BEFORE THE ALCOHOLIC BEVERAGE CONTROL APPEALS BOARD OF THE STATE OF CALIFORNIA

AB-9902

File: 20-517233; Reg: 19089533

ABDULMALIK SALEH HARBI and AHMED MOHAMED SALEH, dba La Loma #11 1313 Road 2 San Pablo, CA 94806, Appellants/Licensees

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DEPARTMENT OF ALCOHOLIC BEVERAGE CONTROL, Respondent

Administrative Law Judge at the Dept. Hearing: David W. Sakamoto

Appeals Board Hearing: October 15, 2021 Telephonic

ISSUED OCTOBER 19, 2021

Appearances: Appellants: Michael G. Zatkin, as counsel for Abdulmalik Saleh

Harbi and Ahmed Mohamed Saleh,

Respondent: Sean D. Klein, as counsel for the Department of Alcoholic Beverage Control.

OPINION

Abdulmalik Saleh Harbi and Ahmed Mohamed Saleh, doing business as La

Loma #11 (appellants), appeal from a decision of the Department of Alcoholic Beverage

Control (Department)¹ suspending their license for 25 days (with 15 days stayed for a

period of two years, provided no further cause for discipline arises during that time),

because appellants conducted a pharmacy without a license, knowingly operated a

¹ The decision of the Department, dated March 17, 2021, is set forth in the appendix.

business that attempted to dispense or furnish dangerous drugs without a license to do so, and offered for sale a drug that was misbranded.

FACTS AND PROCEDURAL HISTORY

Appellants' off-sale beer and wine license was issued on January 19, 2012.

There is no record of prior disciplinary action against the license.

On November 25, 2019, the Department instituted a three-count accusation against appellants as follows:

Count 1: On or about June 13, 2019, respondent-licensee(s) conducted a pharmacy as defined by Business and Professions Code Section 4037(a), at the above licensed location, without a license issued by the California State Board of Pharmacy, in violation of Business and Professions Code Section 4110.

Count 2: On or about June 13, 2019, respondent-licensee, at the above premises, knowingly owned, operated or managed a business that attempted to dispense or furnish dangerous drug(s) as defined by Business and Professions Code Section 4022(a), to wit: Vitacilina, without a license to dispense or furnish such dangerous drug(s), in violation of Health and Safety Code Section 11352.l(b) and Penal Code section 664.

<u>Count 3</u>: On or about June 13, 2019, respondent-licensee, at said premises, held or offered for sale, a drug or device that was misbranded, to-wit: Vitacilina, in violation of Health and Safety Code Section 111440.

(Exh. 1.)

At the administrative hearing held on December 3, 2020, documentary evidence was received and testimony concerning the violation charged was presented by Dr.

Ushma Vora (hereinafter Dr. Vora), a licensed California pharmacist and a clinical drug information coordinator for the Contra Costa Regional Medical Center, and by Department Agent Anthony Sam.

Moad Harbi, brother of co-licensee Abdulmalik Saleh Harbi, who helps out at the licensed premises, and David Hayer, corporate officer of Pac Bev, Inc., testified on behalf of appellants.²

Testimony established that on June 13, 2019, the licensed premises was visited for inspection by Department Agents Sam and Cook and Contra Costa County Environmental Health Department Inspectors Doser and Lopez. The licensed premises operates as a meat market and grocery store.

Near the sales counter, the agents observed four small green boxes of a product labeled "Vitacilina." (Exh. 3; 5.) The printing on the boxes was in Spanish and each box cost \$3.49. (Finding of Fact (FF) ¶ 5.) The agents learned via a phone call with Dr. Vora that the Vitacilina found by the agents requires a prescription to dispense because it contains retinol as an active ingredient in combination with the antibiotic neomycin. (FF ¶ 4.) Dr. Vora testified that Vitacilina is not FDA approved for over-the-counter sales but that it is not a narcotic (RT 17; 27). She also testified that retinol alone (not in combination with neomycin) would not require a prescription. (RT 39-40.) The agents determined that the premises does not hold a pharmacy license after consulting the Department of Consumer Affairs website. (RT 76.) The four boxes of Vitacilina were seized.

The shelves containing the Vitacilina are stocked by a third-party vendor, Safegate International, which provides the premises with health-related products.

² This case was heard concurrently with the hearing regarding the accusation Against Pac Bev, Inc. under file 21-602630 and registration 20089682, because the matters shared common issues of law and fact. Separate decisions were issued in each matter.

Safegate provides the shelving for those products and independently determines which products should be provided on those shelves. (FF ¶ 8.)

Moad Harbi testified that he manages another premises, Evergreen Produce, and helps manage his brother's store — on average, two to three hours per week, without compensation. (RT 106; 121-122.) There was no evidence or testimony offered to establish that he is an employee of La Loma #11. While working at his own premises, his shelves were inspected for non-compliant products, but the Vitacilina he carried was permitted. The inspecting agents told him they were there to let licensees know "what was allowed and what was not allowed and to kind of help us out to determine the difference between each one." (RT 109.) He was given a document informing him that certain medicines from Mexico are not allowed. (RT 108.) He assumed that all premises were being similarly informed, and therefore did not share the document with his brother. (*Id.* at 109.)

No evidence was offered that appellants were given similar notice. No directive or warning about Vitacilina was distributed to appellants prior to the inspection by Department agents and Environmental Health inspectors.

The administrative law judge (ALJ) issued a proposed decision on January 13, 2021, sustaining all three counts of the accusation and recommending that the license be suspended for 25 days for each count (with 15 days suspended for a period of two years, provided no further cause for discipline arises during that time) with the suspensions to run concurrently. The Department adopted the proposed decision in its entirety on March 11, 2021 and a certificate of decision was issued six days later.

Appellants then filed a timely appeal making the following contentions: (1) there was insufficient evidence to support count 1 of the accusation because appellants were

not conducting a pharmacy as defined by Business & Professions Code section 4037(a); (2) there was insufficient evidence to support count 2 of the accusation that respondents "knowingly" attempted to dispense prescription strength Vitacilina; (3) count 3 should be reversed because La Loma # 11 was not the effective seller of the four tubes of prescription Vitacilina; and (4) the penalty is excessive and should be mitigated.

