December 2025 Board Meeting Handouts

5O – Revive Rx

18A – Workshop – Public Comment

A REGULATION relating to the authority of a homeopathic physician who is not licensed as an allopathic or osteopathic physician in Nevada to possess, administer, prescribe and dispense controlled substances and dangerous drugs; and providing other matters properly relating thereto.

17A - Eliab Munyehirwe

19D – Public Hearing LCB File No. R004-25 – Public Comment

21 – Executive Report - Financial Report

50

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

REVIVE Rx,
Pharmacy License No. PH04215,

Respondent.
_____/

CASE NO. 23-411-PH-O

MOTION TO DISMISS

COMES NOW, Respondent REVIVE Rx ("Revive") by and through its undersigned counsel and pursuant to 21 U.S.C. § 337, NRS 639.241(2) and NRCP 12(b)(1) and 12(b) (5), moves the Nevada State Board of Pharmacy (the "Board") to dismiss the Accusation in the above-captioned matter because the Board is without jurisdiction to enforce 21 U.S.C. § 353a, and as a separate defect, the Accusation fails to state a claim upon which relief can be granted because contrary to NRS 639.241, the Accusation "consist[s] merely of charges phrased in language of the statute[s] or regulation[s]."

This Motion is based on the pleadings and papers on file herein and on any oral argument and presentation of evidence the Board may entertain at the hearing(s) on this matter.

RESPECTFULLY SUBMITTED this 7th day of November 2025.

DYER LAWRENCE, LLP

By: ***Francis C. Flaherty***

PISTEVO LAW, LLC

By: ***Philip E. M. Crooker***

MEMORANDUM OF POINTS AND AUTHORITIES

The Nevada State Board of Pharmacy ("Board") filed a Notice of Intended Action and Accusation on March 11, 2025 (the "Accusation") against respondent REVIVE Rx "Revive"). The Board lacks jurisdiction to enforce 21 U.S.C. § 353a, from which the Accusation derives, and the Accusation also fails to provide the requisite specificity and detail to satisfy the requirements of NRS 639.241(2).

I. BASIC FACTS AND PROCEDURAL HISTORY

In NRS 639.090, the Nevada Legislature charged the Board with enforcement of NRS Chapter 639. On or about October 8, 2023, the Board received an email from Anthony Connors ("Connors") wherein he alleged that Revive had violated 21 U.S.C. § 353a. Exhibit ("EX") 1. Mr. Connors did not allege that Revive had violated any provisions of NRS or NAC Chapters 639. Early in the Board's investigation, Revive cautioned Board staff that Connors was not a reliable source and was driven by anti-competitive motives. EX 2 at 1-5. And Revive specifically warned Board staff that it strongly suspected that Mr. Connors was working for one of Revive's industry competitors "to file complaints . . . in an attempt to discredit Revive, force revive to invest extensive time and monetary capital in response to those complaints, and inhibit its ability to compound certain drugs." *Id.* at 3.

Board staff concluded their investigation in issued the Accusation of March 11, 2025. Revive cooperated with Board staff in the investigation by way of answering questions and providing documents. In the sole count of the Accusation, it is alleged that Revive:

- Engaged in unprofessional conduct;
- Violated "***various provisions***" of:
    - 21 U.S.C. § 353a

- NAC 639.67019;
- NAC 639.67067
- NAC 639.67071; "*and/or*"
- NAC 639.757.

Accusation at 3 (emphasis added).

The factual bases in support of the sole count in the Accusation are set forth in Paragraphs 2 and 3 therein. Paragraph 2 asserts that Revive compounded and dispensed drug products to Nevada patients in violation of 21 U.S.C. § 353a. Accusation at 1. Paragraph 3 asserts that Revive "compounded and dispensed high-risk sterile products to Nevada patients with beyond use dates (BUD's) listed" thereon "in excess of USP-797 guidelines." Accusation at 2. Paragraph 3 fails to identify what high-risk sterile products Revive allegedly distributed in a manner contrary to USP-797 guidelines, nor does it provide any specificity that would enable revive to link the allegation to the provisions of NAC 639 identified in Count 1.

