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BEFORE THE DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING

OF THE DEPARTMENT OF COMMERCE

OF THE STATE OF UTAH

IN THE MATTER OF THE LICENSES OF	)	
SKYLINE PHARMACY #2	)	**STIPULATION AND ORDER**
TO OPERATE AS A PHARMACY AND TO	)	
DISPENSE CONTROLLED SUBSTANCES	)	CASE NO. DOPL 2013- 128
IN THE STATE OF UTAH	)	

SKYLINE PHARMACY #2 ("Respondent") and the **DIVISION OF OCCUPATIONAL AND PROFESSIONAL LICENSING** of the Department of Commerce of the State of Utah ("Division") stipulate and agree as follows.

1 Respondent admits the jurisdiction of the Division over Respondent and over the subject matter of this action. David H Blackham is the owner and pharmacist-in-charge of Respondent pharmacy, is an agent for, and is authorized to enter into binding agreements on behalf of Respondent pharmacy

2 Respondent acknowledges that Respondent enters into this Stipulation knowingly and voluntarily.

3 Respondent understands that Respondent has the right to be represented by counsel in this matter and Respondent's signature below signifies that Respondent has either consulted with an attorney or Respondent waives Respondent's right to counsel in this matter.

4. Respondent understands that Respondent is entitled to a hearing before the State of Utah's Board of Pharmacy ("Board"), or other Division Presiding Officer, at which time Respondent may present evidence on Respondent's own behalf, call witnesses, and confront adverse witnesses. Respondent understands that by signing this document Respondent hereby waives the right to a hearing, the right to present evidence on Respondent's own behalf, the right to call witnesses, the right to confront adverse witnesses, and any other rights to which Respondent may be entitled in connection with said hearing. Respondent understands that by signing this document Respondent hereby waives all administrative and judicial review as set forth in Utah Code Ann. §§ 63G-4-301 through 63G-4-405, and Utah Administrative Code R151-46b-12 through R151-46b-15. Respondent and the Division hereby express their intent that this matter be resolved expeditiously through stipulation as contemplated in Utah Code Ann. § 63G-4-102(4).

5. Respondent waives the right to the issuance of a Petition and a Notice of Agency Action in this matter.

6. Respondent understands that this Stipulation and Order, if adopted by the Director of the Division, will be classified as a public document The Division may release this Stipulation and Order, and will release other information about this disciplinary action against Respondent's license, to other persons and entities.

7 Respondent admits the following facts are true

a Respondent pharmacy was first licensed to operate as a Class A retail closed pharmacy and to dispense controlled substances in the State of Utah on or about March 23, 1989.

b. On or about November 6, 2012, the Division received a complaint regarding abandoned prescription medications at a substance abuse treatment center which had moved to another location. The Division recovered the medications as evidence and found that many of the labels on patient's medications were from Respondent's pharmacy.

c. Interviews with current and former employees of the substance abuse treatment center revealed that Respondent would accept back medication for incineration, including controlled substances, from the substance abuse treatment center after their destruction with dish soap.

d On or about November 29, 2012, an inspection was performed at Respondent's pharmacy and the following violations were found:

i. The pharmacists on duty would not always identify themselves by license classification when requested by staff to take an "on hold" telephone call;

ii. References for CFR and Orange Book were not readily retrievable, but PIC did bookmark them while inspectors were present;

iii Controlled substance inventories did not indicate time of day the inventory was performed,

iv. A beyond use date was not clearly labeled as such on the patient label Inspectors found several compounding ingredients and prepared compounding products with missing expiration dates and outdates, which were pulled from the shelves;

v The pharmacy, on several occasions, dispensed controlled substance which were e-prescribed without obtaining a certification authority.