DISCUSSION

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COUNT 1

Appellants contend there is insufficient evidence to support count 1 of the accusation because appellants were not conducting a pharmacy as defined by Business & Professions Code section 4037(a), which defines a pharmacy as follows:

"Pharmacy" means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail.

(AOB at p. 7; Bus. and Prof. Code § 4037(a).) Accordingly, they maintain they are not in violation of section 4110 which states, in relevant part, "No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. . . ." (Bus. and Prof. Code § 4110(a).)

This Board is bound by the factual findings in the Department's decision so long as those findings are supported by substantial evidence. The standard of review is as follows:

We cannot interpose our independent judgment on the evidence, and we must accept as conclusive the Department's findings of fact. [Citations.] We must indulge in all legitimate inferences in support of the Department's determination. Neither the Board nor [an appellate] court may reweigh the evidence or exercise independent judgment to overturn the Department's factual findings to reach a contrary, although perhaps equally reasonable, result. [Citations.] The function of an appellate board or Court of Appeal is not to supplant the trial court as the forum for consideration of the facts and assessing the credibility of witnesses or to substitute its discretion for that of the trial court. An appellate body reviews for error guided by applicable standards of review.

(Dept. of Alcoholic Bev. Control v. Alcoholic Bev. Control Appeals Bd. (Masani) (2004) 118 Cal.App.4th 1429, 1437 [13 Cal.Rptr.3d 826].)

When findings are attacked as being unsupported by the evidence, the power of this Board begins and ends with an inquiry as to whether there is substantial evidence, contradicted or uncontradicted, which will support the findings. When two or more competing inferences of equal persuasion can be reasonably deduced from the facts, the Board is without power to substitute its deductions for those of the Department—all conflicts in the evidence must be resolved in favor of the Department's decision.

(Kirby v. Alcoholic Bev. Control Appeals Bd. (1972) 25 Cal.App.3d 331, 335 [101 Cal.Rptr. 815]; Harris v. Alcoholic Beverage Control Appeals Board (1963) 212 Cal.App.2d 106, 112 [28 Cal.Rptr.74].)

Therefore, the issue of substantial evidence when raised by an appellant, leads to an examination by the Appeals Board to determine, in light of the whole record, whether substantial evidence exists, even if contradicted, to reasonably support the Department's findings of fact, and whether the decision is supported by the findings. The Appeals Board cannot disregard or overturn a finding of fact by the Department merely because a contrary finding would be equally or more reasonable. (Cal. Const. Art. XX, § 22; Bus. & Prof. Code § 23084; Boreta Enterprises, Inc. v. Dept. of Alcoholic Bev. Control (1970) 2Cal.3d 85, 94 [84 Cal.Rptr. 113]; Harris, supra, at p. 114.)

The ALJ made the following findings in regards to this count:

- 1. There was sufficient evidence to sustain count 1 that respondent conducted an unlicensed pharmacy. Section 4110 states no one may conduct a pharmacy without a license. Section 4037, subdivision (a), states: "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail." Section 4022, subdivision (c) defines a "dangerous drug" as: "(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."
- 2. In this instance, respondent's premises was not licensed by the California State Board of Pharmacy. However, it stored and possessed the Vitacilina in order to furnish, sell or dispense it at retail. The Vitacilina herein was a "dangerous drug" because it had retinol as an active ingredient and that such formulation/combination of neomycin and retinol could only be formulated and dispensed by a licensed pharmacist in accordance with a prescription. That formulation was not an existing approved FDA non-prescription/over-the counter drug/medicine. As the licensed premises was not a licensed pharmacy, respondent could not lawfully possess or store that formulation of Vitacilina or furnish, sell, or dispense it because it was a dangerous drug.

Determination of Issues, ¶¶ 1-2.)

Appellants maintain:

In the instant case, there was no evidence or testimony at the hearing that La Loma #11 is a place where the profession of pharmacy is or was practiced. There was no evidence or testimony that La Loma #11 is a place where prescriptions were or are compounded (mixed). There was no evidence or testimony that any chemist, pharmacist, drug maker, technician or prescription filler worked at the premises. There was no evidence or testimony of the presence of any laboratory. There was no evidence or testimony that any drug-making or chemical mixing, or lab equipment or chemicals were present at the premises.

(AOB at p. 8.)

In short, appellants contend that by the plain language of section 4037(a), to be a pharmacy, the premises must be a place where the profession of pharmacy is

practiced and must also be where prescriptions are compounded. Appellants' grocery/convenience store, they contend, is not such a place. We disagree.

As the ALJ notes, appellants possessed and displayed for sale a product which requires a prescription — without the proper licensing to do so. This, by definition, is the sale of a dangerous drug in violation of section 4110.

It is not necessary, as appellants suggest, that one have a laboratory or specially-trained pharmacist on the premises to violate this statute. Indeed, as the Department points out in its reply brief, if taken to its logical extreme, all that would be necessary to avoid liability for the sale of prescription drugs without a license would be to make sure there was no laboratory or pharmacist on site. Clearly, this is not the intent of section 4110.

Count 1 must be sustained.

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COUNT 2

Appellants contend there was insufficient evidence to support count 2 of the accusation that respondents "knowingly" attempted to dispense prescription strength Vitacilina. (AOB at p. 9.)

The ALJ made the following findings on this count:

3. As to Count 2, there was sufficient evidence to establish respondent or his agents or employees violated or attempted to violate Health and Safety Code section 11352.1. Subdivision (b) of that section states, in part: " . . . Notwithstanding Section 4321 of the Business and Professions Code, and in addition to any other penalties provided by law, any person who . . . knowingly owns, manages, or operates a business that dispenses or furnishes a dangerous drug or dangerous device or any material represented as, or presented in lieu of, any dangerous drug or dangerous device, as defined in Section 4022 of the Business and Professions Code without a license to dispense or furnish these products, shall be guilty of a misdemeanor."

