

BOBBI W.Y. LUM-MEW 6299
Regulated Industries Complaints Office
Department of Commerce and Consumer Affairs
State of Hawaii
Leiopapa A Kamehameha Building
235 South Beretania Street, Suite 900
Honolulu, Hawaii 96813
Telephone: 586-2660

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PROF & VOCATIONAL LICENSING DIVISION
DEPT. OF COMMERCE AND CONSUMER AFFAIRS
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DEPT. OF COMMERCE & CONSUMER AFFAIRS
STATE OF HAWAII
HEARING OFFICE

Attorney for Department of Commerce
and Consumer Affairs

BOARD OF PHARMACY
DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS
STATE OF HAWAII

In the Matter of the Miscellaneous Permit of) PHA 2010-26-L
)
US COMPOUNDING, INC.,)
)
Respondent.) ACTION AND BOARD'S FINAL ORDER;
) EXHIBIT "1"
)

248040108

SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION
FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER

Petitioner, DEPARTMENT OF COMMERCE AND CONSUMER AFFAIRS'
REGULATED INDUSTRIES COMPLAINTS OFFICE (hereinafter "RICO" or "Petitioner"),
through its undersigned attorney, and Respondent US COMPOUNDING, INC. (hereinafter
"Respondent"), enter into this Settlement Agreement on the terms and conditions set forth
below.

A. UNCONTESTED FACTS

1. At all relevant times herein, Respondent was permitted by the Board of Pharmacy
(hereinafter the "Board") as a pharmacy under Miscellaneous Permit Number PMP 467. Permit
Number PMP 467 was issued on or about May 2, 2006. The permit will expire on or about
December 31, 2011.

2. Respondent's mailing address for purposes of this action is 2515 College Avenue, Conway, AR 72034.

3. Respondent submitted information that it had been disciplined in the State of Colorado on a renewal form received by the Department of Commerce and Consumer Affairs in late November 2009.

4. RICO alleges Respondent entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy in In the Matter of the Disciplinary Proceeding Regarding the Non-Resident Prescription Drug Outlet Registration of U.S. Compounding, Inc., Registration No. OSP-5611. A true and correct copy of the October 22, 2008 Stipulation and Final Agency Order is attached as Exhibit "1." Although the action was disclosed at the time of renewal, Respondent failed to report the action within thirty (30) days as required by law.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute violations of the following statute(s) and/or rule(s): Hawaii Revised Statutes ("HRS") § 436B-19(15) (failure to report disciplinary action within thirty (30) days) and § 436B-19(13) (disciplinary action in another jurisdiction).

6. The Board has jurisdiction over the subject matter herein and over the parties hereto.

B. REPRESENTATIONS BY RESPONDENT:

1. Respondent is fully aware that Respondent has the right to be represented by an attorney and voluntarily waives that right.

2. Respondent enters into this Settlement Agreement freely, knowingly, voluntarily, and under no coercion or duress.

3. Respondent is aware of the right to have a hearing to adjudicate the issues in the case. Pursuant to HRS § 91-9(d), Respondent freely, knowingly, and voluntarily waives the right to a hearing and agrees to dispose of this case in accordance with the terms and conditions of this Settlement Agreement.

4. Respondent being at all times relevant herein permitted as a pharmacy by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of permits and administrative fines, if the foregoing allegations are proven at hearing.

5. Respondent does not admit to violating any law or rule, but acknowledges that RICO has sufficient cause to file a Petition for Disciplinary Action against Respondent's permit.

6. Respondent enters into this Settlement Agreement as a compromise of the claims and to conserve on the expenses of proceeding with an administrative hearing on this matter.

7. Respondent agrees that this Settlement Agreement is intended to resolve the issues raised in RICO's investigation in RICO Case No. PHA 2010-26-L.

8. Respondent understands this Settlement Agreement is public record pursuant to Hawaii Revised Statutes chapter 92F.

C. TERMS OF SETTLEMENT:

1. Administrative fine. Respondent agrees to pay a fine in the amount of TWO THOUSAND FIVE HUNDRED AND NO/100 DOLLARS (\$2,500.00). Payment shall be made by **cashier's check or money order made payable to "DCCA - Compliance Resolution Fund"** and mailed to the Regulated Industries Complaints Office, Attn: Bobbi W.Y. Lum-Mew,

Esq., 235 S. Beretania Street, 9th Floor, Honolulu, Hawaii 96813. Payment of the fine shall be due at the time this fully executed Settlement Agreement is returned to RICO.

