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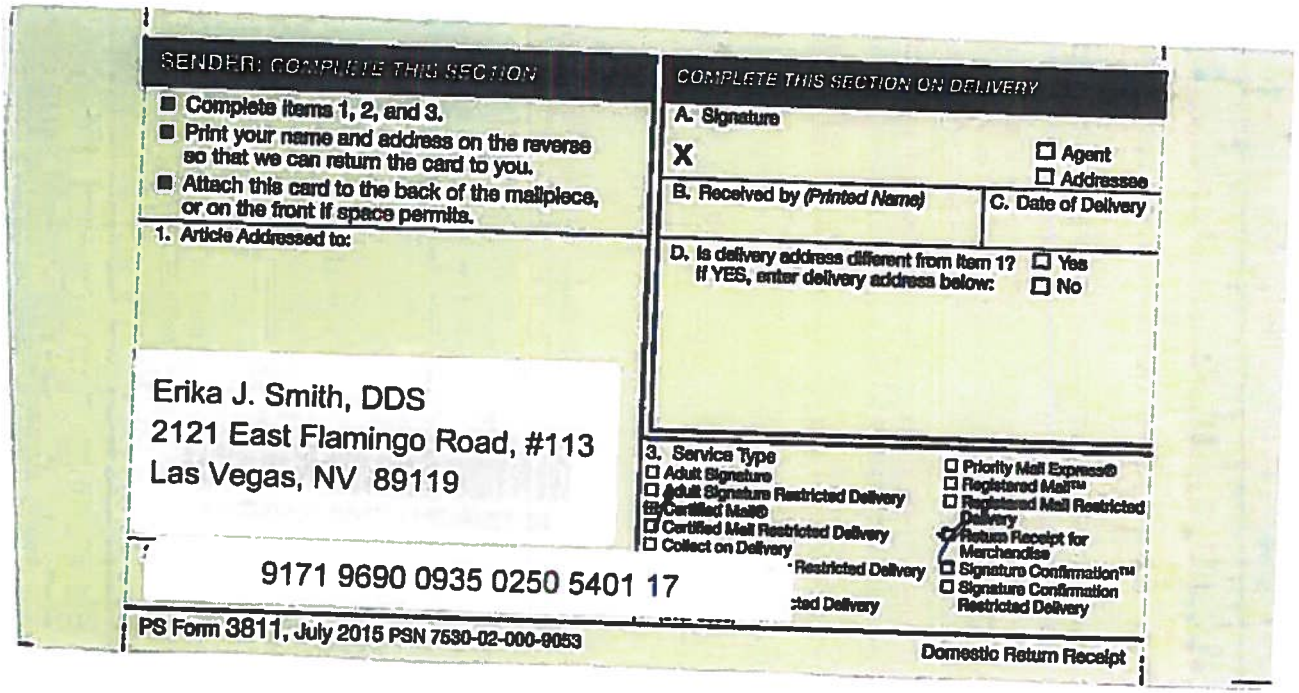
Exhibit A



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1. Article Addressed to:

Erika J. Smith, DDS
2121 East Flamingo Road, #113
Las Vegas, NV 89119

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B. Received by (Printed Name)

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Jesse T. Mai, FNP-C
4324 S. Eastern Avenue – Suite B
Las Vegas, NV 89119
NIA 19-054-CS-S

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FILED
OCT 23 2020
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Answer Due 11/16/20

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1. Article Addressed to:

Jesse T. Mai, FNP-C
4324 S. Eastern Avenue – Suite B
Las Vegas, NV 89119

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COMPLETE THIS SECTION ON DELIVERY

A. Signature
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B. Received by (Printed Name) C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

Answer Due 11/16/20

3. Service Type
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☐ Signature Confirmation™
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Exhibit A

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FAQs >

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5D

To Whom It May Concern: January 8th, 2021

Nevada State Board of Pharmacy

First, I would like to start by thanking you for taking the time to let me say a few words regarding this case regarding Certificate of Registration No. CS25303.

In November of 2016, I moved to Nevada and started practicing as a first time Nurse Practitioner, under a doctor who unbeknownst to me was already being watched by the DEA. In February of 2019, his office where I was employed was raided by the DEA. At that time of their investigation, they interviewed all of us in the office. After the interview they gave me the option to sign my DEA license away. I proceeded to sign the paperwork not knowing that I had an option. I assumed I was just complying with the DEA, given the level of intensity that was occurring that day and being that it was an open investigation, thus not realizing the ramifications that would follow.

During the raid/investigation that day, a Representative from the Nevada Board of Pharmacy was present. Since the Representative was present, I assumed the details of the raid were provided to the Board and therefore didn't think I needed to contact anyone, assuming the Board was involved with the situation and was already following the details of it all.

Shortly after this event, I stopped practicing and moved back home to Missouri. Following the events of that day, The Nevada Board of Nursing opened their own investigation regarding the events of that day and later closed the case based on their review, allowing me to keep my Nurse Practitioner license active without discipline (Please see Attached Files). As of today, that license is expired as I no longer reside in Nevada and therefore have chosen to let it expire rather than keeping up with a license I no longer plan to use in Nevada.

In conclusion, I understand that to hold and maintain a Nevada Board of Pharmacy license requires a Nevada Practicing license, that of which is now expired for me. I understand that not holding a practicing license alone can result in the Board revoking a license, not to mention any findings the Board sees as unfit for use, therefore resulting in a revoked license status within the system. A revoked license status which can make life much harder in one's career. That being said, I would like to ask that the Board review the information I have provided and consider to expire/inactivate my license rather than placing it on revocation.

Thank you for your time and consideration concerning this matter,

Derek C. Braddix

Nevada State Board of
NURSING

September 3, 2019

NOTICE OF COMPLAINT/INVESTIGATION

Derek Christopher Braddix
1233 Cashmere Lane
Saint Peters, MO 63376

Re: Complaint initiated by Nevada State Board of Nursing Staff

Dear Mr. Braddix:

The Nevada State Board of Nursing has initiated a complaint regarding your nursing practice alleging:

On or about February 21, 2019 and an indeterminate time frame prior but no later than 2016, while licensed as an APRN in Nevada you knowingly and intentionally combined, conspired, confederated and agreed with other persons to distribute a variety of controlled substances not for a legitimate medical purpose and while acting outside of the usual course of professional practice.