4. In this matter, Moad, who regularly worked part-time at respondent's premises, was specifically warned about one month prior to the agents/inspectors' June 13, 2019, visit to the licensed premises that some forms of Vitacilina made in Mexico were illegal or improper to dispense or sell at retail. He received that warning specifically from some agents/inspectors. However, because the agents/inspectors told him they were going to visit other businesses in the area, he assumed respondent's licensed premises would be visited in the future. Therefore, he never told the respondents herein, one being his brother - Abdulmalik, about the warning he received concerning Vitacilina. However, that warning provided Moad with sufficient information that he knew or should have known the Vitacilina offered at respondent's premises was an illegal medication that should not be dispensed at respondent's licensed premises that was not a licensed pharmacy. The Vitacilina was on respondent's merchandise shelves and respondent's manager confirmed to the agents is was offered for sale. As respondent is generally chargeable with the knowledge and acts of its employees or agents, there was sufficient evidence to sustain Count 2 of the accusation in that, at minimum, respondent was knowingly attempting to sell a prescription medication without a pharmacy license.

(Findings of Fact, ¶¶ 3-4.)

The courts have consistently found that a licensee may be held liable for the actions of his agents or employees.

The owner of a liquor license has the responsibility to see to it that the license is not used in violation of law and as a matter of general law the knowledge and acts of the employee or agent are imputable to the licensee. [Citation.]

(Harris v. Alcoholic Beverage Control Appeals Board (1961) 197 Cal.App.2d 172, 180 [17 Cal.Rptr. 315].)

The question in this matter, then, is whether helping to manage his brother's store for two to three hours a week, without compensation, makes Moad Harbi an agent of appellants.

Generally, the existence of an agency relationship and the extent of the authority of an agent are questions of fact, and the burden of proving agency, as well as the scope of the agent's authority, rests upon the party asserting the existence of the agency and seeking to charge the principal with the representation of the agent.

(Inglewood Teachers Ass'n v. Public Employment Relations Bd. (1991) 227 Cal.App.3d 767, 780 [278 Cal.Rptr. 228].)

The ALJ found:

7. Moad Harbi (hereafter Moad) testified that although he primarily manages a store known as Evergreen Produce, **he also helped his brother**, co-licensee/respondent Abdulmalik Saleh Harbi (hereafter Abdulmalik), **manage the licensed premises**. . . .

(Findings of Fact, ¶ 7, emphasis added.) Similarly, Moad Harbi testified that he helps manage his brother's store. (RT 106.) The ALJ goes on to find:

4. In this matter, Moad, who regularly worked part-time at respondent's premises, was specifically warned about one month prior to the agents/inspectors' June 13, 2019, visit to the licensed premises that some forms of Vitacilina made in Mexico were illegal or improper to dispense or sell at retail. He received that warning specifically from some agents/inspectors. However, because the agents/inspectors told him they were going to visit other businesses in the area, he assumed respondent's licensed premises would be visited in the future. Therefore, he never told the respondents herein, one being his brother - Abdulmalik, about the warning he received concerning Vitacilina. However, that warning provided Moad with sufficient information that he knew or should have known the Vitacilina offered at respondent's premises was an illegal medication that should not be dispensed at respondent's licensed premises that was not a licensed pharmacy. The Vitacilina was on respondent's merchandise shelves and respondent's manager confirmed to the agents is was offered for sale. As respondent is generally chargeable with the knowledge and acts of its employees or agents, there was sufficient evidence to sustain Count 2 of the accusation in that, at minimum, respondent was knowingly attempting to sell a prescription medication without a pharmacy license.

(Determination of Issues, ¶ 4, emphasis added.) In short, Moad was determined by the ALJ to be appellants' agent, even though he volunteered his time, because by his own

testimony he helped his brother manage the premises and he was personally warned by Department agents while working at another premises that some forms of Vitacilina made in Mexico were illegal to sell.

It is well-settled in alcoholic beverage case law that an agent or employee's on-premises knowledge and misconduct is imputed to the licensee/employer. (See *Yu v. Alcoholic Bev. Control Appeals Bd.* (1992) 3 Cal.App.4th 286, 295 [4 Cal.Rptr.2d 280]; *Kirby v. Alcoholic Bev. Control Appeals Bd.* (1973) 33 Cal.App.3d 732, 737 [109 Cal.Rptr. 291].)

In regards to the imputation of liability to the licensee and the knowledge required to establish responsibility, the *Laube* court noted:

A licensee has a general, affirmative duty to maintain a lawful establishment. Presumably this duty imposes upon the licensee the obligation to be diligent in anticipation of reasonably possible unlawful activity, and to instruct employees accordingly.

(Laube v. Stroh (1992) 2 Cal.App.4th 364, 367 [3 Cal.Rptr.2d 779].) Indeed, in Laube, the court observed that the ALJ's factual findings — notably not subject to review on appeal — include:

[T]he element of the licensee's knowledge of illegal and improper activity on his or her premises; this knowledge may be either actual knowledge or constructive knowledge imputed to the licensee from the knowledge of his or her employees.

(*Ibid.*, citing *Fromberg v. Dept. of Alcoholic Bev. Control* (1959) 169 Cal.App.2d 230, 233-234 [337 P.2d 123].

Both Moad Harbi, and by extension, the licensee, knew or *should have known* that this product was not legal for sale in the premises. The Board is not empowered to

overturn the ALJ's findings on this point and reach a different conclusion. Accordingly, we must affirm count 2.

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COUNT 3

Appellants contend count 3 should be reversed because La Loma # 11 was not the effective "seller of the four tubes of prescription Vitacilina." Instead, they contend that neither they nor their agents played any role in what was on the shelf and that, under this business relationship, the licensees appear to be the agents of Safegate, not vice versa. (AOB at pp. 14-15.)

