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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. 3801

12
13 **GULF COAST PHARMACEUTICALS, INC.**
995 North Halstead Road
14 **Ocean Springs, MS 39564**

A C C U S A T I O N

15 **Permit No. OSD 4567**

16 **KENNETH BRYAN RITCHEY**
17 **75806 Overseas Hwy.**
Islamorada, FL 33036

18 **Certificate No. EXC 20162**

19 Respondents.
20

21 Complainant alleges:

22 **PARTIES**

- 23 1. Virginia Herold (Complainant) brings this Accusation solely in her official
24 capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.
- 25 2. On or about December 30, 2005, the Board of Pharmacy issued Wholesale Permit
26 Number OSD 4567 to Gulf Coast Pharmaceuticals, Inc., with Kenneth Ritchey as President
27 (Respondents). The Wholesale Permit was in full force and effect at all times relevant to the
28 charges brought herein and will expire on December 1, 2010, unless renewed.

1 (d) The board may initiate disciplinary proceedings to revoke or suspend
2 any probationary certificate of licensure for any violation of the terms and conditions
of probation. Upon satisfactory completion of probation, the board shall convert the
probationary certificate to a regular certificate, free of conditions.

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

6 6. Section 4301 of the Code states in pertinent part:

7 The board shall take action against any holder of a license who is guilty
8 of unprofessional conduct or whose license has been procured by fraud or
misrepresentation or issued by mistake. Unprofessional conduct shall include, but is
9 not limited to, any of the following:

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

11 (n) The revocation, suspension, or other discipline by another state of a
12 license to practice pharmacy, operate a pharmacy, or do any other act for which a
license is required by this chapter.

13 (o) Violating or attempting to violate, directly or indirectly, or assisting in
14 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
15 pharmacy, including regulations established by the board or by any other state or
federal regulatory agency.

16 (s) The clearly excessive furnishing of dangerous drugs by a wholesaler
17 to a pharmacy that primarily or solely dispenses prescription drugs to patients of
long-term care facilities. Factors to be considered in determining whether the
18 furnishing of dangerous drugs is clearly excessive shall include, but not be limited to,
the amount of dangerous drugs furnished to a pharmacy that primarily or solely
19 dispenses prescription drugs to patients of long-term care facilities, the previous
ordering pattern of the pharmacy, and the general patient population to whom the
20 pharmacy distributes the dangerous drugs. That a wholesaler has established, and
employs, a tracking system that complies with the requirements of subdivision (b) of
21 Section 4164 shall be considered in determining whether there has been a violation of
this subdivision. This provision shall not be interpreted to require a wholesaler to
22 obtain personal medical information or be authorized to permit a wholesaler to have
access to personal medical information except as otherwise authorized by Section 56
23 and following of the Civil Code.

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

28 ///

1 **DRUGS**

2 8. "Tramadol" is a generic of Ultram and is a dangerous drug as defined by Business
3 and Professions Code section 4022.

4 9. "Carisoprodol" is a generic of Soma and is a dangerous drug as defined by
5 Business and Professions Code section 4022.

6 10. "Butalbital/APAP/Caffeine" also known as Fioricet is a schedule III controlled
7 substance as designated by Health and Safety Code section 11056(c)(3).

8 **CAUSE FOR DISCIPLINE**

9 **(Unprofessional Conduct)**

10 11. Respondent Gulf Coast Pharmaceuticals, Inc., and Kenneth Ritchey (Respondents)
11 are subject to disciplinary action under section 4301(j), (n), (o) and (s), for unprofessional
12 conduct in that in on or about January 20, 2010. *In the Matter of the Complaint Against: Gulf*
13 *Coast Pharmaceuticals (99-W-2139)*, Before the State Board of Pharmacy State of Oklahoma;
14 Case No. 957, Respondent's license was revoked for failure to follow Oklahoma's laws
15 pertaining to the sale of dangerous drugs without having a monitoring program in place. A true
16 and correct copy of the Board's Decision is attached hereto as Exhibit A. The circumstances are
17 as follows:

18 12. On or about August 6 and 24, 2009, the Oklahoma Board of Pharmacy subpoenaed
19 records from Gulf Coast Pharmaceuticals to determine if Respondent was shipping Tramadol,
20 Butalbital/APAP/Caffeine (generic Fioricet) and Carisoprodol into the State of Oklahoma. The
21 records obtained by the Oklahoma Board showed the following:

22 a. Gulf Coast Pharmaceuticals did business with Elk River Pharmacy from December 5,
23 2008, through June 12, 2009. During that time, Gulf Coast Pharmaceuticals and Elk River
24 Pharmacy conducted eighty-three (83) transactions for the sale of 13,832,500 dosage units of
25 Carisoprodol, Tramadol, and Butalbital/APAP/Caffeine by Gulf Coast Pharmaceuticals to Elk
26 River Pharmacy. Gulf Coast Pharmaceuticals used forty-eight (48) invoices to sell the drugs to
27 Elk River Pharmacy at a cost of \$730,815.00, excluding shipping costs.

28 ///

1 b. Elk River Pharmaceuticals, Inc. purchased the following from Gulf Coast
2 Pharmaceuticals:

3 Butalbital/APAP/Caffeine	898,000 tablets
4 Carisoprodol 350mg	6,688,500 tablets
5 Tramadol 50 mg.	6,246,000 tablets

6 c. During a three-day span, December 9-11, 2008, Gulf Coast Pharmaceuticals, Inc.,
7 shipped a total of 1,695,000 dosage units of Carisoprodol, Tramadol, and
8 Butalbital/APAP/Caffeine to Elk River Pharmacy with a cost to Elk River Pharmacy of
9 \$69,438.00.

10 d. The records also showed that a large number of the same medications were shipped to
11 Eagle RX and White Eagle Distribution located at 111 White Eagle Drive in Ponca City, OK.
12 White Eagle RX is a tribal pharmacy that is licensed by the Ponca Tribe.

13 e. During the six (6) week period of June 18, 2009 to July 30, 2009, Gulf Coast
14 Pharmaceuticals, Inc., made sales to White Eagle Pharmacy totaling 2,208,000 dosage units of
15 Carisoprodol, Tramadol, and Butalbital/APAP/Caffeine. Gulf Coast Pharmaceuticals, Inc., used
16 thirteen (13) invoices to sell the drugs to White Eagle Pharmacy at a cost of \$250,470.00,
17 excluding shipping.

18 f. White Eagle Pharmacy purchased the following from June 18, 2009, to July 30, 2009:

19 Butalbital/APAP/Caffeine	275,000 tablets
20 Carisoprodol 350 mg	1,458,000 tablets
21 Tramadol 50 mg.	475,000 tablets

22 g. Neither Elk River Pharmacy nor White Eagle Pharmacy purchased any other drugs from
23 Gulf Coast Pharmaceuticals, Inc.

24 h. Gulf Coast Pharmaceuticals, Inc., admitted that it did not have a "suspicious order
25 monitoring program or a plan for diversion prevention" which meets the requirements of the
26 Oklahoma Board Rules. Gulf Coast Pharmaceuticals, Inc., also admitted that it did not have a
27 method to determine the type of clients it does business with (i.e., retail, hospital, internet, etc.).

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1 **PRAYER**

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

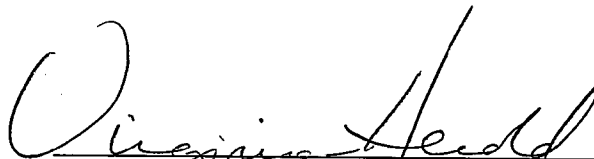
4 1. Revoking or suspending Wholesale Permit Number OSD 4567, issued to Gulf
5 Coast Pharmaceuticals, Inc.;

6 2. Revoking or suspending Certificate Number EXC 20162 to Kenneth Ritchey, as
7 the designated representative of Gulf Coast Pharmaceuticals;

8 3. Ordering Gulf Coast Pharmaceuticals, Inc. and Kenneth Ritchey to pay the Board
9 of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to
10 Business and Professions Code section 125.3; and,

11 4. Taking such other and further action as deemed necessary and proper.