Should these allegations be substantiated, you may have violated the following statutes and/or regulations of the Nevada Nurse Practice Act including but not limited to, NRS 632.347 (1)(g) unprofessional conduct, (n) has engaged in conduct likely to deceive, defraud, or endanger a patient or the general public, and/or NAC 632.890 (18) diverting supplies, equipment or drugs for personal or unauthorized use, (26) failing to abide by any state or federal statute or regulation relating to the practice of nursing, and/or (27) failing to perform nursing functions in a manner consistent with established or customary standards.

Pursuant to NRS 233B.127(3) this letter is to notify you of the allegations and offer you the opportunity to respond if you so choose. The Board will conduct an independent investigation to determine if there has been a violation of the Nurse Practice Act.

Due to the potential for possible action against your license in Nevada, you need to be aware of the following. You have the right to consult with an attorney before you make any response to the allegations, or at any time during the course of an investigation however, it is not mandatory that you have an attorney represent you in any matters before the Board. Disciplinary action against you may affect a license issued by the Nevada State Board of Nursing or any other state. In the event that there is formal disciplinary action taken by the Board, you may be charged for all financial costs related to investigation, settlement, and/or formal hearing of the complaint pursuant to NRS 622.400.

If you are a nursing assistant and the complaint is related to abuse, neglect, or misappropriation, the Board will investigate the alleged misconduct on behalf of the Bureau of Health Care Quality and Compliance. The Bureau may place a federal finding on your certificate in addition to any disciplinary action that may be taken by the Board.

5011 Meadowood Mall Way, Suite 300, Reno, NV 89502-6547 (fax) 775-687-7707
4220 S. Maryland Parkway, Suite B300, Las Vegas, NV 89102-4392 (fax) 702-486-5803
www.nevadanursingboard.org - 888-590-6726 - nursingboard@nsbn.state.nv.us

Nevada State Board of
NURSING

Please return your response to the allegation(s) within (2) two weeks of receipt of this letter (as identified by the date upon which you sign the return receipt) to skmiller@nsbn.state.nv.us Upon completion of the investigation, all information on file regarding the allegations will be reviewed to determine if further steps are appropriate. You will be contacted with the outcome of the investigation.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact me in writing, or by telephone at 702-668-4531.

Sincerely,
NEVADA STATE BOARD OF NURSING

Sally K. Miller, PhD, APRN, FAANP
ARN Consultant/Investigator

Enclosure: Nursing Fact Sheet

5011 Meadowood Mall Way, Suite 300, Reno, NV 89502-6547 (fax) 775-687-7707
4220 S Maryland Parkway, Suite B300, Las Vegas, NV 89102-4392 (fax) 702-486-5803
www nevadanursingboard org - 888-590-6726 - nursingboard@nsbn state nv us

Nevada State Board of
NURSING

December 12, 2019

Derek Braddix
1233 Cashmere Lane
St. Peters, MO 63376

Re: Complaint submitted by Nevada State Board of Nursing Staff

Dear Mr. Braddix:

This letter is to inform you of the disposition of the Nevada State Board of Nursing regarding the complaint filed against you. After a thorough investigation and review of the evidence, the complaint has been closed. Once an investigation is closed, the contents of the investigation remain confidential. However, if new evidence is discovered, the matter may at any time be opened again and investigated further if circumstances so warrant.

Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact this office in writing, or by telephone at 888-590-6726.

Sincerely,
NEVADA STATE BOARD OF NURSING

Sally K. Miller, PhD, APRN, FAANP
APRN Consultant/Investigator

5011 Meadowood Mall Way, Suite 300, Reno, NV 89502-6547 (fax) 775-687-7707
4220 S Maryland Parkway, Suite B300, Las Vegas, NV 89102-4392 (fax) 702-486-5803
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Las Vegas, NV 89119-7524

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Derek Braddix
1233 Cashmere Lane
St Peters, MO 63376

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Nevada State Board of
NURSING

December 12, 2019

Derek Braddix
1233 Cashmere Lane
St. Peters, MO 63376

Re: Complaint submitted by Nevada State Board of Nursing Staff

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Thank you for your cooperation in this matter. If you have any questions, please do not hesitate to contact this office in writing, or by telephone at 888-590-6726.

Sincerely,
NEVADA STATE BOARD OF NURSING

Sally K. Miller, PhD, APRN, FAANP
APRN Consultant/Investigator

FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

November 16, 2020

VIA ELECTRONIC MAIL

Dr. Spencer J. Malkin
President and Chief Executive Officer
Sincerus Florida, LLC
3265 West McNab Road
Pompano Beach, Florida 33069

Dr. Malkin:

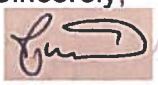
In separate electronic communication, we will be providing a copy of the Establishment Inspection Reports (EIRs) for the inspections conducted at your facility, Sincerus Florida, LLC, located at 3265 West McNab Road, Pompano Beach, FL 33069, from June 19, 2017, through June 26, 2017, and from August 30, 2018, through September 17, 2018, by the U.S. Food and Drug Administration (FDA).

When the Agency concludes that an inspection is "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing these EIRs to you is part of this effort. The copies being provided to you comprises the narrative portion of the reports; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

f you have questions regarding the contents of this letter, you may contact Dayna Martinez Compliance Officer via phone at 787-729-8608 or email at dayna.martinez@fda.hhs.gov

Sincerely,



CDR John W. Diehl, M.S.
Director, Compliance Branch
Office of Pharmaceutical Quality Operations,
Division II

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
1201 Main Street, Suite 7200
Dallas, Texas 75202
www.fda.gov

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Chairman | OFA
Partner | BakerHostetler
1050 Connecticut Avenue, NW
Suite 1100
Washington, D.C. 20036-5403

December 11, 2020

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, Nevada 89521

Re: Interpretation of the Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug and Cosmetic Act

Dear Mr. Dave Wuest:

The Outsourcing Facilities Association (the "OFA") is the trade association representing FDA-registered outsourcing facilities ("503Bs") operating pursuant to Section 503B of the Federal Food, Drug, and Cosmetic Act ("F&DC Act"). OFA's members provide compounding services to patients, healthcare providers, and healthcare facilities, and strive to ensure the specific needs of both providers and patients are met with safe and effective compounded and/or repackaged medications. OFA has been actively following the U.S. Food and Drug Administration's (the "FDA") implementation of the Compounding Quality Act ("CQA") and has brought together members of industry to advocate for a safe, reasonable and practical rollout of the CQA. The OFA recently became aware of a restrictive interpretation of the "Prohibition on Wholesaling Under Section 503B" currently under consideration by the Nevada Board of Pharmacy. We write to urge the Board to consider patient access and patient safety when developing the Board's interpretation of the prohibition on wholesaling.