Testimony established that Safegate is a vendor. Appellants place orders for medications and once those orders come in, Safegate is paid for what it puts on the shelves. (RT 124.) Safegate also provided appellants with invoices for the items it places on the shelves. (Exhibits E, F.) This is not a consignment arrangement. This is the standard relationship between a vendor and retailer where products are provided for a wholesale price then sold at retail. This is true not just for medication. An identical arrangement exists for all the vendors with whom appellants work: Anheuser-Busch, Coca-Cola, Frito-Lay, etc. (RT 130-132.) Under appellants' argument, they would not be responsible for anything sold in their store regardless of the product's illegality. Such an argument must fail.

As discussed in section II, *supra*, appellants are responsible for what takes place and what is sold in the premises — in short, making sure the business is conducted in a lawful manner.

For all the reasons set forth in section II, we affirm count 3.

IV

PENALTY

Appellants contend the penalty is excessive in light of all the evidence and that it should be mitigated or reversed entirely. (AOB at p. 15.)

The Board will not disturb the Department's penalty order in the absence of an abuse of discretion. (*Martin v. Alcoholic Bev. Control Appeals Bd. & Haley* (1959) 52 Cal.2d 287, 291 [341 P.2d 296].) "Abuse of discretion" in the legal sense is defined as discretion exercised to an end or purpose not justified by and clearly against reason, all of the facts and circumstances being considered. [Citations.] (*Brown v. Gordon* (1966) 240 Cal.App.2d 659, 666-667 [49 Cal.Rptr. 901].) If the penalty imposed is reasonable, the Board must uphold it even if another penalty would be equally, or even more, reasonable. "If reasonable minds might differ as to the propriety of the penalty imposed, this fact serves to fortify the conclusion that the Department acted within its discretion." (*Harris v. Alcoholic Bev. Control Appeals Bd.* (1965) 62 Cal.2d 589, 594 [43 Cal.Rptr. 633].)

Rule 144 provides:

In reaching a decision on a disciplinary action under the Alcoholic Beverage Control Act (Bus. and Prof. Code Sections 23000,et seq.), and the Administrative Procedures Act (Govt. Code Sections 11400, et seq.), the Department shall consider the disciplinary guidelines entitled "Penalty Guidelines" (dated 12/17/2003) which are hereby incorporated by reference. Deviation from these guidelines is appropriate where the Department in its sole discretion determines that the facts of the particular case warrant such a deviation - such as where facts in aggravation or mitigation exist.

(Cal. Code Regs., tit. 4, § 144.)

Among the mitigating factors provided by the rule are the length of licensure without prior discipline, positive actions taken by the licensee to correct the problem,

cooperation by the licensee in the investigation, and documented training of the licensee and employees. Aggravating factors include, inter alia, prior disciplinary history, licensee involvement, lack of cooperation by the licensee in the investigation, and a continuing course or pattern of conduct. (Ibid.)

The Penalty Policy Guidelines further address the discretion necessarily involved in an ALJ's recognition of aggravating or mitigating evidence:

Penalty Policy Guidelines:

The California Constitution authorizes the Department, in its discretion[,] to suspend or revoke any license to sell alcoholic beverages if it shall determine for good cause that the continuance of such license would be contrary to the public welfare or morals. The Department may use a range of progressive and proportional penalties. This range will typically extend from Letters of Warning to Revocation. These guidelines contain a schedule of penalties that the Department usually imposes for the first offense of the law listed (except as otherwise indicated). These guidelines are not intended to be an exhaustive, comprehensive or complete list of all bases upon which disciplinary action may be taken against a license or licensee; nor are these guidelines intended to preclude, prevent, or impede the seeking, recommendation, or imposition of discipline greater than or less than those listed herein, in the proper exercise of the Department's discretion.

(lbid.)

At the administrative hearing, the Department recommended a penalty of revocation, stayed for 36 months, and an actual 20-day suspension of the license. However, in the decision, the ALJ agrees with many of appellants' arguments and notes:

6... the evidence did not warrant the high penalty the Department recommended. Respondent neither formulated nor manufactured the prescription Vitacilina. Also, there was no evidence respondent held the licensed premises out to the public or others as a licensed pharmacy or pharmacy of any kind. There was no evidence any drug/medicinal manufacturing, compounding, packaging, or labeling activity or related equipment was on the licensed premises. There was no evidence of any laboratory or like facility on the licensed premises. There

was no evidence respondent promoted the sale of Vitacilina over other general merchandise it carried or made an excessive profit from its sale. The evidence indicated only four tubes of prescription Vitacilina were on the licensed premises.

- 7. Dr. Vora testified retinol is commonly used in products to reduce scarring from wounds and can be used in skin-care products to reduce skin wrinkling. There was no evidence the addition of retinol to the Vitacilina actually made it toxic or hazardous to a user's health. It was only deemed a "dangerous drug" under section 4022 because the addition of retinol required a prescription.
- 8. There was no evidence respondent dispensed a high volume of the Vitacilina.
- 9. There was no evidence any other types of dangerous drugs, prescription drugs, narcotics, controlled substances, or other regulated medical devices were found on the licensed premises.
- 10. There was no evidence the labeling on the prescription Vitacilina seized from the licensed premises, although in Spanish, was factually inaccurate or misleading.
- 11. Respondent has been licensed since 2012 with no prior disciplinary action. Rule 144 indicates the term of discipline free licensure can be a grounds for mitigation. In this instance, respondent's term of discipline free licensure was of a duration to warrant some mitigation.

(Decision at pp. 11-12, emphasis added.)

Nevertheless, the ALJ imposed three concurrent 25-day suspensions, with 15 days stayed for a period of two years. In short, an actual 10-day suspension with the possibility of 15 days more if further discipline is warranted during that two-year period.

Appellants' disagreement with the penalty imposed does not mean the Department abused its discretion. This Board's review of a penalty looks only to see whether it can be considered reasonable, and, if it is reasonable, the Board's inquiry ends there. The penalty here is within the bounds of the Department's discretion, and the Board is simply not empowered to reach a contrary conclusion from that of the

Department — and substitute its own judgment — when, as here, the underlying decision is reasonable and supported by substantial evidence.