12
13
14 DATED: 1/14/11



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

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Exhibit A
(Decision)

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

IN THE MATTER OF THE)
COMPLAINT AGAINST:)
)
Gulf Coast Pharmaceuticals (99-W-2139)) Case No. 957
995 N. Halstead Rd.)
Ocean Springs, MS 39564)

COMPLAINT

COMES NOW, Cindy Hamilton, D.Ph., Compliance Officer of the Oklahoma State Board of Pharmacy ("Board"), being first duly sworn upon oath, and alleges that Respondent, Gulf Coast Pharmaceuticals (99-W-2139), has violated provisions of the Oklahoma Pharmacy Act, 59 O.S. 2001 & Supp. 2008, §353.1 *et seq.*, in the manner set forth below in Counts 1-76.

Pursuant to 59 O.S. Supp. 2008, §353.26(A), the violations described below authorize the Board to take disciplinary action against Respondent which may include revocation or suspension of Respondent's license. Pursuant to 59 O.S. Supp. 2008, §353.7(11), the Board has the power to levy fines not to exceed One Thousand Dollars (\$1000.00) for each count for which any holder of a certificate, license or permit has been found guilty in a Board hearing. Also pursuant to 59 O.S. Supp. 2008, §353.7(11), the Board is empowered to impose (singly or in combination), any of the following corrective disciplinary sanctions: extra continuing education ("CE"), attendance at live CE programs, participation in a rehabilitation program for the impaired.

COUNT 1-62

Respondent has violated OAC 535:20-7-7.3(d) by failing to establish and maintain controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting.

1. Respondent is licensed with the Board as a non-resident wholesaler and has been so licensed since December 16, 2008. Respondent's facility address is Ocean Springs, Mississippi.

Kenneth Ritchey is listed as the President/CEO of Respondent.

2. By subpoena dated August 6 and 24, 2009, records were subpoenaed from Respondent to determine if Respondent was shipping Tramadol, Butalbital/APAP/Caffeine (generic Fioricet), and Carisoprodol into the State of Oklahoma. Records received by the Board from Respondent on August 20 and September 8, 2009, in response to this subpoena showed that Respondent was shipping a large number of medications to Elk River Pharmacy located at 25056 S. 655 Road in Grove, OK. Elk River Pharmacy is a tribal pharmacy that is licensed by the Seneca Cayuga Tribe.

3. Respondent did business with Elk River Pharmacy from December 5, 2008, through June 12, 2009. During that time, Respondent and Elk River Pharmacy conducted eighty-three (83) transactions for the sale of 13,832,500 dosage units of Carisoprodol, Tramadol, and Butalbital/Caffeine/APAP tablets by Respondent to Elk River Pharmacy. Respondent used forty-eight (48) invoices to sell these drugs with a cost to Elk River Pharmacy of \$730,815.00, excluding shipping costs.

4. Breaking it down, Elk River Pharmaceuticals purchased the following from Respondent during the six month period of December 5, 2008, through June 12, 2009:

Butalbital/Caffeine/APAP 898,000 tablets

Carisoprodol 350mg 6,688,500 tablets

Tramadol 50mg 6,246,000 tablets

5. During a three-day span, December 9-11, 2008, Respondent shipped a total of

1,695,000 dosage units of these same three (3) drugs to Elk River Pharmacy with a cost to Elk River Pharmacy of \$69,438.00.

6. Records received by the Board on August 20, 2009, in response to the subpoena dated August 6, 2009, also showed that a large number of these same medications were being shipped by Respondent to White Eagle Rx and White Eagle Distribution located at 111 White Eagle Drive in Ponca City, OK. White Eagle Rx is a tribal pharmacy that is licensed by the Ponca Tribe.