I. Prohibition on Wholesaling Under Section 503B

Generally, Section 503B of the FD&C Act prohibits 503Bs from wholesaling compounded human drug products.[1] However, the statute plainly excludes administration in a healthcare setting and ***dispensing*** pursuant to a patient prescription from this prohibition.[2] Because "dispensing" is not included in the prohibition on wholesaling, under Federal law, a 503B could sell a compounded human drug product to a state-licensed pharmacy or physician, as long as the state-licensed pharmacy or physician will then dispense the product to a patient pursuant to a prescription. This described activity is distinguished from the prohibited act of a 503B selling to a state-licensed pharmacy who would then transfer, sell for office use, or wholesale the compounded product. One transaction between the 503B and purchaser before dispensing is allowed because this is exactly what occurs when a hospital purchases compounded drug product from a 503B and then the hospital pharmacy subsequently fills a medication order ("dispenses") the compounded product to a patient. The wholesale prohibition operates to prohibit any further distribution of compounded

[1] FD&C Act 503B(a)(8).
[2] *Id.*

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product to downstream entities.[3]

Under the FD&C Act, drug products that are compounded by 503Bs are eligible for certain exemptions from the requirements of the FD&C Act, including submission of new drug applications, labeling products with adequate directions for use, and track and trace, as long as the 503B meets certain criteria.[4] Under Section 503B of the FD&C Act, one such criteria is that the 503B is prohibited from wholesaling the compounded product. Specifically, the statute states that a drug compounded by a 503B can qualify for the aforementioned exemptions if "[t]he drug will not be ***sold*** or ***transferred*** by an entity other than the outsourcing facility that compounded such drug (emphasis added)."[5] The statute then clarifies that the aforementioned restriction "does not prohibit administration of a drug in a health care setting or ***dispensing*** a drug pursuant to a prescription executed in accordance with section 503(b)(1) (emphasis added)."[6] Section 503(b)(1) of the FD&C Act is the requirement that certain products be dispensed pursuant only to a prescription. Specifically, the statute states that "[a] drug intended for use in man…shall be dispensed only (i) upon a written prescription of a practitioner licensed by law to administer such drug…."[7] Further, the statute also requires that the compounded product be labeled with certain information prohibiting ***resale***, specifically the phrase "Not for resale."[8] Dispense however is distinct from resale. The resale of a compounded drug that is labeled "not for resale" in accordance with section 503B is a prohibited act.[9] Dispensing however is permitted.

When crafting Section 503B, Congress specifically differentiated the terms sold, transferred, dispensing, and resale. Thus, Section 503B works to prohibit 503Bs from selling compounded drug product to a traditional wholesaler who then resells the compounded drug to another downstream entity for administration or dispensing. However, a 503B may sell a compounded product to a physician or a 503A pharmacy. In other words, the purchaser or recipient must use the product for administration or dispense the compounded product. While Section 503B does not define the term ''wholesale distribution'' further, Section 503 of the FD&C Act does define the term "wholesale distribution." Specifically, ''wholesale distribution'' does not include— "the purchase or other acquisition by a **dispenser**, hospital, or other health care entity of a drug for use by such **dispenser**, hospital, or other health care entity (emphasis added)."[10] Under this definition, and the interpretation that should be applied to Section 503B, a 503B can sell a compounded drug product to a physician or 503A who then dispenses the drug to a patient.

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[3] For example, a 503B may not sell compounded human drug product to a wholesaler who then sells the compounded human drug product to a hospital, pharmacy, or physician. This activity is expressly prohibited under Section 503B. *See* FD&C Act 503B(a)(8).
[4] FD&C Act Section 503B(a).
[5] FD&C Act 503B(a)(8).
[6] *Id.*
[7] FD&C Act 503B(b)(1).
[8] FD&C Act 503B(b)(10)(A)(iii)(IX).
[9] FD&C Act 301(ccc)(1).
[10] FD&C Act 503(e)(4)(G).

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Congress's intent to allow physicians and pharmacies to have the ability to dispense human compounded drug product to their patients was articulated by Representative Pallone during the House Debate:

> The bill will permit compounders who wish to practice outside the scope of traditional pharmacy to register as outsourcing facilities but those who choose to remain traditional pharmacies will continue to be regulated as they are under current law. ***This gives doctors and hospitals the ability to purchase compounded drugs for their patients made in a facility that is subject to stringent FDA quality standards and oversight*** (emphasis added).[11]

The FDA seems to agree with Congress's intent as illustrated in the *Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act,* Guidance for Industry.[12] This guidance sets forth the FDA's policy concerning certain prescription requirements for compounding human drug products for identified individual patients under Section 503A of the FD&C Act and it is instructive for our discussion here as the FDA agrees that "[o]utsourcing facilities, which are subject to CGMP requirements, FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that provide greater assurance of the quality of their compounded drug products"[13] compared to products compounded by a physician or in a 503A pharmacy. The FDA even states that "[b]ecause drug products compounded in accordance with section 503A are exempt from CGMP requirements, there is an inherently greater chance of a production mistake or contamination."[14] Thus, when a compounded drug product is required, it is preferable for a physician or a 503A pharmacy to obtain such products from a 503B which is subject to the robust quality standards of cGMP, rather than having the physician or 503A compound the product.

II. Patient Access and Patient Safety

Congress contemplated a mitigation strategy for drug shortages when it created the option for facilities to register with the FDA as a 503B, distinguishing the work of these facilities from traditional pharmaceutical compounding. Because 503Bs are subject to enhanced FDA scrutiny, these 503Bs may compound and distribute drugs without a patient-specific prescription. Registration with the FDA enables a facility to compound and distribute drugs without a patient-specific prescription, provided that the facility meets certain statutory conditions. 503Bs may compound drugs from bulk drug substance when the drug is on shortage.

The public health emergency caused by COVID-19 illustrated the necessary need 503Bs fill in the pharmaceutical supply chain. Due to COVID-19, many hospitals were and are still currently

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[11] Floor Debate on H.R. 3204 (Sept. 28. 2013) (statement of Rep. Pallone) at 14:40, the Honorable Frank Pallone, YOUTUBE, https://www.youtube.com/watch?v=suLWdacjcY0.
[12] U.S. FOOD & DRUG ADMIN., PRESCRIPTION REQUIREMENT UNDER SECTION 503A OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, GUIDANCE FOR INDUSTRY (Dec. 2016).
[13] *Id.* at 14.
[14] *Id.* 6–7.

