

LOUISIANA BOARD OF WHOLESALE DRUG DISTRIBUTORS

Board Meeting

MINUTES

September 22, 2009

AGENDA ITEM 1 - Call to Order

The meeting was called to order by Robert Broadus, Chairman, at approximately 9:40 am. The meeting was held in Baton Rouge, Louisiana at the administrative office of the Board located at 12046 Justice Avenue, Suite C.

AGENDA ITEM 2 - Roll Call

It was noted by Mr. Broadus that those members in attendance were Mr. Broadus, William Crates, Randall Brooks, Wayne Gremillion, and Michael Davis; Hersh Paul and Eric Vidrine was absent; also present were John Liggio, Kimberly Barbier, George Lovechio, and Celia Cangelosi. The Board members in attendance constituted a quorum. There were no guests in attendance. Mr. Michael Davis was introduced as the newest Board member appointed by the Governor on August 19, 2009. Mr. Davis replaces Mr. Andy Milligan who resigned from the Board in December 2008. Mr. Davis' term is currently set to expire on April 27, 2010 but should be extended to the full five year term (through 2014) upon his confirmation by the Legislature at that time. Mr. Davis was made welcome.

[Agenda Item 3a was deferred to the end of the meeting; the Board continued with Agenda Item 3b.]

[The Board returned to Agenda Item 3a after Agenda item 9b.]

AGENDA ITEM 3a - Disciplinary Matters/ Administrative Enforcement Action Hearing

The hearing for Docket No. 2009EA1029, EMCOC LLC dba USEMC (respondent), 2 Klarides Village Drive, #213, Seymour CT was opened and presided over by Mr. Broadus. It was noted that no representatives of the Respondent were present at the hearing. Ms. Cangelosi presented the Board's case against the Respondent. Ms. Cangelosi introduced Board exhibits numbered 1, 2, 3, 4, and 5. The exhibits were accepted into evidence. Ms. Cangelosi swore in witnesses - Mr. Lovechio, Ms. Barbier, and Mr. Liggio - who presented testimony.

Motion was made by Mr. Crates to enter into executive session for deliberation, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.

Motion was made by Mr. Crates to return to regular session, seconded by Mr. Davis, and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.

The Board Order for Docket No. 2009EA1029, EMCOC LLC dba USEMC, 2 Klarides Village Drive, #213, Seymour CT was read into record by Mr. Brooks. **Motion was made by Mr. Brooks to accept the Board Order as presented, seconded by Mr. Crates, and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.**

[The Board returned to Agenda Item 9c after conclusion of Agenda Item 3a.]

[Agenda Item 3b was discussed after Agenda Item 2.]

AGENDA ITEM 3b – Disciplinary Matters/ Enforcement Actions- Consent Agreements

Mr. Gremillion, Compliance Officer, presented consent agreements for review and approval as follows:

1. Mr. Gremillion presented the Consent Agreement executed for Docket No. 2009EA1001 for Afton Medical LLC, Santa Rosa CA; violation - wholesale distribution of legend drugs/devices in Louisiana without a license; Louisiana license no. 6322 issued July 2, 2009. **Motion was made by Mr. Crates to accept the consent agreement as executed and presented, seconded by Mr. Brooks and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.**
2. Mr. Gremillion presented the Consent Agreement executed for Docket No. 2009EA1007 for Coloplast Corp, Minneapolis MN; violation - wholesale distribution of legend drugs/devices in Louisiana without a license; Louisiana license no. 6307 issued June 19, 2009. **Motion was made by Mr. Crates to accept the consent agreement as executed and presented, seconded by Mr. Brooks and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.**
3. Mr. Gremillion presented the Consent Agreement executed for Docket No. 2009EA1009 for Curlin Medical Inc., Huntington Beach CA; violation - wholesale distribution of legend drugs/devices in Louisiana without a license; Louisiana license no. 6316 issued June 29, 2009. **Motion was made by Mr. Brooks to accept the consent agreement as executed and presented, seconded by Mr. Crates and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.**
4. Mr. Gremillion presented the Consent Agreement executed for Docket No. 2009EA1011 for GE Healthcare/ Datex Ohmeda Inc., Wauwatosa WI;