While we might consider a lesser penalty more appropriate, and wish the Department would issue a warning rather than an accusation in such cases, we cannot say the penalty constitutes an abuse of discretion. The penalty imposed complies with the guidelines of rule 144. Accordingly, we reluctantly affirm.

ORDER

The decision of the Department is affirmed.³

SUSAN A. BONILLA, CHAIR
MEGAN McGUINNESS, MEMBER
SHARLYNE PALACIO, MEMBER
ALCOHOLIC BEVERAGE CONTROL
APPEALS BOARD

³ This final order is filed in accordance with Business and Professions Code section 23088, and shall become effective 30 days following the date of the filing of this order as provided by section 23090.7 of said code.

Any party, before this final order becomes effective, may apply to the appropriate court of appeal, or the California Supreme Court, for a writ of review of this final order in accordance with Business and Professions Code section 23090 et seq.

APPENDIX

BEFORE THE DEPARTMENT OF ALCOHOLIC BEVERAGE CONTROL OF THE STATE OF CALIFORNIA

IN THE MATTER OF THE ACCUSATION AGAINST:

ABDULMALIK SALEH HARBI AND AHMED MOHAMED SALEH LA LOMA #11 1313 ROAD 20 SAN PABLO, CA 94806

OFF-SALE GENERAL - LICENSE

Respondent(s)/Licensee(s)
Under the Alcoholic Beverage Control Act

CONCORD DISTRICT OFFICE

File: 20-517233

Reg: 19089533

CERTIFICATE OF DECISION

It is hereby certified that, having reviewed the findings of fact, determination of issues, and recommendation in the attached proposed decision, the Department of Alcoholic Beverage Control adopted said proposed decision as its decision in the case on March 11, 2021. Pursuant to Government Code section 11519, this decision shall become effective 30 days after it is delivered or mailed.

Any party may petition for reconsideration of this decision. Pursuant to Government Code section 11521(a), the Department's power to order reconsideration expires 30 days after the delivery or mailing of this decision, or if an earlier effective date is stated above, upon such earlier effective date of the decision.

Any appeal of this decision must be made in accordance with Business and Professions Code sections 23080-23089. For further information, call the Alcoholic Beverage Control Appeals Board at (916) 445-4005, or mail your written appeal to the Alcoholic Beverage Control Appeals Board, 1325 J Street, Suite 1560, Sacramento, CA 95814.

On or after April 27, 2021, a representative of the Department will contact you to arrange to pick up the license certificate.

Sacramento, California

Dated: March 17, 2021

RECEIVED

MAR 17 2021

Alcoholic Beverage Control Office of Legal Services

Matthew D. Botting General Counsel

BEFORE THE DEPARTMENT OF ALCOHOLIC BEVERAGE CONTROL OF THE STATE OF CALIFORNIA

IN THE MATTER OF THE ACCUSATION AGAINST:

Abdulmalik Saleh Harbi and Ahmed Mohamed Saleh	} File: 20-517233
Dba: La Loma #11	}
1313 Road 20	} Reg.: 19089533
San Pablo, CA 94806	}
·	} License Type: 20
Respondent	}
<u>-</u>	Word Count Estimate: 33,500
	}
	Rptr: Joan Columbina, CSR-5435
Regarding Their Type-20 Off-Sale Beer and Wine	} Emerick and Finch Reporters
License Under the State Constitution and the Alcoholic	}
Beverage Control Act.	PROPOSED DECISION
	.}

Administrative Law Judge David W. Sakamoto, Administrative Hearing Office, Department of Alcoholic Beverage Control. (hereafter the ALJ) heard this matter in Martinez, California on Dec. 3, 2020.

Sean Klein, Attorney III, Office of Legal Services, Department of Alcoholic Beverage Control, represented the Department of Alcoholic Beverage Control. (hereafter the Department)

Richard D. Warren, attorney-at-law, represented co-licensee-respondents Abdulmalik Saleh Harbi and Ahmed Mohamed Saleh. (hereafter respondent)

This case was heard concurrently with the hearing regarding the accusation Against Pac Bev, Inc. under file: 21-602630 and registration 20089682. Mr. Warren represented the respondent-licensees in each case. He and the Department's counsel, Mr. Klein, requested the matters be heard concurrently due to common questions of law and fact and to promote efficiency of witness testimony. The ALJ agreed to the request so there is one common record for the consolidated hearing. The exhibits were marked consecutively during the consolidated hearing resulting in a common exhibit list for both matters. A separate proposed decision is to be submitted for each accusation. After oral evidence, documentary evidence, and evidence by oral stipulation on the record were received, the matter was argued. The ALJ also asked for post-hearing briefs to be submitted. The Department

submitted a brief that was marked as Exhibit 9. No brief was received from respondent.¹ The matter was submitted for decision on December 17, 2020.

The Department's accusation alleged cause for suspension or revocation of respondent's license exists under California State Constitution, Article XX, section 22, and Business and Professions Code section 24200, subdivision (a) and (b), on the grounds that:²

Count 1: "On or about June 13, 2019, respondent-licensee(s) conducted a pharmacy as defined by Business and Professions Code Section 4037(a), at the above licensed location, without a license issued by the California State Board of Pharmacy, in violation of Business and Professions Code Section 4110."

Count 2: "On or about June 13, 2019, respondent-licensee, at the above premises, knowingly owned, operated or managed a business that attempted to dispense or furnish dangerous drug(s) as defined by Business and Professions Code Section 4022(a), to wit: Vitacilina, without a license to dispense or furnish such dangerous drug(s), in violation of Health and Safety Code Section 11352.1(b) and Penal Code section 664."

Count 3: "On or about June 13, 2019, respondent-licensee, at said premises, held or offered for sale, a drug or device that was misbranded, to-wit: Vitacilina, in violation of Health and Safety Code Section 111440."