7. Respondent began doing business with White Eagle Pharmacy on June 18, 2009. During the six (6) week period June 18, 2009, through July 30, 2009, Respondent made sales to White Eagle Pharmacy totaling 2,208,000 dosage units of Carisoprodol, Tramadol, and Butalbital/Caffeine/APAP. Respondent used thirteen (13) invoices to sell these drugs with a cost to White Eagle Pharmacy of \$250,470.00, excluding shipping costs.

8. An itemized list of White Eagle Pharmacy's purchases from Respondent from June 18, 2009 to July 30, 2009 is as follows:

Butalbital/Caffeine/APAP	275,000 tablets
Carisoprodol 350mg	1,458,000 tablets
Tramadol 50mg	475,000 tablets

9. Neither Elk River Pharmacy nor White Eagle Pharmacy purchased any other drugs from Respondent. Respondent did not report these purchases to the Board.

10. When subpoenaed, Respondent admitted that it does not have a "suspicious order monitoring program or a plan for diversion prevention" which is required per Oklahoma rules. When asked per subpoena, Respondent also admitted that it does not have a method to determine the type of clients it does business with (i.e. retail, hospital, internet, etc.).

11. Medications listed on eleven (11) separate invoices were shipped to Elk River Pharmacy from December 5, 2008 to December 15, 2008, prior to Gulf Coast Pharmaceuticals becoming licensed with the Oklahoma Board of Pharmacy.

COUNT 63-73

Respondent has violated 59 O.S. Supp. 2008, § 353.18 A.1 by engaging in the sale of dangerous drugs without first procuring a license from the Oklahoma State Board of Pharmacy.

12. Paragraphs 1 through 11 are incorporated by reference.

COUNT 74

Respondent has violated OAC 535:25-7-6(a) and (b) by failing to recognize the State Board of Pharmacy as the governing body in the State of Oklahoma and reporting to them any violation of pharmacy laws or regulations that may come to its attention.

13. Paragraphs 1 through 11 are incorporated by reference.

COUNT 75

Respondent has violated OAC 535:25-9-3 by directly violating (or indirectly, through actions of another), or by assisting or abetting in the violation of, or by conspiring to violate, any provision of the Oklahoma Pharmacy Act, (59 O.S. 2001 & Supp. 2008, § 353 et seq.), the Prescription Drug Marketing Act (21 U.S.C., Sec. 331 et seq.), the Robinson-Patman Act (15 U.S.C., Sec. 13 et seq.), or federal, state and local laws and rules.

14. Paragraphs 1 through 11 are incorporated by reference.

COUNT 76

Respondent has violated OAC 535:25-7-3(a) and (b) by failing to conduct business at all times in

conformity with all federal, state and municipal laws and by failing to conduct itself at all times in a manner that will entitle it to the respect and confidence of the community in which it practices.

14. Paragraphs 1 through 11 are incorporated by reference.

Accordingly, the undersigned issues this Complaint on behalf of the Board on the 29th day of December, 2009.

Cindy Hamilton

CINDY HAMILTON, D.Ph.
COMPLIANCE OFFICER
OKLAHOMA STATE BOARD OF PHARMACY

STATE OF OKLAHOMA)
) ss
COUNTY OF OKLAHOMA)

SUBSCRIBED AND SWORN to before me on this 29th day of December, 2009.

Rhonda Jenkins
NOTARY PUBLIC

My Commission Expires:



RECEIVED

JAN 19 2010

BEFORE THE STATE BOARD OF PHARMACY
STATE OF OKLAHOMA

OK STATE BOARD
OF PHARMACY

IN THE MATTER OF THE)
COMPLAINT AGAINST:)

Gulf Coast Pharmaceuticals, Inc. ⁸⁸(~~89~~-W-2139)) Case No. 957
995 N. Halstead Rd.)
Ocean Springs, MS 39564)

AGREED FINDINGS OF FACT, CONCLUSIONS OF LAW AND FINAL ORDER

This matter came for hearing on January 20, 2010, before the Oklahoma State Board of Pharmacy ("Board"). Board members Gourley, Hampton, Osborn, Richards, Spoon, and Lassiter were present. President Spoon presided. Brinda K. White, Assistant Attorney General, served as prosecutor for the Board. Respondent was represented by legal counsel David Pomeroy and Lance E. Schreiter.