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experiencing difficulties accessing FDA-approved drug products used for patients with COVID-19. Fortunately, 503B outsourcing facilities exist and the FDA provided them greater latitude to compound drugs used for hospitalized patients with COVID-19.[15]

Patients suffer from access issues caused by drug shortages every day. In fact, according to the American Society of Health System Pharmacists, in the third quarter of 2020, the United States experienced 265 active drug shortages.[16] Patients should not suffer because manufacturers cannot maintain a secure supply chain. Recently, U.S. News Health profiled "the dire consequences these shortages pose, which include unsafe practices, compromised patient care and potentially harmful medication errors."[17] 503Bs can fill the gap to ensure patients have access.

For traditional pharmacies or physicians to compound a medication, under federal law, a compounder must receive a prescription in order to compound medications via a 503A pharmacy. Arguably, this patient-specific requirement exists because 503A compounding pharmacies are held to the lesser quality standard of USP <795> and USP <797> as USP standards do not require as many safety checks like the standards set forth under Section 503B. cGMPs are not part of the USP standards. Nevertheless, we do not want another compounding disaster to occur like the New England Compounding Center (NECC) catastrophe caused by compounding under the 503A regulatory pathway. Section 503B did not exist at the time of NECC. Section 503B was enacted to secure patient access and patient safety.

III. Conclusion

The OFA respectfully urges the Board to adopt a reasonable interpretation of the wholesale prohibition under Section 503B to allow a physician or 503A pharmacy to dispense drug product compounded under the robust safety and quality standards of 503Bs.

Sincerely,

LR

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[15] U.S. FOOD & DRUG ADMIN., TEMPORARY POLICY FOR COMPOUNDING OF CERTAIN DRUGS FOR HOSPITALIZED PATIENTS BY OUTSOURCING FACILITIES DURING THE COVID-19 PUBLIC HEALTH EMERGENCY (Revised May 21, 2020).

[16] American Society of Health-System Pharmacists, Drug Shortages Statistics, https://www.ashp.org/Drug-Shortages/Shortage-Resources/Drug-Shortages-Statistics.

[17] Linda Marsa, *Tackling Dangerous Drug Shortages*, U.S. NEWS HEALTH (Oct. 22, 2020), https://health.usnews.com/health-care/patient-advice/articles/tackling-dangerous-drug-shortages.

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www.hoganlovells.com

December 11, 2020

By Electronic Mail

J. David Wuest, R.Ph.
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Ste 206
Reno Nevada 89521
dwuest@pharmacy.nv.gov

Re: Sincerus Pharmaceuticals, Inc. Application for Outsourcing Facility License; Interpretation of the Prohibition on Wholesaling Under Section 503B of the Federal Food, Drug, and Cosmetic Act

Dear Mr. Wuest:

I am writing on behalf of Sincerus Pharmaceuticals, Inc. (Sincerus), an outsourcing facility under section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA), in response to statements made at the Nevada State Board of Pharmacy (the Board) meeting on October 14, 2020, indicating that the Board may believe that the wholesaling prohibition under section 503B(a)(8) of the FDCA[1] prohibits the distribution of compounded drugs to physicians' offices for dispensing by physicians to their patients pursuant to a prescription. As discussed below, the language of the 503B wholesaling prohibition expressly states that it does not prohibit such dispensing and, therefore, should not prevent the Board from approving Sincerus's application for an out-of-state outsourcing facility license.

The wholesaling prohibition explicitly excludes "dispensing" from the prohibition on wholesaling. In addition, an overly restrictive interpretation of the wholesaling prohibition that bars dispensing a 503B-compounded drug pursuant to a prescription would have an adverse effect on public health by precluding hospital outpatient dispensing of 503B-compounded drugs and by encouraging other forms of compounding that are less well-controlled than 503B compounding. Moreover, the Board's interpretation is preempted by federal law because it undermines FDA's ability to implement the federal statute in a coherent manner, particularly pending issuance of FDA's anticipated guidance interpreting the federal wholesaling prohibition. For these reasons, as described in further detail below, we respectfully request that the Board grant Sincerus a Nevada outsourcing facility license.

[1] 21 USC 353b(a)(8).

I. Background

a. *Prohibition on Wholesaling Under Section 503B*

In general, section 503B of the FDCA exempts drugs compounded by a registered outsourcing facility from the requirements regarding submission of new drug applications, labeling of drugs with adequate directions for use, and drug supply chain security requirements if certain conditions are satisfied.[2] One such statutory condition is that the 503B outsourcing facility is prohibited from engaging in wholesaling of the compounded product. Specifically, the statute provides, in relevant part, that the exemptions will apply if:

> The drug will not be sold or transferred by an entity other than the outsourcing facility that compounded such drug. ***This paragraph does not prohibit*** administration of a drug in a health care setting or ***dispensing a drug pursuant to a prescription*** executed in accordance with [21 USC 353(b)(1)].[3]

21 USC 353(b)(1) refers to the requirement that certain products be dispensed only "upon a written prescription of a practitioner licensed by law to administer such drug...." In addition, section 503B requires that the label of a 503B-compounded product include certain other types of information, including, in relevant part, the statement "Not for resale" and, in some cases, "Office Use Only."[4]

b. *Relevant Nevada state law*

In Nevada, outsourcing facilities are required to apply to the Board as an out-of-state outsourcing facility.[5] An outsourcing facility is defined as "a facility at one geographic location or address that (1) is engaged in the compounding of sterile drugs;[6] and (2) has registered with the Secretary of Health and Human Services as an outsourcing facility pursuant to 21 USC 353b."[7] Additionally, an outsourcing facility is not generally required to be licensed as a

---

[2] *See* 21 USC 353b(a).

[3] 21 USC 353b(a)(8) (emphasis added).

[4] *Id.* at 353b(a)(10)(A)(iii)(IX). The statement, "Office Use Only" is not required if it is known that the compounded drug will be "dispensed or distributed ... pursuant to a prescription for an individual identified patient," rather than administered in the office. Accordingly, under current policies and procedures, drugs that Sincerus anticipates will be dispensed by a physician pursuant to a prescription, rather than administered in the office, are no longer be labeled as "Office Use Only."

[5] *See* NAC 639.6915.

[6] Under Section 503B, a facility that compounds sterile drugs is also eligible to compound non-sterile drugs as an outsourcing facility. *See* FDA, *Guidance: For Entities Considering Whether to Register As Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (Aug. 2015) at 8, *available at* https://www.fda.gov/media/90971/download/.