FINDINGS OF FACT

- 1. The Department filed the accusation on November 25, 2019. On December 2, 2019, the Department received respondent's Notice of Defense that requested a hearing on the accusation. The Department conducted a hearing on December 3, 2020.
- 2. On January 19, 2012, the Department issued respondent a type-20 license for its premises at 1313 Road 20, San Pablo, California. A type-20 license permitted respondent to retail in beer and wine for off premises consumption.
- 3. Respondent had no history of prior disciplinary action.

¹ Respondent had the option of not submitting a brief.

² All further section references are to the California Business and Professions Code unless noted otherwise.

- 4. On June 13, 2019, Alcoholic Beverage Control Agent Anthony Sam, Alcoholic Beverage Control Agent Cook, Contra Costa County Environmental Health Department Inspector Joe Doser, and Contra Costa County Environmental Health Inspector Josephina Lopez inspected the licensed premises that was operating as a market/grocery. Among the merchandise held out for sale on a display shelf near a sales counter, they located four small green boxes of a product labeled "Vitacilina". The other printing on the boxes was in Spanish. The agents learned by a phone call with licensed pharmacist Ushma Vora at the Contra Costa Regional Medical Center that the Vitacilina the agents found required a prescription to dispense because it contained retinol-A as an active ingredient.
- 5. Licensed premises manager Raheeb Saleh told ABC Agent Sam the Vitacilina was for sale. Some of the items had price tags on them. One of the packages, Exhibit 3, had a price tag of \$3.49 on it.
- 6. Co-licensee Ahmed Mohamed Saleh arrived at the licensed premises and indicated to the agents the licensed premises was not licensed as a pharmacy. The agents confirmed on the California Department of Consumer Affairs' website the licensed premises was not a licensed pharmacy. The agents seized the four boxes of Vitacilina that contained retinol-A.
- 7. Moad Harbi (hereafter Moad) testified that although he primarily manages a store known as Evergreen Produce, he also helped his brother, co-licensee/respondent Abdulmalik Saleh Harbi (hereafter Abdulmalik), manage the licensed premises. Evergreen Produce is also in the San Pablo area. Moad testified that approximately one month prior to June 13, 2019, inspectors came to Evergreen Produce and gave him some paperwork regarding certain medicines from Mexico that were not allowed. It listed "Vitacilina" among them. However, the type of Vitacilina he carried at Evergreen Produce was determined to be lawful for him to sell at retail. There was no evidence Evergreen Produce was a licensed pharmacy. Moad testified he never mentioned that information about Vitacilina to Abdulmalik because the inspectors told Moad they would be visiting other local area businesses and he assumed they would soon visit the licensed premises to provide the same information directly to Abdulmalik.
- 8. Moad testified Safegate International, an outside vendor, provided the over-the-counter medicinal and health related products at the licensed premises, including the Vitacilina product. Safegate provided certain shelving in the licensed premises and ultimately decided which products should be stocked on those shelves. Safegate's salesman regularly monitored and re-stocked its products as needed. Safegate would invoice respondent for the goods supplied to respondent for resale. Although respondent could suggest products to Safegate to stock on those shelves, Safegate made the final decision. Respondent would simply check the invoices to insure the ordered goods were actually received at the licensed premises.

- 9. Respondent used Safegate's services for approximately 3-4 years prior to the agents' June 13, 2019, investigation at the licensed premises. Moad testified this system of a specialized vendor servicing specifically designated shelving, coolers, and even freezers for a limited product line was commonly done for other products such as Frito-Lay products, certain beers, and even ice cream products.
- 10. After the agents' investigation, Moad contacted Safegate regarding whether there was any problem carrying the Vitacilina it supplied. Safegate indicated there should not be any problem with respondent retailing that product. Moad testified that while respondent initially stopped selling Vitacilina, about six months ago respondent resumed carrying the legally approved formulation of that product.
- 11. Dr. Ushma Vora (hereafter Dr. Vora) a licensed California pharmacist and a clinical drug information coordinator for the Contra Costa Regional Medical Center testified at the hearing regarding the product known as "Vitacilina". On June 13, 2019, she was the one who the agents conferred with to determine if the Vitacilina found at the licensed premises was or was not a prescription medication. She indicated to them it was a prescription medication because it contained neomycin with retinol, a form of vitamin A.
- 12. The tubes of Vitacilina seized by the agents at the licensed premises were individually packaged in green colored product boxes of two sizes. The boxes were approximately one inch by one inch by five or six inches. The boxes were labeled "Vitacilina". However, the balance of the text on the boxes that contained the tubes of Vitacilina were in Spanish as was the text on the tubes of medication inside the boxes. While the printing on the boxes or tubes were not formally translated, the type, style, and format of information printed on the cartons seemed consistent with what one might expect to see on such type product. Neither party asserted the product was not Vitacilina nor not the medication described on the packaging nor that it did not contain retinol as so labeled. The labeling also indicated it was made in Mexico.
- 13. Dr. Vora testified the Vitacilina seized at the licensed premises needed to be dispensed only by way of a prescription because the medication was a combination of neomycin, a topical anti-biotic, but was combined with retinol, which can be used to reduce scarring from wounds, as an active ingredient. Dr. Vora found a U.S. Food and Drug Administration (FDA) registered and approved form of Vitacilina in two drug indexes she searched. However, that contained only neomycin or neomycin sulfate as an active ingredient. That approved product used labeling in English not Spanish. The approved version of Vitacilina was consistent with what she saw on Exhibit A (approved Vitacilina product) that lists only neomycin sulfate as an active ingredient. Retinol was not specified as an active ingredient. She could not find any FDA approved Vitacilina where the neomycin was added with retinol as an active ingredients, that would have to be compounded by a pharmacist by way of a prescription.

14. Dr. Vora testified neither neomycin nor retinol are narcotics. She indicated retinol was also sold as a skin-care product to reduce skin wrinkling. She testified she thought she had seen a regulation requiring labeling on approved drugs must be printed in English.