e. Respondent also engages in general compounding The following concerns were found during the compounding inspection·

i. No Material Safety Data Sheets (MSDS) were on site and available for inspection; therefore, inspectors could not tell if personnel had appropriate garbing material;

ii. The pharmacy did not have master worksheets on all formulas. Those that were present were missing evaluation and testing requirements, specific equipment required, and a sample label

iii. The prescription labels were missing the unique lot number, beyond use dates, and the phrase "this is a compounded preparation;"

iv. Expiration dates for compounded medications found on the shelf of the pharmacy contained no supporting documentation—e g no stability information and no sterility information-- and several expiration dates exceeded the six month limit,

v The pharmacy did not have any standard operating procedures to review;

vi. The pharmacy did not have ongoing quality control program to monitor and evaluate personnel and compliance with USP-NF 795;

vii The pharmacy prepared a prescription for a commercially available medication-- Roxicodone 5mg/5ml in November 2012. The pharmacist in charge reported that the practitioner was contacted and authorization was received after all pharmacies in a 35 mile radius were contacted for availability

f Respondent admitted to Division inspectors that from approximately January 2011 to May 2011 Respondent dispensed a limited formulary and a limited day's supply (one to two days per prescriptions) to the local substance abuse treatment center to be dispensed in weekend admissions of new patients to the treatment center. At such time a replacement supply would be restocked at the addiction treatment center in the pharmacy. The formulary dispensing was never reported to the Utah Controlled Substance Database

g Respondent admitted that the pharmacy has accepted destroyed medication back from patients for incineration. The pharmacist in charge reported that only medications dissolved with dish soap in a plastic container would be accepted. The pharmacist in charge was unsure if he has accepted back controlled

substances or compounded medications because he did not inspect for specifics, only that they had been destroyed by dish soap addition.

8. Respondent admits that Respondent's conduct described above is unprofessional conduct as defined in Utah Code Ann § 58-1-501(2)(a), § 58-17b-502(14), § 58-17b-602(5)(h), § 58-17b-603(2), Utah Administrative Code R156-17b-502(2), (6), (9), (11), and (16); R156-17b-603(1) and (3); R156-17b-605(1)(f), R156-17b-614(a)(1), (e)(3) and (4), (i), and (j)(5); R156-37-502(2) and R156-37-606, and 21 CFR 1307.21 and 21 CFR 1311, and unlawful conduct as defined in Utah Code Ann. § 58-1-501(d) Respondent agrees by engaging in such conduct the Division is justified in taking disciplinary action against Respondent's license pursuant to Utah Code Ann § 58-1-401(2)(a) and (b) Respondent agrees that an Order, which constitutes disciplinary action against Respondent's license by the Division pursuant to Utah Administrative Code R156-1-102(6) and Utah Code Ann § 58-1-401(2). may be issued in this matter providing for the following action against Respondent's license.

(1) Respondent's licenses shall be revoked. Those revocations shall be immediately stayed. Respondent's licenses shall be subject to a term of probation for a period of three years. The period of probation shall commence on the date the Division Director signs the attached Order. During the period of probation Respondent's license shall be subject to all of the following terms and conditions. If the Board or Division later deems any of the conditions unnecessary such deletions may be made by an amended order issued unilaterally by the Division

a. **Meeting with Compliance Specialist.** Respondent's pharmacist in charge (PIC) shall meet with the Division Compliance Specialist Connie Call within two weeks of the effective date of this Order to schedule a meeting for the purpose of discussing the terms and conditions of this Stipulation and Order. An appointment with Ms Call can be scheduled by contacting her by phone at (801) 530-6295 or by email at ccall@utah.gov

b. **Written Practice Plan.** Respondent shall submit a written practice plan along with policies and procedures for compounding, to the Division and Board, within 30 days of the effective date of this Stipulation and Order The Board will review the practice plan, policies, and procedures for compounding If the Board does not approve the practice plan at the first Board meeting, Respondent will cease all compounding until the Board approves a practice plan submitted by Respondent.

c **Meetings with the Board.** Respondent's pharmacist-in-charge (PIC) shall meet with the Board at the Board's next scheduled meeting following the signing of the accompanying Order The PIC shall meet with a Division staff person prior to the PIC's first meeting with the Board to review this agreement For the remainder of the duration of probation, the PIC shall meet with the Board or with the Division, as directed by the Division, annually or at such other greater or lesser frequency as the Division may direct.

d. **Compliance with Laws Governing Pharmacies.** Respondent shall come into compliance with all statutes and administrative rules governing pharmacies in the State of Utah within 60 days of the date of this Stipulation and Order.

e. **Inspection** Respondent shall undergo an inspection conducted by a Division approved inspector within the six months of the effective date of this Stipulation and Order. Before probation shall be terminated, Respondent shall undergo an inspection conducted by a Division-approved inspector and be found in full compliance with the inspection.