[7] NAC 639.6912.

pharmacy, unless the outsourcing facility "dispense[s] dangerous drugs or controlled substances for identified individual patients pursuant to a prescription."[8]

Nevada also allows physicians with the required authorization to dispense prescriptions drugs: A "practitioner who wishes to dispense controlled substances or dangerous drugs" must apply to the Board for authorization to dispense such products.[9] In this context, the term "dispense" is defined to mean "to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery."[10] "Dangerous drugs" are defined under state law to mean, among other things, prescription drugs (i.e., "any drug, other than a controlled substance, unsafe for self-medication or unsupervised use, and includes the following: (1) Any drug which has been approved by the Food and Drug Administration for general distribution and bears the legend 'Rx Only;' … or (3) Any drug which, pursuant to the Board's regulations, may be sold only by prescription because the Board has found those drugs to be dangerous to public health or safety").[11] In addition, a dispensing practitioner is authorized to "[p]roduce and affix appropriate labels to containers" that contain the drugs that are to be dispensed.[12]

Furthermore, under Nevada law, practitioners are permitted to compound drugs and dispense these products to patients. Specifically, NAC 639.742(5) provides:

> [A] dispensing practitioner may compound drug products if he or she complies with the provisions of NAC 639.661 to 639.690, inclusive, as if:
>
> (a) He or she were a pharmacist;
> (b) His or her practice site was a pharmacy; and
> (c) Any dispensing technician involved in the compounding was a pharmaceutical technician.

c. *Factual Background*

Sincerus is an FDA-registered 503B outsourcing facility engaged in the compounding of sterile and non-sterile human drug products that are sold to doctors' offices and hospitals for administration in a physician's office or other healthcare setting or dispensing pursuant to a prescription by physicians to their patients. All of Sincerus's compounded drug products are manufactured in strict compliance with cGMP requirements and applicable quality standards.

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[8] NAC 639.6916.

[9] NAC 639.742(1).

[10] NRS 639.0065(1).

[11] NAC 639.010 (citing NRS 454.201).

[12] NAC 639.742(4)(e).

Indeed, on November 16, 2020, FDA issued an FMD-145 letter, closing out FDA's two most recent inspections of Sincerus.[13]

On May 5, 2020, Sincerus submitted to the Board an application for an out-of-state outsourcing facility license.[14] At the Nevada Board of Pharmacy meeting on October 14, 2020, some members of the Board and staff expressed concern that the wholesaling prohibition under federal law prohibits Sincerus from providing compounded products to physicians for dispensing to their patients pursuant to prescriptions.[15] During the meeting, the Board and staff indicated their belief that physician "dispensing" was the same as "resale," and that the federal statute did not permit practitioners to "resell" or "re-dispense." In the course of the discussion, staff also suggested that instead, under Nevada law, "practitioners could compound the drug themselves, and then dispense them." Sincerus explained its belief, supported by the language of 503B, that the wholesaling prohibition did not prohibit dispensing of the product by practitioners pursuant to a prescription. The application was tabled to allow Sincerus to further discuss the matter with Board staff. We are submitting this letter to provide a more detailed analysis in support of our interpretation of the wholesaling prohibition in section 503B of the FDCA in order to address the Board's concerns.

II. Analysis

a. The federal wholesaling prohibition does not extend to sales to doctors' offices for dispensing a drug to patients pursuant to a prescription

As described above, under section 503B of the FDCA, outsourcing facilities are prohibited from wholesaling compounded drug products. Although section 503B does not define "wholesaling," it states that the drug must not "be sold or transferred by an entity other than the outsourcing facility that compounded such drug."[16] If read broadly and in isolation, without further qualification – as suggested by the Board – this language would prohibit a hospital or other healthcare entity, as well as a physician, from administering, dispensing, and obtaining payment for a 503B-compounded drug. However, Congress expressly limited the wholesaling prohibition by specifying that it ***does not include*** either "administration in a healthcare setting" or "dispensing" pursuant to a patient prescription.[17] Therefore, section 503B allows for compounded drugs to be both administered in a doctor's office and dispensed by a doctor for outpatient use by the doctor's patients pursuant to a prescription for each individual patient.

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[13] *See, e.g.*, FDA letter from CDR John W. Diehl, M.S. to Dr. Spencer J. Malkin, dated November 16, 2020, closing out FDA's two most recent inspections of Sincerus.

[14] Sincerus Florida, LLC, Application for Out-of-State Outsourcing Facility License (May 5, 2020).

[15] Nevada State Board of Pharmacy, October 15-15 Board Meeting Minutes, *available at* https://bop.nv.gov/uploadedFiles/bop.nv.gov/content/board/ALL/2018_Meetings/3.%20October%202020%20Meeting%20Minutes.pdf, at 24 of 33.

[16] 21 USC 353b(a)(8).

[17] *Id.*

Although 503B-compounded products are required to be labeled with the phrase, "Not for resale",[18] "dispensing" a product is distinct from "resale" of a compounded drug. In requiring 503B-compounded drugs to be labeled "Not for resale," Congress did not intend to prevent them from being dispensed pursuant to a prescription or administered for office use or in a healthcare facility. Such a reading would render meaningless the exclusions from the wholesaling prohibition and prohibit charging patients for ***any*** 503B-compounded drugs, even if administered in the hospital or doctor's office. Viewing outpatient dispensing as a prohibited "resale" would also mean that outpatient dispensing of 503B compounded drugs from hospitals and clinics was prohibited, and it would necessarily prohibit charging for in-office administration and even hospital administration of 503B-compounded drugs. Instead, when there is a tension between two provisions in a statute, courts generally interpret both provisions in a way that renders them compatible, not contradictory.[19] Here that means recognizing that the "not for resale" labeling requirement does not prohibit a healthcare facility from administering or dispensing a 503B-compounded drug to a patient pursuant to a prescription, even if the physician or healthcare facility ultimately receives compensation for a drug that was dispensed or administered.[20]

It is clear from the crafting of section 503B that the statutory wholesaling prohibition was intended to prohibit a 503B outsourcing facility from selling compounded drug product to a wholesaler who is engaged in the resale of the compounded drug to ***another*** entity for administration or dispensing. In other words, Congress intended for there to be only a single transaction between the entity compounding the drug product and the entity dispensing or administering the product in a healthcare setting. This setup would allow for the traditional route for outsourced compounded products, whereby a healthcare provider purchases a compounded drug product and subsequently dispenses and/or administers the product to a patient. In some cases, the healthcare provider may dispense the compounded drugs on an outpatient basis, including to patients upon discharge from the hospital or to patients that were never admitted to the hospital.