LEGAL BASIS OF DECISION

- 1. Article XX, section 22 of the California Constitution and Business and Professions section 24200, subdivision (a) provides that a license to sell alcoholic beverages may be suspended or revoked if continuation of the license would be contrary to public welfare or morals.
- 2. Business and Professions Code Section 24200, subdivision (b), provides that a licensee's violation, or causing or permitting of a violation, of any penal provision of California law prohibiting or regulating the sale of alcoholic beverages is also a basis for the suspension or revocation of the license.
- 3. Business and Professions Code section 4110, subdivision (a) states: "No person shall conduct a pharmacy in the State of California unless he or she has obtained a license from the board. A license shall be required for each pharmacy owned or operated by a specific person. A separate license shall be required for each of the premises of any person operating a pharmacy in more than one location. The license shall be renewed annually. The board may, by regulation, determine the circumstances under which a license may be transferred."
- 4. Business and Professions Code section 4037, subdivision (a), states: "'Pharmacy' means an area, place, or premises licensed by the board in which the profession of pharmacy is practiced and where prescriptions are compounded. 'Pharmacy' includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail."
- 5. Health and Safety Code section 11352.1, subdivision (b) states: "Notwithstanding Section 4321 of the Business and Professions Code, and in addition to any other penalties provided by law, any person who knowingly and unlawfully dispenses or furnishes a dangerous drug or dangerous device, or any material represented as, or presented in lieu of, any dangerous drug or dangerous device, as defined in Section 4022 of the Business and Professions Code, or who knowingly owns, manages, or operates a business that dispenses or furnishes a dangerous drug or dangerous device or any material represented as, or presented in lieu of, any dangerous drug or dangerous device, as defined in Section 4022 of

the Business and Professions Code without a license to dispense or furnish these products, shall be guilty of a misdemeanor..."

- 6. Health and Safety Code section 111440 states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."
- 7. Business and Professions Code section 4022 states: "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self-use in humans or animals, and includes the following:
- "(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.
- "(b) Any device that bears the statement: 'Caution: federal law restricts this device to sale by or on the order of a _____,' 'Rx only,' or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.
- "(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."
- 8. Penal Code section 664 generally makes it a criminal offense to attempt to commit a crime.

DETERMINATION OF ISSUES

- 1. There was sufficient evidence to sustain count 1 that respondent conducted an unlicensed pharmacy. Section 4110 states no one may conduct a pharmacy without a license. Section 4037, subdivision (a), states: "Pharmacy" includes, but is not limited to, any area, place, or premises described in a license issued by the board wherein controlled substances, dangerous drugs, or dangerous devices are stored, possessed, prepared, manufactured, derived, compounded, or repackaged, and from which the controlled substances, dangerous drugs, or dangerous devices are furnished, sold, or dispensed at retail." Section 4022, subdivision (c) defines a "dangerous drug" as: "(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."
- 2. In this instance, respondent's premises was not licensed by the California State Board of Pharmacy. However, it stored and possessed the Vitacilina in order to furnish, sell or dispense it at retail. The Vitacilina herein was a "dangerous drug" because it had retinol as an active ingredient and that such formulation/combination of neomycin and retinol could only be formulated and dispensed by a licensed pharmacist in accordance with a prescription. That formulation was not an existing approved FDA non-prescription/over-the counter drug/medicine. As the licensed premises was not a licensed pharmacy, respondent could not lawfully possess or store that formulation of Vitacilina or furnish, sell, or dispense it because it was a dangerous drug.

- 3. As to Count 2, there was sufficient evidence to establish respondent or his agents or employees violated or attempted to violate Health and Safety Code section 11352.1. Subdivision (b) of that section states, in part: "...Notwithstanding Section 4321 of the Business and Professions Code, and in addition to any other penalties provided by law, any person who...knowingly owns, manages, or operates a business that dispenses or furnishes a dangerous drug or dangerous device or any material represented as, or presented in lieu of, any dangerous drug or dangerous device, as defined in Section 4022 of the Business and Professions Code without a license to dispense or furnish these products, shall be guilty of a misdemeanor."
- 4. In this matter, Moad, who regularly worked part-time at respondent's premises, was specifically warned about one month prior to the agents/inspectors' June 13, 2019, visit to the licensed premises that some forms of Vitacilina made in Mexico were illegal or improper to dispense or sell at retail. He received that warning specifically from some agents/inspectors. However, because the agents/inspectors told him they were going to visit other businesses in the area, he assumed respondent's licensed premises would be visited in the future. Therefore, he never told the respondents herein, one being his brother-Abdulmalik, about the warning he received concerning Vitacilina. However, that warning provided Moad with sufficient information that he knew or should have known the Vitacilina offered at respondent's premises was an illegal medication that should not be dispensed at respondent's licensed premises that was not a licensed pharmacy. The Vitacilina was on respondent's merchandise shelves and respondent's manager confirmed to the agents is was offered for sale. As respondent is generally chargeable with the knowledge and acts of its employees or agents, there was sufficient evidence to sustain Count 2 of the accusation in that, at minimum, respondent was knowingly attempting to sell a prescription medication without a pharmacy license.
- 5. There was sufficient evidence to sustain count 3 in that respondent, at the licensed premises, held or offered for sale a drug or device that was misbranded in violation of Health and Safety Code section 111440 that states: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded." Section 111397, subdivision (s) states: "(a) Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department of Public Health is misbranded."
- 6. In this instance, the evidence established the Vitacilina seized at respondent's premises was a dangerous drug because it required a prescription for use. The evidence also indicated it was manufactured in Mexico and Dr. Vora further testified it was not FDA approved. Therefore, the Vitacilina was misbranded.

