STATE OF MISSOURI
MISSOURI BOARD OF PHARMACY

IN RE:	)
	)
WICKLIFFE PHARMACEUTICAL INC. d/b/a	)
WICKLIFFE VETERINARY PHARMACY	)
4340 Georgetown Road	)
Lexington, KY 40511	)
Permit No.: 2010015142	)

SETTLEMENT AGREEMENT BETWEEN MISSOURI BOARD OF PHARMACY AND WICKLIFFE PHARMACEUTICAL INC. d/b/a WICKLIFFE VETERINARY PHARMACY

Come Now Wickliffe Pharmaceutical Inc. d/b/a Wickliffe Veterinary Pharmacy ("Respondent" or the "Pharmacy") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its

permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document, as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 2010015142, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo

JOINT STIPULATION OF FACTS

1. The Board is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo[1], for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.

2. Wickliffe Pharmaceutical Inc. d/b/a Wickliffe Veterinary Pharmacy, located at 4340 Georgetown Road, Lexington, Kentucky ("Respondent"), is permitted by the Board under permit number 2010015142. Respondent's permit was at all times relevant herein current and active.

3. On or about January 15, 2015, the Board received notice that the United States Food and Drug Administration ("FDA") had taken action against Respondent based upon an investigation it had conducted.

[1] All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise stated.

4. On or about June 3, 2015, the Board issued a Letter of Warning to Respondent based on the information provided with the January 15, 2015 correspondence.

Kentucky Order

5. On or about November 5, 2015, the Board received notice that Respondent and the Kentucky Board of Pharmacy ("Kentucky Board") had executed an Agreed Order in October, 2015 (the "Kentucky Order").

6. In the Kentucky Order, the parties agreed that the following facts subjected Respondent to discipline under KRS 315.121:

a. On or about March 24, 2014, toltrazuril 227mg/pyrimethamine 340mg/ml paste was dispensed by Respondent and administered to two horses who subsequently died. Two tubes of this paste were tested for potency by the FDA with the results being: (1) Tube 1: pyrimethamine 82% of declared potency and toltrazuril 83% of declared potency; and (2) Tube 2: pyrimethamine 80% of declared potency and toltrazuril 82% of declared potency. The potency testing indicated that the compounded preparation was adulterated, in violation of KRS 217.055 and KRS 315.121(l)(h).

b. On or about March 28, 2014, toltrazuril 416mg/pyrimethamine 17mg/ml suspension was compounded by Respondent and administered to horses, two of which died and six of which were hospitalized. FDA lab testing of this product indicated pyrimethamine was 2380% of the declared potency and toltrazuril was 3.74% of the declared potency. The potency testing indicated that the compounded preparation was adulterated, in violation of KRS 217.055 and KRS 315.121(l)(h).

c. Technicians were performing functions without the immediate supervision of a pharmacist, in violation of 201 KAR 2:045, Section 3; and KRS 315.020(1).

d. There was no documented stability data to substantiate the extended beyond use date ("BUD") of various compounded sterile preparations ("CSPs") and compounded nonsterile preparations ("CNSPs"), in violation of KRS 315.121(l)(a).

e. Hazardous drugs were improperly stored and handled, in violation of KRS 315.121(l)(a).

f. A container of Phenylbutazone alfalfa flavor did not have a tight fitting lid, in violation of KRS 315.121(l)(a).

g. Respondent transferred Active Pharmaceutical Ingredients ("APIs") into smaller containers that were not identified with the component name, original supplier lot or control number, transfer date and expiration date, in violation of KRS 315.121(1)(a).

h. Some hazardous drugs had not been prepared in a Biological Safety Cabinet or Compounding Aseptic Containment Isolator in violation of KRS 315.121(l)(a).

i. Prescription labels did not always correctly identify the identity of the dispensing pharmacist, as required by 201 KAR 2:076, Section 4; and KRS 315.121 (l)(a) and (h).

j. Prescription labels did not contain adequate directions for use as required by 201 KAR 2:076, Section 4; and KRS 315.121(1)(a) and (h).

k. A person known as "Sylvia," who was not registered as a technician nor licensed as a pharmacist or pharmacist intern, made an over-the-counter product for another company in a nonsterile compounding room in the pharmacy, in violation of 201 KAR 2:100, Section 1; and KRS 315.121(1)(h).

l. Drug Utilization Review was not performed by a pharmacist on all prescriptions as required by 201 KAR 2:210, Section 4, and in violation of KRS 315.121(l)(h).

m. CSPs were dispensed utilizing a prescriber whose license and/or DEA number was/were not current, in violation of 201 KAR 2:076, Section 4(1)(f) and (g); and KRS 315.121(1)(a) and (h).

n. Respondent permitted prepared prescription medications to be left outside the pharmacy for pickup, in violation of 201 KAR 2:100, Section 4; and KRS 315.121(1)(a) and (h).

o. Respondent permitted someone to work for at the Pharmacy who was not appropriately registered with the Kentucky Board of Pharmacy in violation of KRS 315.121(1)(g).