This interpretation of the 503B wholesaling prohibition is also supported by the legislative history, purpose, and structure of the statute. Prohibiting the sale of 503B-compounded drug product to physicians who dispense the drug to patients would undermine

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[18] 21 USC 353b(a)(10)(A)(iii)(IX).

[19] *See FDA v. Brown & Williamson Tobacco Corp.*, 529 US 120, 133 (2000) ("A court must … interpret the statute 'as a symmetrical and coherent regulatory scheme,' and 'fit, if possible, all parts into an harmonious whole.' ") (internal citations omitted)).

[20] Similarly, the "Office Use Only" labeling requirement does not preclude a physician from dispensing a drug pursuant to a prescription, excluded from the 503B wholesaling prohibition. Although FDA has never defined the term "office use," its plain meaning encompasses both administration and dispensing in the office pursuant to a prescription—both of which are carved out of the wholesaling prohibition. For example, a 503B-compounded drug that is distributed for potential office administration may be labeled "Office Use Only," excluded from the wholesaling prohibition, and subsequently relabeled by the physician for dispensing pursuant to a prescription, in accordance with Federal law (21 USC 353(a)(8)) and Nevada law (NAC 639.742(4)(e)), which allows for such re-labeling. However, Sincerus initiated a policy change so as not to label drugs "Office Use Only" that are anticipated to be dispensed by a physician pursuant to a prescription rather than administered in the office.

Congressional intent with regard to 503B compounding activities, which was to "give[] ***doctors*** and hospitals the ability to purchase compounded drugs for their patients made in a facility that is subject to stringent FDA quality standards and oversight."[21] Furthermore, FDA guidance regarding the prescription requirement for 503A pharmacies makes clear that ***503B outsourcing facilities*** are the appropriate source for compounded drugs for ***doctors' offices***, known as "office use" or "office stock."[22] Although neither statute nor FDA has defined the terms "office stock" and "office use," their plain meaning encompasses both office administration and office dispensing.

Furthermore, at the same time, and within the same statute, as Congress enacted 503B as part of the Drug Quality and Security Act,[23] Congress also amended the definition of the term "wholesale distribution" as part of the Drug Supply Chain Security Act (DSCSA).[24] Consistent with the 503B wholesaling prohibition, this definition of "wholesale distribution" expressly exempted "the purchase or other acquisition by a dispenser."[25] In addition, DSCSA defined "dispenser" in relevant part as "a person authorized by law to dispense or administer prescription drugs."[26] Thus, under the DSCSA, the acquisition of a drug by a physician is not considered wholesale distribution. Congress's concurrent, express exclusion of transactions with physicians from the meaning of wholesale distribution further supports the exclusion of such transactions from the 503B wholesaling prohibition.

b. Divergent state interpretations of the wholesale prohibition would impede FDA's federal implementation of section 503B

As noted above, Congress clearly did not intend to restrict 503B compounding such that doctors' offices would be prohibited from administering 503B-compounded drugs or dispensing them pursuant to a prescription. The Board's position conflicts with Congress's approach and undermines the federal 503B compounding scheme. As a result, it is preempted by federal law.

According to federal preemption principles, a state law or requirement is preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress."[27] Thus, state requirements are preempted where they interfere with the delicate

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[21] Floor Debate on HR 3204 (statement of Rep. Pallone), Cong. Rec. 159:10 (Sep. 28, 2013) at 14648 (emphasis added).

[22] *See* FDA, *Guidance for Industry: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (Dec. 2016) at 10-11.

[23] Pub. L. No. 113-54, 127 Stat. 587 (Nov. 27, 2013).

[24] *See* 21 USC 353(e)(4).

[25] 21 USC 353(e)(4)(G).

[26] 21 USC 360eee(3)(A).

[27] *See Arizona v. United States*, 132 S Ct. 2492, 2501 (2012) (quoting *Hines v. Davidowitz*, 312 US 341, 349 n.4 (2001)).

balance of policy objectives undertaken by Congress and/or a federal agency such as FDA.[28] In addition, state requirements are preempted where they undermine a federal policy favoring a uniform national approach rather than patchwork state regulation.[29] Here, the Board's interpretation of the wholesaling prohibition contradicts the clear language and intent of the statute and will impede FDA's ability to implement the statute in a coherent and effective manner and ensure a consistent approach to regulated entities nationwide. Moreover, FDA has acknowledged that federal guidance on interpreting the wholesaling provision is needed and has indicated its intent to issue guidance interpreting the wholesaling prohibition under section 503B of the FDCA.[30] Therefore, pending issuance of FDA's guidance interpreting the prohibition, a state may not enforce an interpretation of the wholesale provision that includes dispensing that is expressly permitted by 503B.

In fact, FDA has specifically identified state differences in licensing requirements for outsourcing facilities and differences among states' interpretations of the wholesaling prohibition as areas of concern.[31] More generally, FDA has highlighted the importance of alignment among the states and consistency regarding licensure and registration of compounders registered as outsourcing facilities under Section 503B of the FDCA. For example, as FDA noted in its preliminary recommendations for aligning federal and state regulation of 503B compounding outsourcing facilities, "FDA-State regulation alignment is particularly important in three specific areas: licensure and registration, filling of patient-specific prescriptions, and compliance with current good manufacturing practice (CGMP) requirements."[32] FDA noted that consistency in the federal and state regulation of outsourcing facilities "is important to their success, and by extension, successful implementation of the Drug Quality and Security Act [section 503B]."[33] FDA further highlighted that greater alignment between federal and state requirements would reduce conflicts, burdens, and confusion on the part of outsourcing facilities, which "in turn will help foster the success of the outsourcing facilities, which the [statute] created to help to address national concerns about oversight and quality of compounding practices."[34] Federal law simply leaves no room for states to take a divergent view on these issues.

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[28] *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 350 (2001).

[29] *Nash v. Florida Indus. Comm.*, 389 U.S. 235, 239 (1967) ("a state law cannot stand that 'either frustrates the purpose of the national legislation or impairs the efficiency of those agencies of the Federal government to discharge the duties, for the performance of which they were created.' ").

[30] *See* CDER, Outsourcing Facility Information (Sep. 2017) at 8 (noting that "FDA intends to issue a policy document on [the wholesaling prohibition provision at 21 USC 353b(a)(8)] in the future"), *available at* https://www.fda.gov/media/107569/download.