II. LAW

> (a) Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter [(21 U.S.C. §§ 301 - 399i)] ***shall be by and in the name of the United States***. Subpoenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any proceeding under this section.
>
> (b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

21 U.S.C. § 337(a),(b)(1) (emphasis added).

NRS 639.241(2) provides in relevant part:

> The accusation is a written statement of the charges alleged and must set forth in ordinary and concise language the acts or omissions with which the respondent

> is charged ***to the end that the respondent will be able to prepare a defense.*** The accusation must specify the statutes and regulations which the respondent is alleged to have violated, ***but must not consist merely of charges phrased in language of the statute or regulation.***

(Emphasis added).

The Nevada Supreme Court has amplified the basic fairness mandate of NRS 639.241(2) and made clear that "[a]lthough proceedings before administrative agencies may be subject to more relaxed procedural and evidentiary rules, due process guarantees of fundamental fairness still apply. Administrative bodies must follow their established procedural guidelines and give notice to the defending party of 'the issues on which decision will turn and . . . the factual material on which the agency relies for decision so that he may rebut it.'" *Dutchess Bus. Servs. v. Nevada State Bd. of Pharm.*, 124 Nev. 701, 711, 191 P.3d 1159, 1166 (2008) (quoting *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 U.S. 281, 288-89 n.4, 95 S. Ct. 438, 443 n.4 (1974)).

NRCP 12(b)(1) provides that a complaint may be dismissed for lack of subject matter jurisdiction and NRCP 12(b)(5) states that a complaint may be dismissed for failure to state a claim upon which relief may be granted.

III. ARGUMENT

A. 21 U.S.C. § 337a Preempts Board Action and Divests the Board of Jurisdiction

21 U.S.C. § 337a plainly states that Nevada, *i.e.*, the Board, simply does not have jurisdiction to enforce 21 U.S.C. § 353a, and that particular statute is not within the list of exceptions allowing state enforcement set forth in 21 U.S.C. § 337a(b)(1). There is nothing vague or ambiguous about the express preemption of state law expressed by Congress in section 337a. As observed by the Ninth Circuit:

> The statutory prohibition on private enforcement gives the FDA discretion to temper enforcement or not to enforce in circumstances it deems appropriate. If state law facilitates enforcement beyond what the FDA has deemed appropriate, then state law claims may indeed "stand as an obstacle" to FDA's enforcement discretion by enabling what the FDA regards as over-enforcement.

Nexus Pharms., Inc. v. Cent. Admixture Pharm. Servs., 48 F.4th 1040, 1048 (2022). The *Nexus* Court continued: "Proceedings to enforce or restrain violations of the FDCA, ***including the compounding statute***, must be by and in the name of the United States." *Id.* at 1049 (emphasis added); *see also Heckler v. Chaney*, 470 U.S. 821, 831, 105 S. Ct. 1649, 1655 (1985) ("This Court has recognized on several occasions over many years that an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion.").

Also helpful for this Board's analysis, the court explained:

> The "Guidance for Industry" documents issued by the FDA . . . "describe the agency's current thinking on a topic." They are helpful for that purpose, showing how and why the agency's enforcement policies operate as they do. The agency thinks compounded drugs "serve an important role for patients whose needs cannot be met by an FDA-approved product."

Nexus. 48 F.4th at 1050. And in its Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug and Cosmetic Act: Guidance for Industry, issued in January 7, 2025 (the "2025 FDA Interim Policy"), a copy of which is attached hereto as Exhibit 3, the FDA explained that the "revision does not change the FDA's policy with respect to bulk drug substances that were nominated for inclusion on the 503A bulks list before the publication date of this guidance." EX 3 at 1.

The 2025 FDA Interim Policy also explained that in the wake of passage of the Drug Quality and Security Act, the "FDA recognized that patients may have a medical need for treatment with certain drugs that they may have received prior to enactment of

the DQSA, but that were compounded from bulk drug substances that the Agency had not yet evaluated for inclusion on the 503A bulks list." *Id.* at 11. Therefore, in developing its "2017 503A Interim Policy Guidance, FDA weighed [] public health interests and concluded that, at that early stage of section 503A implementation, the potential patient benefits of such a policy outweighed the risks." *Id.*

Thus, the FDA has been engaged in the very process described by the *Nexus* Court, in the block quote immediately above, demonstrating why the Board is completely preempted by 21 U.S.C. § 337a from enforcing 21 U.S.C. § 353a.