7. KRS 315.121(1)(a) and (h) provides that the Kentucky Board may impose discipline against a permit holder as follows:

> (1) The board may refuse to issue or renew a license, permit, or certificate to, or may suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensee, permit holder, or certificate holder for the following reasons:
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> (a) Unprofessional or unethical conduct;
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> * * *
>
> (h) Being found by the board to be in violation of any provision of this chapter, KRS Chapter 217, KRS Chapter 218A, or the administrative regulations promulgated pursuant to these chapters;

8. In the Kentucky Order, Respondent was fined One Hundred Thousand Dollars ($100,000.00).

9. In the Kentucky Order, Respondent was placed on probation for a minimum period of three years from October 23, 2015.

Oregon Order

10. On or about March 1, 2016, the Board received notice that Respondent and the Board of Pharmacy of the State of Oregon (the "Oregon Board") executed a Consent Order on February 10, 2016 (the "Oregon Order").

11. In the Oregon Order, Respondent admitted that the facts alleged in Notice of Proposed Disciplinary Action filed by the Oregon Board were true, that Respondent violated the statutes and rules cited in the Notice and that cause existed under ORS § 689.405 for disciplinary action against Respondent.

12. The Notice alleged that the conduct subjecting Respondent to discipline in Kentucky constituted grounds for discipline in Oregon.

13. Respondent was placed on probation by the Oregon Board for the duration of its probation with the Kentucky Board.

Alabama Order

14. On or about March 18, 2016, the Board received notice that Respondent and the Alabama State Board of Pharmacy (the "Alabama Board") executed a Consent Order on March 7, 2016 (the "Alabama Order").

15. In the Alabama Order, Respondent was found guilty of violating the Alabama Pharmacy Practice Act based on the conduct set out in the Statement attached as Exhibit A to the Alabama Order and implicated by the Kentucky Order.

16. The permit issued to Respondent in Alabama was placed on probation for the same period of time as the probation of Respondent's pharmacy permit in the Kentucky.

17. Respondent also was required to pay an administrative fine of $10,000.00.

Colorado Order

18. On or about April 25, 2016, the Board received notice that Respondent and the Colorado State Board of Pharmacy (the "Colorado Board") had executed a Stipulation and Final Agency Order on April 18, 2016 (the "Colorado Order").

19. In the Colorado Order, Respondent admitted that its conduct which served as the basis for the Kentucky Agreed Order was true and that it constituted violations of the Colorado Revised Statutes and Colorado Board Rules.

20. The Colorado Order further stated that Respondent's conduct constituted grounds for disciplinary action Respondent as a prescription drug outlet.

21. Respondent was placed on indefinite probation by the Colorado Board concurrent with the Kentucky Order until Respondent submits documentation to the Colorado Board that Respondent's Kentucky pharmacy registration is active and unencumbered with the Kentucky Board.

Texas Order

22. On or about May 23, 2016, the Board received notice that Respondent and the Texas State Board of Pharmacy (the "Texas Board") had executed an Agreed Board Order on May 3, 2016 (the "Texas Order").

23. In the Texas Order, Respondent admitted that the conduct which served as the basis for the Kentucky Order was substantially similar to conduct proscribed by the Texas Pharmacy Act, the Texas Pharmacy Board Rules and the Texas Food, Drug and Cosmetic Act.

24. In the Texas Order, Respondent agreed to probation for three (3) years and a probation fee of $1,200.

Cause to Discipline in Missouri

25. Cause exists for Petitioner to take disciplinary action against Respondent's permit in Missouri under §338.055.2(5), (8) and (13), RSMo, which state in pertinent parts:

> 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
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> > (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
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> > * * *
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> > (8) Denial of licensure to an applicant or disciplinary action against an applicant or the holder of a license or other right to practice any profession regulated by this chapter granted by another state, territory, federal agency, or country whether or not voluntarily agreed to by the licensee or applicant, include, but not limited to, surrender of the license upon grounds for which denial or discipline is authorized in this state;
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> > * * *
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> > (13) Violation of any professional trust or confidence.

