disciplinary action under Code sections 4301(j) and (o),
7 for violating statutes regulating controlled substances and dangerous drugs and state laws
8 governing pharmacy, in that Respondents sold misbranded drugs, as defined by Health & Safety
9 Code sections 111330 and 111430, in violation of Health and Safety Code section 111440, as set
10 forth in paragraphs 29 through 33, which are incorporated herein by reference.

11 **SIXTH CAUSE FOR DISCIPLINE**

12 **(Delivery or Proffering of Misbranded Drugs)**

13 39. Respondents are subject to disciplinary action under Code sections 4301(j) and (o),
14 for violating statutes regulating controlled substances and dangerous drugs and state laws
15 governing pharmacy, in that Respondents delivered or proffered for delivery misbranded drugs,
16 as defined by Health & Safety Code sections 111330 and 111430 in violation of Health and
17 Safety Code section 111450, as set forth in paragraphs 29 through 33, which are incorporated
18 herein by reference.

19 **PRAYER**

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

22 1. Revoking or suspending Pharmacy Permit Number PHY 47303, issued to Mediratta
23 RX Inc., doing business as People's Pharmacy;

24 2. Revoking or suspending Sterile Compounding License Number LSC 99478, issued to
25 Mediratta RX Inc., doing business as People's Pharmacy;

26 3. Revoking or suspending Pharmacist License Number RPH 57047, issued to Rashimi
27 Mediratta;

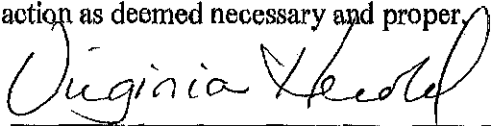
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4. Ordering Mediratta RX Inc., doing business as People's Pharmacy, and Rashimi Mediratta to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

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

DATED: 1/31/17



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

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