The Complaint in this matter is incorporated by reference into this Order.

The Board and Respondent hereby agree to the following Findings of Fact, Conclusions of Law and Final Order. Respondent has been advised of its right to contest the allegations against it, to cross-examine witnesses, and to present witnesses and evidence in its own defense. Respondent hereby knowingly and voluntarily waives these rights. In addition, Respondent understands and acknowledges that this document is a public record that must be provided to anyone requesting it. Furthermore, Respondent understands and acknowledges that this Order does not affect any criminal, civil or administrative charges that may be brought by any governmental entity other than the Board.

Should this Order not be accepted by the Board, Respondent agrees that neither the presentation of the Order to the Board nor the Board's consideration of the Order will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be

grounds for precluding the Board or any individual member of the Board from further participating in proceedings related to the matters set forth in the Order.

AGREED FINDINGS OF FACT

1. Respondent is licensed with the Board as a non-resident wholesaler and has been so licensed since December 16, 2008. Respondent's facility address is Ocean Springs, Mississippi. Kenneth Ritchey is listed as the President/CEO of Respondent.

2. By subpoena dated August 6 and 24, 2009, records were subpoenaed from Respondent to determine if Respondent was shipping Tramadol, Butalbital/APAP/Caffeine (generic Fioricet), and Carisoprodol into the State of Oklahoma. Records received by the Board from Respondent on August 20 and September 8, 2009, in response to this subpoena showed that Respondent was shipping a large number of medications to Elk River Pharmacy located at 25056 S. 655 Road in Grove, OK. Elk River Pharmacy is a tribal pharmacy that is licensed by the Seneca Cayuga Tribe.

3. Respondent did business with Elk River Pharmacy from December 5, 2008, through June 12, 2009. During that time, Respondent and Elk River Pharmacy conducted eighty-three (83) transactions for the sale of 13,832,500 dosage units of Carisoprodol, Tramadol, and Butalbital/Caffeine/APAP tablets by Respondent to Elk River Pharmacy. Respondent used forty-eight (48) invoices to sell these drugs with a cost to Elk River Pharmacy of \$730,815.00, excluding shipping costs.

4. Breaking it down, Elk River Pharmaceuticals, Inc. purchased the following from Respondent during the six month period of December 5, 2008, through June 12, 2009:

Butalbital/Caffeine/APAP	898,000 tablets
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Carisoprodol 350mg 6,688,500 tablets

Tramadol 50mg 6,246,000 tablets

5. During a three-day span, December 9-11, 2008, Respondent shipped a total of 1,695,000 dosage units of these same three (3) drugs to Elk River Pharmacy with a cost to Elk River Pharmacy of \$69,438.00.

6. Records received by the Board on August 20, 2009, in response to the subpoena dated August 6, 2009, also showed that a large number of these same medications were being shipped by Respondent to White Eagle Rx and White Eagle Distribution located at 111 White Eagle Drive in Ponca City, OK. White Eagle Rx is a tribal pharmacy that is licensed by the Ponca Tribe.

7. Respondent began doing business with White Eagle Pharmacy on June 18, 2009. During the six (6) week period June 18, 2009, through July 30, 2009, Respondent made sales to White Eagle Pharmacy totaling 2,208,000 dosage units of Carisoprodol, Tramadol, and Butalbital/Caffeine/APAP. Respondent used thirteen (13) invoices to sell these drugs with a cost to White Eagle Pharmacy of \$250,470.00, excluding shipping costs.

8. An itemized list of White Eagle Pharmacy's purchases from Respondent from June 18, 2009 to July 30, 2009 is as follows:

Butalbital/Caffeine/APAP 275,000 tablets

Carisoprodol 350mg 1,458,000 tablets

Tramadol 50mg 475,000 tablets

9. Neither Elk River Pharmacy nor White Eagle Pharmacy purchased any other drugs from Respondent. Respondent did not report these purchases to the Board.