- violation - wholesale distribution of legend drugs/devices in Louisiana without a license; Louisiana license no. 6332 issued July 22, 2009. **Motion was made by Mr. Crates to accept the consent agreement as executed and presented, seconded by Mr. Davis and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.**
5. Mr. Gremillion presented the Consent Agreement executed for Docket No. 2009EA1015 for LMA North America Inc., San Diego CA; violation - wholesale distribution of legend drugs/devices in Louisiana without a license; Louisiana license is applied for and pending. **Motion was made by Mr. Crates to accept the consent agreement as executed and presented, seconded by Mr. Brooks and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.**
 6. Mr. Gremillion presented the Consent Agreement executed for Docket No. 2009EA1019 for Zevex Inc. dba MOOG, Salt Lake City UT; violation - wholesale distribution of legend drugs/devices in Louisiana without a license; Louisiana license no. 6315 issued September 15, 2009. **Motion was made by Mr. Brooks to accept the consent agreement as executed and presented, seconded by Mr. Crates and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.**
 7. Mr. Gremillion presented the Consent Agreement executed for Docket No. 2009EA1025 for MTS Concepts dba Trace Medical; violation - wholesale distribution of legend drugs/devices in Louisiana without a license; agreed to cease and desist distributing into Louisiana; will not apply for licensure - does not plan to do any more business in Louisiana. **Motion was made by Mr. Crates to accept the consent agreement as executed and presented, seconded by Mr. Davis and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, and Mr. Davis; AGAINST: None; ABSTAINED: Mr. Gremillion; ABSENT: Mr. Paul and Mr. Vidrine.**

Mr. Liggio presented information regarding the 29 enforcement action cases opened in April 2009. All cases have now been resolved - 21 cases have concluded with consent agreements with 18 of these applying for licensure; seven cases were closed with no action taken; and one case concluded in administrative hearing. No formal action on this item was taken. Mr. Liggio noted he found that the state of Colorado also goes after non-licensees but compared to our \$1,000 fine Colorado assesses a \$5,000 fine.

AGENDA ITEM 4 - Call for Additional Agenda Items [*for discussion in Agenda Item 9b*]

1. Mr. Liggio - Proposed Rule Amendment
2. Mr. Liggio - Resignation Letter
3. Mr. Liggio - Plumbers and Mechanical Contractors; Physical Therapist

4. Mr. Liggio – Board of Pharmacy Meeting Update; Food and Drug Unit Report

Motion was made by Mr. Gremillion to add the presented items to the agenda for discussion in Agenda Item 9b, seconded by Mr. Davis, and passed by voice vote – FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, Mr. Gremillion, and Mr. Davis; AGAISNT: None; ABSTAINED: None; ABSENT: Mr. Paul and Mr. Vidrine.

AGENDA ITEM 5a – Approval of Meeting Minutes/ June 16, 2009

The minutes of the June 16, 2009 Board meeting were presented. **Motion was made by Mr. Gremillion to dispense with full reading of the minutes and to accept the minutes as presented, seconded by Mr. Brooks, and passed by voice vote – FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, Mr. Gremillion, and Mr. Davis; AGAISNT: None; ABSTAINED: None; ABSENT: Mr. Paul and Mr. Vidrine.**

AGENDA ITEM 6a – Financial Matters/ Financial Statements

Financial information was presented for June, July, and August 2009. General discussion was held. No formal action on this item was taken.

AGENDA ITEM 6b – Financial Matters/ Attestation Report for Fiscal Year 2009

Mr. Liggio presented the 2009 Attestation report as prepared and submitted to the Legislative Auditor by Mr. Michael Glover, CPA. Mr. Liggio noted a discrepancy in the attestation findings pertaining to the requirement of a liability/ reserve account for the accrual of funds for anticipated OGB retiree benefits. This liability is to be shown in the accounting system as reserved moneys from retained earnings. This amount is calculated annually by OGB. When this account was created in the accounting system and the OGB calculated amount added it adjusted the budget for 2009 into a deficit. All adjustments recommended by Mr. Glover have been made into the accounting system. No formal action on this item was taken.

AGENDA ITEM 7a – Licensing Issues/ New Licenses Issued

A list of approximately 84 new licenses as issued by the Board office on behalf of the Board since the June 16, 2009 Board meeting was available for review. No formal action on this item was taken.