2. Failure to Comply with Settlement Agreement. If Respondent fails to fully and timely comply with the terms of this Settlement Agreement as set forth in paragraph(s) C.1 above, Respondent's permit shall be automatically revoked upon RICO's filing of an affidavit with the Board attesting to such failure. In case of such revocation, Respondent shall turn in all indicia of the permit to the Executive Officer of the Board within ten (10) days after receipt of notice of the revocation. In case of such revocation, Respondent understands Respondent cannot apply for a new permit until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become permitted again, Respondent must apply to the Board for a new permit pursuant to and subject to HRS §§ 92-17, 436B-21, and all other applicable laws and rules in effect at the time.

3. Possible further sanction. The Board, at its discretion, may pursue additional disciplinary action as provided by law to include further fines and other sanctions as the Board may deem appropriate if Respondent violates any provision of the statutes or rules governing the conduct of pharmacies in the State of Hawaii, or if Respondent fails to abide by the terms of this Settlement Agreement.

4. Approval of the Board. Respondent agrees that, except for the representations, agreements and covenants contained in Paragraphs C.5, C.6, C.7 and C.8 below, this Settlement Agreement shall not be binding on any of the parties unless and until it is approved by the Board.

5. No Objection if Board Fails to Approve. If the Board does not approve this Settlement Agreement, does not issue an order pursuant thereto, or does not approve a lesser

remedy, but instead an administrative hearing is conducted against Respondent in the Board's usual and customary fashion pursuant to the Administrative Procedure Act, Respondent agrees that neither Respondent nor any attorney that Respondent may retain, will raise as an objection in any administrative proceeding or in any judicial action, to the Board's proceeding against Respondent on the basis that the Board has become disqualified to consider the case because of its review and consideration of this Settlement Agreement.

6. Any Ambiguities Shall be Construed to Protect the Consuming Public. It is agreed that any ambiguity in this Settlement Agreement is to be read in the manner that most completely protects the interests of the consuming public.

7. No Reliance on Representations by RICO. Other than the matters specifically stated in this Settlement Agreement, neither RICO nor anyone acting on its behalf has made any representation of fact, opinion or promise to Respondent to induce entry into this Settlement Agreement, and Respondent is not relying upon any statement, representation or opinion or promise made by RICO or any of its agents, employees, representatives or attorneys concerning the nature, extent or duration of exposure to legal liability arising from the subject matter of this Settlement Agreement or concerning any other matter.

8. Complete Agreement. This Settlement Agreement is a complete settlement of the rights, responsibilities and liabilities of the parties hereto with respect to the subject matter hereof; contains the entire agreement of the parties; and may only be modified, changed or amended by written instrument duly executed by all parties hereto.

IN WITNESS WHEREOF, the parties have signed this Settlement Agreement on the date(s) set forth below.

DATED: Conway, AR, 5-24-10
(CITY) (STATE) (DATE)

US COMPOUNDING, INC.

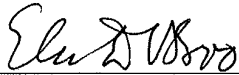
By: Eddie Howe
Its president

DATED: Honolulu, Hawaii, MAY 27 2010

Bobbi W. Y. Lum-Mew
BOBBI W. Y. LUM-MEW
Attorney for Department of Commerce and
Consumer Affairs

IN THE MATTER OF THE MISCELLANEOUS PERMIT OF US COMPOUNDING, INC.;
SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY
ACTION AND BOARD'S FINAL ORDER; CASE NO. PHA 2010-26-L; EXHIBIT "1"

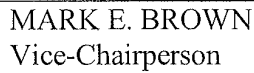
APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII




ELWIN D.H. GOO
Chairperson

JUNE 17, 2010

DATE



MARK E. BROWN
Vice-Chairperson



LAURIE H. Y. KAWAMURA



GARRETT A. LAU



KARL H. MIYAMOTO



PATRICK ADAMS

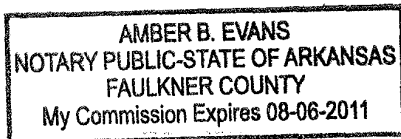


STANLEY M. CHOW

PVL 07/01/09

STATE OF Arkansas)
) SS.
COUNTY OF Faulkner)

On this 24th day of May, 2010, before me personally appeared Eddie Glover, to me known to be the person described, and who executed the foregoing instrument on behalf of U.S. Compounding as President, and acknowledged that he/she executed the same as his/her free act and deed.



Amber Evans
Name:

Notary Public, State of

My Commission expires: 8-6-2011

**BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO**

Case No. 2008-2689

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF THE DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG OUTLET REGISTRATION OF **U.S. COMPOUNDING, INC.**, REGISTRATION NO. OSP-5611,

RESPONDENT PHARMACY.