10. Respondent admits that it does not have a "suspicious order monitoring program or

a plan for diversion prevention" which meets the requirements of Oklahoma rules. Respondent also admits that it does not have a method to determine the type of clients it does business with (i.e. retail, hospital, internet, etc.).

11. Medications listed on eleven (11) separate invoices were shipped to Elk River Pharmacy from December 5, 2008 to December 15, 2008, after application for license by Gulf Coast Pharmaceuticals, Inc. but prior to such license being issued by the Oklahoma Board of Pharmacy.

AGREED CONCLUSIONS OF LAW

1. The Board has jurisdiction over this matter and over the Respondent pursuant to 59 O.S. §§ 353.7 and 353.26.
2. Any Finding of Fact which is properly a Conclusion of Law is hereby incorporated by reference and vice versa.
3. Respondent has admitted to violating OAC 535:20-7-7.3(d) by failing to establish and maintain adequate controls and systems that protect against, detect, and document any instances of theft, diversion, or counterfeiting sufficient to comply with Oklahoma rules, as set forth in Counts 1-62 of the Complaint.
4. Respondent has admitted to violating 59 O.S. Supp. 2008, § 353.18 A.1 by engaging in the sale of drugs to pharmacies licensed by Indian tribes without first procuring a license from the Oklahoma State Board of Pharmacy, as set forth in Counts 63-73 of the Complaint.
5. Respondent has admitted to violating OAC 535:25-7-6(a) and (b) by failing to recognize the State Board of Pharmacy as the governing body in the State of Oklahoma and reporting to them any violation of pharmacy laws or regulations that may come to its attention, as set forth in Count 74 of the Complaint.

6. Respondent has admitted to violating OAC 535:25-7-3(a) and (b) by failing to conduct business at all times in conformity with the Oklahoma Pharmacy Act and rules promulgated thereunder and by failing to conduct itself at all times in a manner that will er.tit le it to the respect and confidence of the community in which it practices, as set forth in Count 75 of the Complaint.

7. Pursuant to 59 O.S. §353.7(11), for any registrant who violates any provision of the Oklahoma Pharmacy Act including the Board's rules, the Board has authority to levy fines not to exceed One Thousand Dollars (\$1000.00) for each violation; to reprimand, place on probation or suspend or revoke the license of a licensee; to require extra hours of continuing education and to require participation in a rehabilitation program for the impaired.

8. Based on the above Agreed Findings of Fact, Respondent is subject to disciplinary action pursuant to 59 O.S. §§ 353.7 and 353.26.

AGREED ORDER

1. Respondent, Gulf Coast Pharmaceuticals, Inc., holder of wholesaler license No. ~~99~~⁸⁸ W-2139, admits to guilt on the counts set forth above.

2. Respondent's license is hereby revoked.

3. Respondent is hereby fined Three Hundred Dollars (\$300.00) per count for a total fine of Twenty-two Thousand Five Hundred Dollars (\$22,500.00). The fine is due immediately.

4. Failure of Respondent to abide by any of the terms of this Agreed Order could result in further disciplinary action as allowed by the Oklahoma Pharmacy Act or the Board's rules.

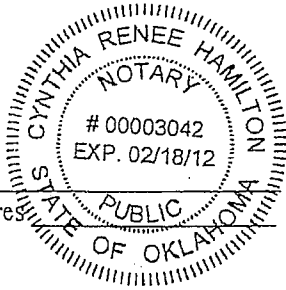
5. The Board retains jurisdiction over the instant case until all matters are finally resolved as set forth in this Order.

All participating members vote "Aye".

State of Oklahoma)

County of Pottawatomie) ss.

Subscribed and sworn before me on this the 20th day of January, 2010.



Cynthia Renee Hamilton
Notary Public

My Commission No. _____
My Commission Expires _____

AGREED AND APPROVED:

David Pomeroy
David Pomeroy, OBA #7209
Lance E. Schneider, OBA #19564
Attorneys for Respondent