[31] *See* FDA Responses to Action Items from March 18-19, 2015 Inter-governmental Working Meeting (describing the variation in licensing of outsourcing facilities in different states and specifically referring to the prohibition on wholesaling as a source of confusion), *available at* https://www.fda.gov/drugs/human-drug-compounding/fda-responses-action-items-march-18-19-2015-inter-governmental-working-meeting.

[32] FDA, Preliminary Recommendations for Aligning Federal and State Regulation of Compounders Registered as Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act at 1, *available at* https://www.fda.gov/media/100224/download.

[33] *Id.*

[34] *Id.* at 3-4.

In addition, FDA has recognized that the imposition of state requirements that differ from federal law "have the potential to undermine the development of outsourcing facilities as a source of compounded drugs that are prepared subject to higher quality standards." As described in further detail in the next section, the Board's interpretation of the wholesaling prohibition, not only conflicts with the statutory scheme dictated by Congress in section 503B of the FDCA, but also would have adverse public health implications.

c. Interpreting the wholesaling prohibition to not allow dispensing a 503B-compounded drug pursuant to a prescription would have an adverse effect on public health

Disallowing 503B outsourcing facilities from providing product manufactured under cGMP to physicians' offices for dispensing could have several significant ramifications for the public health, because it would encourage other types of compounding that are less well-controlled than 503B compounding: (1) This approach would incentivize compounding by physicians themselves, even though physicians are not subject to the same stringent quality and manufacturing standards as 503B outsourcing facilities; (2) a broadly-interpreted, blanket prohibition on wholesaling would impede the ability of hospitals to dispense or administer 503B-compounded product in the outpatient setting; and (3) this prohibition would encourage or incentivize 503A pharmacy compounding for dispensing by physicians, contrary to both Nevada law and FDA policy goals for the compounding program. Moreover, these scenarios have the potential to put patients at risk of serious harm from contaminated compounded products.

Nevada law permits practitioners to compound drugs and dispense these products to patients.[35] Disallowing a 503B outsourcing facility from providing compounded drugs to physicians would incentivize or encourage physician compounding, which is not subject to cGMP or even requirements relating to insanitary conditions.[36] This would put patients at risk of receiving contaminated products and would undermine the very purpose of the federal 503B provisions.

FDA has acknowledged concerns relating to physician compounding of drug products. In a 2016 working group, FDA noted that "potential issues related to physician compounding" included "concerns about the ability to ensure physician adherence to and awareness of quality standards through sufficient oversight."[37] FDA also specifically noted that "[c]oordinating oversight across multiple federal and state agencies (such as state boards of pharmacy, state boards of medicine, state and local departments of health) presents challenges" and that it does not generally inspect physicians' offices, and therefore is often not aware of problems until a

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[35] NAC 639.742(5).

[36] *See* FDA, *Guidance for Industry: Insanitary Conditions at Compounding Facilities* (Nov. 2020) at 1, n.3, *available at* https://www.fda.gov/media/124948/download (stating that with regard to insanitary conditions requirements, FDA intends to use enforcement discretion for physicians compounding for in-office administration).

[37] *See* Summary of Proceedings, September 20-21, 2016, Inter-governmental Working Meeting on Compounding, *available at* https://www.fda.gov/media/103527/download.

problem arises.[38] There have been reports of serious adverse events resulting from physician compounding, including in 2016 when patients developed fungal blood infections after receiving contaminated compounded IV medications prepared at an outpatient clinic.[39] As a policy and public health matter, a physician should be permitted to obtain compounded products from a 503B outsourcing facility instead of compounding themselves, given the higher quality and manufacturing standards to which 503B compounders are subject.

The restriction on physician dispensing of 503B-compounded drugs would also, by logical extension, prohibit ***hospital outpatient dispensing*** of such drugs, which is a widely used practice for non-patient-specific drugs—providing patient access to unavailable drugs by the safest means possible. For example, 503B-compounded drugs are often dispensed on an outpatient basis for home hospice use and for home dialysis.[40] Outsourcing facilities have a played a critical role in addressing chronic shortages of a number of outpatient drugs, including peritoneal dialysis solutions, which have been exacerbated during the COVID-19 emergency. In addition, outsourcing facilities frequently compound for outpatient dispensing certain drugs for parenteral antimicrobial therapy, where customized dosing and admixture are often necessary.[41] If Nevada interprets the wholesaling prohibition to preclude office dispensing of 503B-compounded drugs, that interpretation would necessarily extend to outpatient dispensing by hospitals and other healthcare facilities, which will either induce the same drugs to be compounded by 503A pharmacies or lead to shortages that will adversely affect patient care.

Sincerus recognizes that Nevada state law prohibits ***pharmacies*** from providing drugs for sale in doctors' offices.[42] Pharmacies are defined in Nevada state law as "every store or shop licensed by the Board where drugs, controlled substances, poisons, medicines or chemicals are stored or possessed, or dispensed or sold at retail, or displayed for sale at retail, or where prescriptions are compounded or dispensed."[43] 503B outsourcing facilities are *not* pharmacies under federal law or Nevada law, and they are only required to register as pharmacies if directly

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[38] *Id.*

[39] *See* A. Vasquez, *et al.*, *Notes from the Field:* Fungal Bloodstream Infections Associated with a Compounded Intravenous Medication at an Outpatient Oncology Clinic, CDC Morbidity and Mortality Weekly Report (Nov. 18, 2016), *available at* https://www.cdc.gov/mmwr/volumes/65/wr/mm6545a6.htm?s_cid=mm6545a6_w.

[40] *See* Advancing American Kidney Health, Executive Order 13879, 84 FR 33817, 33818 (July 15, 2019) (creating payment incentives for greater use of home dialysis to "improve quality of life and care for patients who require dialysis.").

[41] *See, e.g.,* 2018 Infectious Disease Society of America Clinical Practice Guideline for the Management of Outpatient Parenteral Antimicrobial Therapy, *available at* https://academic.oup.com/cid/article/68/1/e1/5175018#124458579. These drugs, which are compounded by outsourcing facilities and relied upon for outpatient dispensing, include cefazolin, ceftazidime, gentamicin, metronidazole, polymyxin B, vancomycin, and sodium thiosulfate.

[42] *See* NAC 639.757(4) (prohibiting sale of a drug by pharmacies to a practitioner, unless the practitioner will be administering the drug to a patient or the compounded drug is a highly concentrated drug product that is not commercially available).