IT IS HEREBY STIPULATED by and between the Colorado State Board of Pharmacy ("Board") and U.S. Compounding, Inc. ("Respondent Pharmacy"), to resolve all matters pertaining to Board Case Number 2008-2689 as follows:

1. The Board has jurisdiction over Respondent Pharmacy, its registration as a non-resident prescription drug outlet, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of title 12, article 22, C.R.S. (2008), otherwise known as the Pharmaceuticals and Pharmacists Act.
2. Respondent Pharmacy has been registered by the Board as a non-resident prescription drug outlet in the State of Colorado at all times relevant to this disciplinary action.
3. Respondent Pharmacy's address of record with the Board and current location is 2515 College Avenue, Conway, Arkansas 72034.
4. Respondent Pharmacy does not contest these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.
5. On or about October 29, 2007, Board staff sent informational letters to all registered non-resident pharmacies, including Respondent Pharmacy, which detailed the Board's Electronic Prescription Drug Monitoring Program (PDMP) and notified them of the requirement that all non-resident pharmacies provide the Board with copies of their DEA registrations and begin submitting data to the PDMP retroactive to July 1, 2007.
6. As of January 4, 2008, Respondent Pharmacy had not provided a copy of its DEA registration to the Board and had not submitted the required data to the PDMP database.
7. On or about January 4, 2008, Board staff sent a second letter to the pharmacies that had not complied with the October 29, 2007 letter, including Respondent Pharmacy.

EXHIBIT 1

8. As of March 3, 2008, after two notices, Respondent Pharmacy had not submitted the required data to the PDMP database for any of the required reporting periods.
9. On March 3, 2008, the Board initiated a complaint against Respondent Pharmacy because Respondent Pharmacy failed to comply with the data submission requirements of the PDMP.
10. Respondent Pharmacy does not contest that the conduct described above constitutes a violation of §12-22-708, C.R.S. and that such conduct provides grounds for disciplinary action against Respondent Pharmacy's non-resident prescription drug outlet registration.

DISPOSITION

\$5,000.00 Fine with Surcharge and Terms

11. **Fine with Surcharge.** Respondent Pharmacy accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S., Respondent Pharmacy shall pay a fine of Five Thousand Dollars and No Cents (\$5,000.00). Respondent Pharmacy understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 15% of this fine. Respondent Pharmacy shall therefore pay a total amount of Five Thousand, Seven Hundred Fifty Dollars and No Cents (\$5,750.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Pharmacy submits this signed Final Agency Order to the Board.
12. **Compliance.** Respondent Pharmacy shall at all times be registered with the Board, and shall comply with the data submission requirements of the PDMP.
13. **Advisements and Waivers.** Respondent Pharmacy enters into this Final Agency Order freely and voluntarily, whether or not Respondent Pharmacy has consulted with legal counsel. Respondent Pharmacy acknowledges its understanding that it has the following rights:
 - a. To have a formal notice of hearing and charges served upon it;
 - b. To respond to said formal notice of charges;
 - c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
 - d. To appeal this Board order.

Respondent Pharmacy freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

14. **Acknowledgments.** The undersigned authorized agent of Respondent Pharmacy has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent Pharmacy has consulted with legal counsel, that Respondent Pharmacy understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable. Respondent Pharmacy is not relying on any statements, promises or representations from the

Board other than as may be contained in this Final Agency Order. Respondent Pharmacy further acknowledges that it is not entering into this Final Agency Order under any duress.

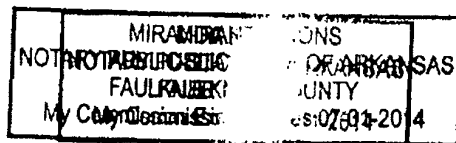
15. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Respondent Pharmacy to take all appropriate steps to comply fully with this Final Agency Order. Respondent Pharmacy acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Pharmacy to comply with all terms and conditions of this Final Agency Order.
16. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties in this case. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.
17. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.
18. **Effective Date.** This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Eddie Glover
Authorized Agent of Respondent Pharmacy

Dated: 10-14-08

Subscribed and sworn to before me in the County of Faulkner, State of Arkansas, this 14 day of October, 2008 by Eddie Glover in his/her capacity as an authorized agent of U.S. Compounding, Inc.



Miranda Irons
Notary Public

My commission expires:

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

DONE AND EFFECTIVE THIS 22nd DAY OF October, 2008.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

APPROVED AS TO FORM

JOHN W. SUTHERS
Attorney General

Joanna Lee Kaye
JOANNA LEE KAYE, #20486*
Assistant Attorney General
Business and Licensing Section

Attorneys for State Board of Pharmacy

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