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Department of Commerce and Consumer Affairs
State of Hawaii
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DEPT. OF COMMERCE
AND CONSUMER AFFAIRS

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HEARINGS OFFICE

STATE OF HAWAII

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 Wholesale Prescription) PHA 2012-36-L
Drug Distributor License of)
)
OWENS & MINOR DISTRIBUTION INC.,) SETTLEMENT AGREEMENT PRIOR TO
) FILING OF PETITION FOR DISCIPLINARY
) ACTION AND BOARD'S FINAL ORDER;
Respondent.) EXHIBIT "1"
)

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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 OWENS & MINOR DISTRIBUTION 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 licensed by the Board of Pharmacy (hereinafter the "Board") as a Wholesale Prescription Drug Distributor under License No. PWD 126. License Number PWD 126 was issued on or about May 5, 2008. The license will expire on or about December 31, 2013.

2. Respondent's mailing address for purposes of this action is c/o Charles H. Burr, Esq., Senior Counsel, Regulatory, Owens & Minor Distribution Inc., 9120 Lockwood Boulevard, Mechanicsville, Virginia 23116-2015.

3. Respondent notified the Board that it had been disciplined in the State of Colorado. Respondent had entered into a Stipulation and Final Agency Order in In the Matter of Disciplinary Proceeding Regarding the In-State Prescription Drug Wholesaler Registration of Owens & Minor Distribution Inc. Registration No. WHI 6008 in Case No. 2012-002778. The matter stemmed from Respondent's failure to timely submit an application to the Colorado Board of Pharmacy detailing a change in designated representative. Attached as Exhibit "1" is a true and correct copy of the Stipulation and Final Agency Order. Respondent paid a fine of \$1,000.00 and an additional surcharge of \$100.00.

4. RICO alleges that Respondent has had disciplinary action taken against it in another jurisdiction for reasons as provided by the Hawaii law and rules.

5. The foregoing allegations, if proven at an administrative hearing before the Board, would constitute a violation of the following statute and/or rule: Hawaii Revised Statutes ("HRS") § 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 represented by Charles H. Burr, Esq., Senior Counsel, Regulatory.
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 licensed as a wholesale prescription drug distributor by the Board acknowledges that Respondent is subject to penalties including but not limited to, revocation, suspension or limitation of license 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 license.

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 2012-36-L.

8. Respondent states that the State of Colorado Stipulation and Final Agency Order was specifically limited to an application of Colorado law to Respondent's facility in Denver, Colorado and was unrelated to Hawaii law, to Respondent's licensed facility in Hawaii or to any activities conducted by Respondent in Hawaii.

9. Respondent understands that this Settlement Agreement may be subject to reporting requirements.

10. 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 FIVE HUNDRED AND NO/100 DOLLARS (\$500.00). Payment shall be made by **business check 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 within thirty (30) days of the date that this Settlement Agreement is approved by the Board.

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 C.1 above, Respondent's license 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 license 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 license until the expiration of at least five (5) years after the effective date of the revocation. Respondent understands that if Respondent desires to become licensed again, Respondent must apply to the Board for a new license 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 wholesale prescription drug distributors 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: Mechanicville, Virginia, 3-25-13.
(CITY) (STATE) (DATE)

OWENS & MINOR DISTRIBUTION INC.

By: [Signature]
Its Sr. Vice President, General Counsel & Corporate Secretary

DATED: Honolulu, Hawaii, MAR 28 2013.

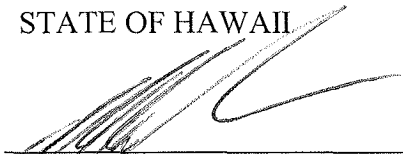
[Signature]
BOBBI W. Y. LUM-MEW
Attorney for Department of Commerce and Consumer Affairs

APPROVED AS TO FORM:

[Signature]
CHARLES H. BURR
Attorney for Respondent

IN THE MATTER OF THE WHOLESALE PRESCRIPTION DRUG DISTRIBUTOR'S
LICENSE OF OWENS & MINOR DISTRIBUTION INC.; SETTLEMENT AGREEMENT
PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL
ORDER; CASE NO. PHA 2012-36-L; EXHIBIT "1"


APPROVED AND SO ORDERED:
BOARD OF PHARMACY
STATE OF HAWAII



MARK E. BROWN
Chairperson

4/18/13

DATE



PATRICK ADAMS
Vice Chairperson



TODD INAFUKU



GARRETT A. LAU

CAROLYN S. J. MA



JILL OLIVEIRA GRAY



LYDIA KUMASAKA

PVL 07/15/11

STATE OF Virginia)
) SS.
COUNTY OF Hanover)

On this 25th day of March, 2013 before me personally appeared Grace R. den Hartog, to me known to be the person described, and who executed the foregoing instrument on behalf of Owens & Minor Distribution, Inc. as Senior Vice President General Counsel & Corporate Secretary, and acknowledged that he/she executed the same as his/her free act and deed.