[43] NRS 639.012.

dispensing to patients.[44] Again, as a policy matter, it is reasonable that Nevada would prohibit 503A pharmacies from supplying compounded drugs to doctors' offices for dispensing, as these entities are exempt from the stringent quality standards required of 503B outsourcing facilities. However, there is no reasonable justification for disallowing federally registered 503B outsourcing facilities from doing so. Although Nevada law generally prohibits pharmacies from selling compounded drugs to doctors office for dispensing, that prohibition does not extend to outsourcing facilities and should not influence Nevada's interpretation of the federal prohibition on wholesaling.

In fact, allowing 503B, but not 503A, facilities to supply physicians' offices for outpatient dispensing would be consistent with FDA's views on 503A pharmacy compounding. FDA has stated that 503A pharmacies cannot supply "office stock" because they cannot compound without individual prescriptions.[45] In contrast, FDA has encouraged 503B facilities to compound for physicians' offices.[46] Using the wholesaling prohibition to block 503B facilities from serving this role would encourage 503A pharmacies to compound drugs for outpatient dispensing, which FDA has said is contrary to law. In guidance on 503A pharmacy compounding, FDA stated, "Outsourcing facilities [under section 503B], which are subject to CGMP requirements, FDA inspections according to a risk-based schedule, specific adverse event reporting requirements, and other conditions that provide greater assurance of the quality of their compounded drug products" as compared to products compounded by a physician or a 503A pharmacy.[47] FDA further notes, "Because drug products compounded in accordance with section 503A are exempt from CGMP requirements, there is an inherently greater chance of a production mistake or contamination."[48] Thus, only 503B facilities are permitted to fill this role.

III. Conclusion

For the reasons described above, the Board should not deny Sincerus a 503B outsourcing facility license based on the federal wholesaling prohibition. It is clear that the federal statute was not intended to restrict 503B compounding to prohibit the dispensing of 503B-compounded product by physicians' offices to patients. To interpret the statute in this manner would undermine the federal implementation of the 503B provisions, particularly in light of FDA's stated intent to issue guidance on this particular provision, and would, therefore be preempted. Furthermore, interpreting the statute to restrict 503B compounding in this manner would have negative

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[44] NAC 639.6916.

[45] FDA, *Guidance for Industry: Prescription Requirement Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (Dec. 2016) at 10, *available at* https://www.fda.gov/files/drugs/published/Prescription-Requirement-Under-Section-503A-of-the-Federal-Food--Drug--and-Cosmetic-Act-Guidance-for-Industry.pdf.

[46] *Id.* at 10-11 (stating "...some compounded drug products are kept as office stock/for office use by hospitals, clinics, or health care practitioners to administer to patients who present with an immediate need for a compounded drug product. Hospitals, clinics, and health care practitioners can obtain non-patient-specific compounded drug products from outsourcing facilities registered under section 503B.").

[47] *Id.* at 11.

[48] *See id.* at 6-7.

implications for the public health, including by impeding hospital outpatient dispensing and administration of 503B-compounded drugs and by encouraging forms of compounding that are not subject to the same controls as 503B compounding.

Sincerus appreciates the Board's time and attention to this important matter. Please do not hesitate to contact us with any questions.

Sincerely,

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SFY21 MONTHLY BUDGET REPORT
NEVADA STATE BOARD OF PHARMACY
CURRENT MONTH: Dec 20

REVENUES	APPROVED BUDGET	BUDGET AMENDMENTS	REVISED BUDGET	CURRENT MONTH REVENUE/EXPENSE	PRIOR MONTH(s) REVENUE/EXPENSE	PROJECTIONS THROUGH 6/30/2020	TOTAL REVENUE/EXPENSE SFY21	DIFFERENCE
Beginning Balance	$ 2,133,664		$ 2,133,664	$ -	$ 2,234,060	$ -	$ 2,234,060	$ 100,396
Renewal Fees	$ 4,576,617		$ 4,576,617	$ 13,660	$ 4,525,270	$ 96,870	$ 4,635,800	$ 59,183
Registration Fees	$ 687,460		$ 687,460	$ 88,470	$ 294,658	$ 304,333	$ 687,460	$ -
Misc. Revenue	$ 155,000	$ (154,000)	$ 1,000	$ 200	$ 382	$ 582	$ 1,164	$ 164
Recovered Costs	$ -	$ 28,000	$ 28,000	$ 1,500	$ 7,913	$ 9,413	$ 18,826	$ (9,174)
CC Processing Fees	$ -	$ 107,500	$ 107,500	$ 1,601	$ 230,128	$ 1,000	$ 232,728	$ 125,228
Paper Use Fee	$ -	$ -	$ -	$ -	$ 40	$ -	$ 40	$ 40
Change MGR RPh	$ -	$ 11,500	$ 11,500	$ 1,050	$ 2,710	$ 3,760	$ 7,520	$ (3,980)
Inspections	$ -	$ 7,000	$ 7,000	$ 75	$ 225	$ 300	$ 600	$ (6,400)
Interest Income	$ 30,500		$ 30,500	$ 1,078	$ 10,992	$ 18,430	$ 30,500	$ -
Late Fees	$ 25,000		$ 25,000	$ 4,055	$ 17,575	$ 3,370	$ 25,000	$ -
Total Revenues	**$ 7,608,241**	$ -	**$ 7,608,241**	**$ 111,689**	**$ 7,323,953**	**$ 438,057**	**$ 7,873,699**	**$ 265,458**

EXPENSES								
Payroll	$ 2,897,623	$ 81,597	$ 2,979,220	$ 241,294	$ 1,193,572	$ 1,517,865	$ 2,952,731	$ (26,489)
Operating	$ 909,437	$ (81,597)	$ 827,840	$ 33,937	$ 362,246	$ 266,749	$ 662,933	$ (164,907)
Equipment	$ 30,000		$ 30,000	$ 1,796	$ 6,691	$ 21,513	$ 30,000	$ -
In-State Travel	$ 110,000		$ 110,000	$ -	$ 17,452	$ 92,548	$ 110,000	$ -
Out-of-State Travel	$ 65,000		$ 65,000	$ -	$ -	$ 65,000	$ 65,000	$ -
DAG Cost	$ 12,000		$ 12,000	$ 46	$ 540	$ 11,413	$ 12,000	$ -
Aid for Education	$ 2,000		$ 2,000	$ -	$ -	$ 2,000	$ 2,000	$ -
Reserve	$ 3,582,181		$ 3,582,181	$ -	$ -	$ 4,039,035	$ 4,039,035	$ 456,854
Total Expenses	**$ 7,608,241**	$ -	**$ 7,608,241**	**$ 277,074**	**$ 1,580,501**	**$ 6,016,123**	**$ 7,873,699**	**$ 265,458**
Balance	$ -	$ -	$ -				$ -	$ -