f **Payment of Costs.** Failure of Respondent to pay the costs associated with this Stipulation and Order constitutes a violation of the Stipulation and Order.

g. **Active License.** Respondent shall maintain active licenses at all times during the period of this agreement.

h. **Address Changes** Respondent shall immediately notify the Division in writing of any change in Respondent's residential or business address

9. Upon approval by the Director of the Division, this Stipulation and Order shall be the

final compromise and settlement of this non-criminal administrative matter Respondent acknowledges that the Director is not required to accept the terms of this Stipulation and Order and that if the Director does not do so, this Stipulation and the representations contained therein shall be null and void, except that the Division and the Respondent waive any claim of bias or prejudgment they might otherwise have with regard to the Director by virtue of his having reviewed this Stipulation, and this waiver shall survive such nullification.

10. Respondent shall abide by and comply with all applicable federal and state laws, regulations, rules and orders related to the Respondent's licensed practice If the Division files a Petition alleging that Respondent has engaged in new misconduct or files an Order to Show Cause Petition alleging that Respondent has violated any of the terms and conditions contained in *this Stipulation and Order, the period of Respondent's probation shall be tolled during the period* that the Petition or Order to Show Cause Petition has been filed and is unresolved.

11. This document constitutes the entire agreement between the parties and supersedes and cancels any and all prior negotiations, representations, understandings or agreements between the parties regarding the subject of this Stipulation and Order There are no verbal agreements that modify, interpret, construe or affect this Stipulation. Respondent agrees not to take any action or make any public statement, that creates, or tends to create, the impression that any of the matters set forth in this Stipulation and Order are without factual basis. A public statement includes statements to one or more Board members during a meeting of the Board Any such action or statement shall be considered a violation of this Stipulation and Order However, Respondent reserves the right to discuss any and all mitigating circumstances, as Respondent sees fit, concerning Respondent's admissions with the Board

12. The accompanying Order becomes effective immediately upon the approval of this Stipulation and signing of the Order by the Division Director. Respondent shall comply with all the terms and conditions of this Stipulation immediately following the Division Director's signing of the Order page of this Stipulation and Order. Respondent shall comply with and timely complete all the terms and conditions of probation. If a time period for completion of a term or condition is not specifically set forth in the Stipulation and Order, Respondent agrees that the time period for completion of that term or condition shall be set by the Division or Board Failure to comply with and timely complete a term or condition shall constitute a violation of the Stipulation and Order and may subject Respondent to revocation or other sanctions.

13. If Respondent violates any term or condition of this Stipulation and Order, the Division may take action against Respondent, including imposing appropriate sanction, in the manner provided by law. Such sanction may include revocation or suspension of Respondent's license, or other appropriate sanction.

14. Respondent understands that the disciplinary action taken by the Division in this Stipulation and Order may adversely affect any license that Respondent may possess in another state or any application for licensure Respondent may submit in another state.

15 Respondent has read each and every paragraph contained in this Stipulation and Order. Respondent understands each and every paragraph contained in this Stipulation and Order Respondent has no questions about any paragraph or provision contained in this Stipulation and Order.

DIVISION OF OCCUPATIONAL &
PROFESSIONAL LICENSING

BY: _____
RICHARD J. OBORN
Bureau Manager

DATE: 3/26/13

RESPONDENT

BY: _____
DAVID H. BLACKHAM

DATE: 3/20/13

JOHN E. SWALLOW
ATTORNEY GENERAL

BY: _____
L. MITCHELL JONES
Counsel for the Division

DATE: 26 Mar 2013

ORDER

THE ABOVE STIPULATION, in the matter of **SKYLINE PHARMACY #2**, is hereby approved by the Division of Occupational and Professional Licensing, and constitutes my Findings of Fact and Conclusions of Law in this matter. The issuance of this Order is disciplinary action pursuant to Utah Administrative Code R156-1-102(6) and Utah Code Ann. § 58-1-401(2). The terms and conditions of the Stipulation are incorporated herein and constitute my final Order in this case.

DATED this 28th day of March, 2013

DIVISION OF OCCUPATIONAL AND
PROFESSIONAL LICENSING

MARK B. STEINAGEL
Director

Investigator Brittany Hutsch