AGENDA ITEM 7b – Licensing Issues/ 2010 License Renewal Update

Mr. Liggio presented information and copies of revised forms proposed for the upcoming 2010 license renewal period. Mr. Liggio noted that after discussion between Ms. Barbier and himself regarding some of the problems encountered during the 2009 renewal period, Ms. Barbier took the initiative in revising the renewal procedure along with amending the renewal form and license certificate form. This revised renewal procedure is anticipated to make the renewal process progress more smoothly saving on employee time with preparation, mailings, and processing renewals; and savings in costs on supplies, postage, and copying. No formal action on this item was taken.

Mr. Liggio recommended that the Board present a recognition reward award of \$500 to Ms. Barbier for showing a readiness and ability in administration of her duties by her exemplary initiative and innovation in developing and implementing the new renewal ideas and improving upon the existing renewal procedures resulting in anticipated increase in productivity and saving to the Board. **Motion was made by Mr. Crates to reward Ms. Barbier with a \$500 award for recognition of her initiatives and innovations with regards to the license renewal process, seconded by Mr. Gremillion, and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, Mr. Gremillion, and Mr. Davis; AGAISNT: None; ABSTAINED: None; ABSENT: Mr. Paul and Mr. Vidrine.**

AGENDA ITEM 8a - Statutes and Rules/ Rule Promulgation Update

Mr. Liggio presented a copy of the final rule published in the August 20, 2009 *Louisiana Register* for rule amendments promulgated in LAC 46:XCI Chapters 1, 3, 5, 7, and 8. These rule amendments were effective August 20, 2009. Also presented were promulgation tracking reports for the rule amendments currently in promulgation for LAC 46:XCI.103; LAC 46:XCI.301 and 311; and LAC 46:XCI.901. No formal action on this item was taken.

AGENDA ITEM 9a - General/ License Verification Fee - VAWD

Mr. Liggio presented information regarding his contact with the director of the VAWD program with reference to the rule amendment for LAC 46:XCI.801.A.6 - license verification fee of \$15. After discussion, the Board instructed Board office personnel to accept payment of the required fee for license verifications per each verification submission only.

AGENDA ITEM 9b - General/ Additional Agenda Items (*added per Agenda Item 4*)

1. Proposed Rule Amendments

Mr. Liggio presented amendment to LAC 46:XCI.303.B. The Board reviewed and discussed the proposed amendment. **Motion was made by Mr. Davis to approve the amendment to LAC 46:XCI.303.B and authorize promulgation of the amendment, seconded by Mr. Crates, and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, Mr. Gremillion, and Mr. Davis; AGAISNT: None; ABSTAINED: None; ABSENT: Mr. Paul and Mr. Vidrine.**

2. Resignation Letter

Mr. Liggio presented a letter received via fax from Mr. Eric Vidrine noting his inability to attend this September 22, 2009 Board meeting and his intent to submit a resignation letter to the Governor. Mr. Vidrine's business has become such that he feels he does not have the time to devote proper attention to his duties as a member of the Board. The Board instructed Mr.

Liggio to contact the Louisiana Association of Wholesale Drug Distributors about finding a replacement for Mr. Vidrine's seat to be submitted to the Governor upon Mr. Vidrine's formal resignation.

3. Plumbers and Mechanical Contractors; Physical Therapist

Mr. Liggio presented information regarding his contact with a representative of the Louisiana Plumbers Board about plumbers, who hold special licenses issued by the Plumbers Board, and mechanical contractors both of which install gas systems in hospitals and/or other medical locations that require testing with medical grade nitrogen. Mr. Liggio had informed the Plumbers Board that plumbers and mechanical contractors do not have licensing authority to procure and possess legend (Rx) gases. Mr. Liggio had suggested to the Plumbers Board that the only way the plumbers or mechanical contractors can use legend gases for testing of installed gas systems is (1) to procure and possess the legend gas under the auspice of a practicing physician's license who is contracted by the plumber or mechanical contractor as their medical director; (2) the hospital or other medical facility can provide the legend gas to the contractor for use in testing of the gas system installed; or (3) the plumber or mechanical contract can have the hospital set up an account to purchase the gas (through the hospital) and the plumber or mechanical contractor will then pay the hospital's account themselves. The Board agreed with Mr. Liggio's assessment.