26. Cause to discipline Respondent exists under §338.055.2(5), RSMo, in that Respondent's conduct forming the basis for the Kentucky Order, the Oregon Order, the Alabama Order, the Colorado Order and the Texas Order constitutes incompetency, misconduct, gross negligence, dishonesty, fraud and/or misrepresentation in the performance of Respondent's functions or duties as a licensed pharmacy.

27. Cause exists to discipline Respondent exists under § 338.055.2(8), RSMo, in that the aforementioned disciplinary actions in Kentucky, Oregon, Alabama, Colorado and Texas is grounds for which discipline is authorized Missouri.

28. Cause to discipline Respondent exists under §338.055.2(13), RSMo in that the conduct forming the basis for the Kentucky Order, the Oregon Order, the Alabama Order, the Colorado Order and the Texas Order constitutes a violation of professional trust and confidence.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

A. Respondent's pharmacy permit number 2010015142 shall be placed on **PROBATION UNTIL OCTOBER 23, 2018.** The period of probation shall constitute the disciplinary period. The terms of discipline shall be as follows:

The following terms apply for the entire disciplinary period.

1. Respondent shall pay all required fees for licensing to the Board and shall renew its pharmacy license prior to October 31 of each licensing year.

2. Respondent shall comply with all provisions of Chapter 338, Chapter 195, and all applicable federal and state drug laws, rules and regulations and with all federal and state criminal laws. "State" here includes the State of Missouri and all other states and territories of the United States.

3. If requested, Respondent shall provide the Board a list of all licensed pharmacists employed by the Respondent, and the individuals' current home addresses and telephone numbers.

4. If, after disciplinary sanctions have been imposed, Respondent fails to keep its pharmacy license current, the period of unlicensed status shall not be deemed or taken as any part of the time of discipline so imposed.

5. Respondent shall report to the Board, on a preprinted form supplied by the Board office, once every six (6) months (due by each January 1 and July 1), beginning

with whichever date occurs first after this Agreement becomes effective, stating truthfully whether or not it has complied with all terms and conditions of its disciplinary order.

6. Respondent shall not serve as an intern training facility for Missouri interns.

7. Respondent shall make a representative of the pharmacy available for personal interviews to be conducted by a member of the Board or the Board of Pharmacy staff. Said meetings will be at the Board's discretion and may occur periodically during the disciplinary period. Respondent will be notified and given sufficient time to arrange these meetings.

8. Respondent's failure to comply with any condition of discipline set forth herein constitutes a violation of this disciplinary Agreement.

9. The parties to this Agreement understand that the Board of Pharmacy will maintain this Agreement as an open record of the Board as provided in Chapters 324, 338, 610, RSMo.

B. Upon the expiration of said discipline, Respondent's license as a pharmacy in Missouri shall be fully restored if all other requirements of law have been satisfied; provided, however, that in the event the Board determines that the Respondent has violated any term or condition of this Settlement Agreement, the Board may, in its discretion, after an evidentiary hearing, vacate and set aside the discipline imposed herein and may suspend, revoke, or otherwise lawfully discipline the Respondent.

C. No order shall be entered by the Board pursuant to the preceding paragraph of this Settlement Agreement without notice and an opportunity for hearing before the Board in accordance with the provisions of Chapter 536, RSMo.

D. If the Board determines that Respondent has violated a term or condition of this Settlement Agreement, which violation would also be actionable in a proceeding before the Administrative Hearing Commission or the circuit court, the Board may elect to pursue any lawful remedies or procedures afforded it and is not bound by this Settlement Agreement in its

determination of appropriate legal actions concerning that violation. If any alleged violation of this Settlement Agreement occurred during the disciplinary period, the Board may choose to conduct a hearing before it either during the disciplinary period, or as soon thereafter as a hearing can be held to determine whether a violation occurred and, if so, it may impose further discipline. The Board retains jurisdiction to hold a hearing to determine if a violation of this Settlement Agreement has occurred.

E. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.

F. Respondent hereby waives and releases the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs, and expenses, and compensation, including, but not limited to, any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. §1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

_____REQUESTS

___X___DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE AS A PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's license and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's license. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's license, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect 15 days after the document is signed by the Board's Executive Director.

RESPONDENT

WICKLIFFE PHARMACEUTICAL INC.
d/b/a WICKLIFFE VETERINARY
PHARMACY

By: _____
As Authorized Agent for
WICKLIFFE PHARMACEUTICAL INC.
d/b/a WICKLIFFE VETERINARY
PHARMACY

Printed: Jacqueline S. Bernard

Date: 11/15/16

PETITIONER

MISSOURI BOARD OF
PHARMACY

By: _____
KIMBERLY GRINSTON
Executive Director

Date: 11/30/16

NEWMAN, COMLEY & RUTH P.C.

By: _____
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Pharmacy