This 8-page SETTLEMENT AGREEMENT PRIOR TO FILING OF PETITION FOR DISCIPLINARY ACTION AND BOARD'S FINAL ORDER document dated

March 25, 20 13 was acknowledged before me by Grace R. den Hartog this 25th day of March, 20 13, in the City of _____, in the County of Hanover, in the State of Virginia.



Kimberly M. Barton
Name: Kimberly M. Barton
Notary Public, State of Virginia
My Commission expires: 9-30-15

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2012-002778

DEPARTMENT OF COMMERCE
AND CONSUMER AFFAIRS

2012 NOV 13 P 2:39

CONSUMER COMPLAINTS
SECTION

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE IN-STATE PRESCRIPTION DRUG WHOLESALER REGISTRATION OF OWENS & MINOR DISTRIBUTION, INC., REGISTRATION NO. WHI 6008,

Respondent.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Owens & Minor Distribution, Inc. ("Respondent") to resolve all matters pertaining to Board Case Number 2012-002778, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent, its registration as an in-state prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.
2. Respondent was originally registered as an in-state prescription drug wholesaler in the State of Colorado on December 7, 2006, being issued registration number WHI 6008, and has been so registered at all times relevant to this disciplinary action.
3. Respondent admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.
4. Respondent failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, 95 days transpired between October 28, 2011, the date the previous designated representative ceased the position, and February 1, 2012, the date the application and fee were received.
5. Respondent's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

EXHIBIT "1"

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drug.

12-22-802. Wholesaler license requirements

(2)(b) An applicant for a license shall pay any reasonable fee required by the accreditation body or the board and comply with any rules promulgated by the board;

(3)(VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board, including but not limited to the information in subsection (5) of this section; and

(5)(i) Update all of the information required in this part 8 whenever changes occur.

Regulation 15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

- (c) Be employed by the applicant in a full-time managerial position;
- (d) Be actively involved in and aware of the actual daily operation of the wholesaler;
- (e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;
- (f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."
- (g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;
- (h) Not have an felony convictions pursuant to federal, state, or local law; and
- (i) Undergo a background check as required by CRS 12-22-803.

(9) Wholesalers that distribute animal drugs exclusively are exempt from the requirements of 15.01.11(a)(8).

(b) Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

Regulation 15.01.14 Change of name, location, or ownership, or designated representative

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

6. The Board finds and concludes, and Respondent agrees, that based upon Respondent's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

7. **Fine with Surcharge.** Pursuant to §12-22-125.2(5), C.R.S., Respondent shall pay a fine of One Thousand Dollars and No Cents (\$1,000.00). Respondent 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 10% of this fine. Respondent shall therefore pay a total amount of One Thousand One Hundred Dollars and No Cents (\$1,100.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent submits this signed Final Agency Order to the Board.

8. **Compliance.** Respondent shall submit all future applications detailing a change in designated representative and fee to the Board within the time frame specified by Board rule or statute at the time of such designated representative change. position

9. **Other Requirements.** Respondent acknowledges and agrees that, as a condition of this Final Agency Order, Respondent shall:

- a. promptly pay all Respondent's own fees and costs associated with this Final Agency Order;
- b. comply fully with this Final Agency Order; and
- c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

10. **Advisements and Waivers.** Respondent enters into this Final Agency Order freely and voluntarily, whether or not Respondent has consulted with legal counsel. Respondent acknowledges its understanding that it has the following rights:

- a. to have 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 Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and
- d. to appeal this Final Agency Order.

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

11. **Acknowledgments.** Respondent has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent has consulted with legal counsel, that Respondent understands its legal consequences and agrees that none of its terms or conditions are unconscionable. Respondent is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent further acknowledges that it is not entering into this Final Agency Order under any duress.

12. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent to take all appropriate steps to comply fully with this Final Agency Order. Respondent acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board 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 Respondent's 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 to comply with all terms and conditions of this Final Agency Order.

13. **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 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.

14. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

15. **Effective Date.** This Final Agency Order shall become effective upon signature by a Board representative.