Mr. Liggio also presented information regarding independent physical therapists who need to procure and possess legend devices for use on patients to do their jobs. Mr. Liggio has an upcoming meeting set with an attorney representing one of the Board's wholesaler/distributor licensees and representatives of the Louisiana Physical Therapy Board. Mr. Liggio had previously informed these individuals that physical therapists do not have licensing authority to procure and possess legend drugs or devices and the only ways a physical therapist can procure and possess legend drugs or devices for use in their jobs would be (1) for the Physical Therapy Board to open their statutes and try to give the physical therapists such authorization on their license; (2) the physical therapist can procure and possess a legend drug or device from a prescription written to their patient by a licensed physician; or (3) the physical therapist can contract to work with a practicing physician as their medical director to procure and possess legend drugs and devices under the auspice of the physician's license. The Board agreed with Mr. Liggio's assessment.

4. Board of Pharmacy and Food & Drug Unit

Mr. Liggiro reported that he had met with Louisiana Board of Pharmacy representatives regarding entities dispensing medical gases and devices to the consumer/ patient by prescription. These entities may not be wholesalers and therefore would not be required to be licensed by the LBWDD since they are only dispensing product directly to the consumer/ patient. The Board of Pharmacy agreed to look into this matter as it may be these entities should be licensed by the Board of Pharmacy for dispensing to patients via a doctor's prescription.

The Board of Pharmacy had been told by a representative of the Food & Drug Unit of the Department of Health and Hospitals that when doing inspections of their permittees (warehouse sanitation) the Food & Drug Unit also looks at prescriptions for drugs, gases/oxygen and medical devices as dispensed by these permittees to the consumer/ patient. The Board of Pharmacy indicated they had a problem with this in that the Food & Drug Unit does not have authority with regards to dispensing by prescription.

The Food & Drug Unit recently informed Mr. Liggiro that they have reviewed their statutory authority and have found that they do not have the authority to require permitting of warehouses storing medical devices only; so they will no longer required medical device only warehouses to permit.

No formal action on this item was taken.

Mr. Liggiro presented information regarding a previous licensee, Advantage Dose, that did not renew its wholesale distributor license for 2009. The Board office had come across information that Advantage Dose had instituted a full product recall at the end of 2009 as ordered by the Food & Drug Administration. Advantage Dose operations had been shut down by the FDA due to GMP problems. Mr. Liggiro had contacted Morris & Dickson, a Louisiana licensee located in Shreveport LA, who owned Advantage Dose. Mr. Liggiro was informed by a Morris & Dickson representative that Advantage Dose is now defunct and no longer in existence and that Morris & Dickson has the authority to handle the recall and destruction of recalled product on their behalf. Mr. Liggiro had explained to the Morris & Dickson representative the proper procedures required for such actions. No formal action on this item was taken.

[The Board broke for lunch after Agenda Item 9b at approximately 12:25 pm.]

[The Board returned to regular session at approximately 12:55 pm and returned to Agenda Item 3a.]

[The Board returned to Agenda Item 9c after conclusion of Agenda Item 3a.]

AGENDA ITEM 9c - General/ Confirmation of Next Board Meeting Date

The date of Tuesday, December 15, 2009 was tentatively set for the next Board meeting.

AGENDA ITEM 10 - Executive Session

[Executive Session was held during Agenda Item 3a.]

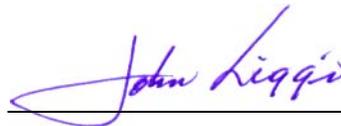
AGENDA ITEM 11 - Adjournment

There being no further business before the Board, **motion was made by Mr. Gremillion to adjourn the meeting, seconded by Mr. Crates, and passed by voice vote - FOR: Mr. Broadus, Mr. Crates, Mr. Brooks, Mr. Gremillion, and Mr. Davis; AGAINST: None; ABSTAINED: None; ABSENT: Mr. Paul and Mr. Vidrine.**

The meeting adjourned at approximately 2:00 pm.



Randall Brooks
Board Secretary/Treasurer



John Liggin
Executive Director

Approved and accepted by the full Board -

Date: December 15, 2009