- 7. Additionally, the Vitacilina was also misbranded because the labeling on the seized Vitacilina was printed in Spanish not English. With respect to drug labeling, 21 Code of Federal Regulations § 201.15(c) states, "All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear therein in the English language: Provided, however, That in the case of articles distributed solely in the Commonwealth of Puerto Rico or in a Territory where the predominant language is one other than English, the predominant language may be substituted for English." California Health and Safety Code section 108800 even specifies that: "Cautionary statements that are required by law, or regulations adopted pursuant to law, to be printed upon the labels of containers in which dangerous drugs, poisons, and other harmful substances are packaged shall be printed in the English language in a conspicuous place in type of conspicuous size in contrast to the typography, layout, or color of the other printed matter on the label." In this instance, California is a state not a Territory where the predominate language is not English. The Vitacilina was not labeled in English so was misbranded in that respect.
- 8. Except as set forth in this decision, all other allegations in the accusation lack merit as do any defenses respondent raised to them.

PENALTY

- 1. In assessing an appropriate measure of discipline, the Department's penalty guidelines are in California Code of Regulations, title 4, section 144. (hereafter rule 144) Under rule 144, if the licensee knowingly permitted the sale, or negotiations for the sales, of controlled substances or dangerous drugs on the licensed premises in violation of section 24200.5, subdivision (a), license revocation is specified. Rule 144 does not specify a penalty for the type of dangerous drug involved in this matter.
- 2. Rule 144 permits imposition of a revised penalty based on the presence of aggravating or mitigating factors. Rule 144 contains a non-exhaustive list of some of those factors, e.g. prior disciplinary history, licensee involvement, continuing course or pattern of conduct, length of licensure free of prior discipline or problems, positive action by licensee to correct problem, and documented training of licensee and employees.
- 3. The Department recommended the license be revoked, with such revocation stayed for a period of 36 months, and a 20-day license suspension.³ It indicated respondent's offering of the Vitacilina, a dangerous drug, was clearly contrary to public welfare and morals. Further, respondent was responsible for the products it offered for sale and had a non-

³ It was assumed the "stayed-revocation" was akin to a time of probation and that absent a violation(s) occurring during the "stayed-time" the revocation would be permanently stayed. However, the 20 day license suspension would need to be served.

delegable duty to know which were lawful and which were not. That duty could not be delegated to outside vendors who supplied goods for resale to respondent.

- 4. Respondent argued formal charges in this case were completely unwarranted and this was not a case involving narcotics or controlled substances. Respondent contended there was an absence of aggravating factors should a penalty be imposed. Respondent argued it reasonably assumed its vendor was supplying respondent lawful products. Lastly, it contended it had no prior violations since being licensed at this premises.
- 5. In determining an appropriate penalty in this matter, respondent is responsible for conducting its ABC licensed business in a lawful manner. In this instance, about one month prior to the agents' visit to the licensed premises, Moad Harbi was informed by agents who visited Evergreen Produce that some forms of Vitacilina from Mexico were illegal to sell. Moad also testified he worked at the licensed premises. For at least that following month, Moad never inspected the licensed premises shelves to determine if the Vitacilina it carried was the illegal version. Moad never informed his brother of this issue so that his brother could have checked for the product himself. Moad testified he did not tell his brother of this information because agents told him they were visiting other stores in the area and he assumed the agents would eventually check the licensed premises themselves. However, Moad should not have assumed that was going to occur. He should have promptly made the inspection himself or notified the respondent so they could inspect their Vitacilina to determine if respondent had the illegal version for sale, which, in fact, it did. To that extent, respondent's agent or employee, Moad, had been given notice of the problem and failed to act promptly to prevent dispensing the prescription formulation of Vitacilina at the licensed premises.
- 6. However, the evidence did not warrant the high penalty the Department recommended. Respondent neither formulated nor manufactured the prescription Vitacilina. Also, there was no evidence respondent held the licensed premises out to the public or others as a licensed pharmacy or pharmacy of any kind. There was no evidence any drug/medicinal manufacturing, compounding, packaging, or labeling activity or related equipment was on the licensed premises. There was no evidence of any laboratory or like facility on the licensed premises. There was no evidence respondent promoted the sale of Vitacilina over other general merchandise it carried or made an excessive profit from its sale. The evidence indicated only four tubes of prescription Vitacilina were on the licensed premises.
- 7. Dr. Vora testified retinol is commonly used in products to reduce scarring from wounds and can be used in skin-care products to reduce skin wrinkling. There was no evidence the addition of retinol to the Vitacilina actually made it toxic or hazardous to a user's health. It was only deemed a "dangerous drug" under section 4022 because the addition of retinol required a prescription.

- 8. There was no evidence respondent dispensed a high volume of the Vitacilina.
- 9. There was no evidence any other types of dangerous drugs, prescription drugs, narcotics, controlled substances, or other regulated medical devices were found on the licensed premises.
- 10. There was no evidence the labeling on the prescription Vitacilina seized from the licensed premises, although in Spanish, was factually inaccurate or misleading.
- 11. Respondent has been licensed since 2012 with no prior disciplinary action. Rule 144 indicates the term of discipline free licensure can be a grounds for mitigation. In this instance, respondent's term of discipline free licensure was of a duration to warrant some mitigation.
- 12. Upon assessing the facts and circumstances with respect to the penalty and in consideration of rule 144, this matter warrants a penalty less than what the Department recommended.
- 13. Except as set forth in this decision, all other arguments, contentions, and assertions raised by the parties with respect to the penalty are without merit.

ORDER

- 1. Count 1, Count 2 and Count 3 are sustained.
- 2. As to each sustained count, respondent's license is suspended for a period of 25 days, with 15 of the 25 days of suspension stayed for a period of 24 months commencing the date the decision in this matter becomes final, upon the condition that no subsequent final determination is made, after hearing or upon stipulation and waiver, that cause for disciplinary action occurred during the period of the stay. Should such a determination be made, the Director of the Department of Alcoholic Beverage Control may, in the Director's sole discretion and without further hearing, vacate the stay and impose the 15 stayed days of suspension, and should no such determination be made, the stay shall become permanent.

3. As the sustained violations arise from one basic event/transaction, the penalty assessed for each count shall run concurrently to the other counts.

Dated Janua	ary 13, 2021	David W. Sakamoto Administrative Law Judge
	Adopt Non-Adopt: By: Date:	