B. The Accusation Does Not Meet The Pleading Requirements of NRS 639.241(2) or of Due Process.

Aside from the allegation of a federal law violation discussed *supra*, the sole and single count in the Accusation (Paragraph 9) alleges that Revive violated NAC 639.945(1)(i), which states unprofessional conduct as a basis for discipline wherein a licensee "[p]erform[s] any of his or her duties . . . in an incompetent, unskillful or negligent manner." When the Board seeks to discipline a licensee for unprofessional conduct without sufficient specificity, there is a deprivation of due process. *See Nevada State Bd. of Pharmacy v. Garrigus*, 88 Nev. 277, 279, 496 P.2d 748, 749 (1972) ("The accused pharmacists have a right to know what they violated."); *Morrison v. Warren*, 375 F.3d 468, 473 (6th Cir. 2004) ("Due process requires notice of the charges and a meaningful opportunity to contest the evidence."). Revive's opportunity to "contest the evidence" in this matter will not be "meaningful" because it does not have adequate "notice of the charges."

Perhaps in an attempt to provide some specificity, the Accusation claims that Revive engaged in unprofessional conduct because it "violated ***various provisions*** of 21 U.S.C. § 353a, NAC 639.67019, NAC 639.67067, NAC 639.67071 ***and/or*** NAC 639.757." (Emphasis added).

But this "various"-"and/or" laundry list does nothing to cure the ambiguity of the Accusation and Revive's uncertainty regarding what it actually allegedly did wrong or failed to do:

- NAC 639.67019 establishes a pharmacy record retention schedule and inspection mandate for the records a pharmacy must obtain as set forth in an addition 61 other sections of the NAC Chapter 639. The Accusation states nothing about a failure to maintain records or denial or obstruction of the Board's right to inspect any Revive records.
- NAC 639.67067 defines high-risk sterile compounded drug products and establishes storage protocols therefor, but there is nothing in the Accusation stating that Revive improperly stored high-risk sterile compounded drugs.
- NAC 639.67071 requires pharmacies to test high-risk sterile compounded drugs prepared for injection or ophthalmic use to ensure sterility and sets forth details regarding the testing requirements, but there is nothing in the Accusation stating that Revive failed to test high-risk sterile compounded drugs prepared for injection or ophthalmic use.
- NAC 639.757 sets forth the circumstances under which a pharmacy is not required to obtain a license as a manufacturer to compound drugs, and the components of the regulation thereafter are derivative of 21 U.S.C. §353a, which as discussed *supra*, this Board is prohibited from enforcing pursuant to 21 U.S.C. §3373a. *See also Nexus*, 48 F.4th at 1049.

The bedrock of administrative due process is notice and the opportunity to be heard. Vague allegations, such as the ones contained in the Accusation fall far short of this standard. Regarding due process, "the crucial focus is at all times on whether notice was given which

provided the party with an adequate opportunity to prepare and present its evidence." *NLRB v. Complas Industries, Inc.*, 714 F.2d 729, 734 (1983). And in this instance, the Nevada Legislature has taken the additional step of reminding the Board of its due process obligation in NRS 639.241(2) by prohibiting an accusation that "consist[s] merely of charges phrased in language of the statute or regulation." To the contrary, per NRS 639.241(2) the Accusation must "set forth in ordinary and concise language the acts and omissions with which the respondent is charged."

Paragraph 2 of the Accusation is preempted by 21 U.S.C. § 337a, but aside from that, there is no specificity regarding when Revive allegedly dispensed compounded injectable peptides and dispensed other drug products in capsule form or how the dispensing of those injectable peptides and capsules violated 21 U.S.C. § 353a(b)(1). Paragraph 3 of the Accusation alleges that Revive dispensed high-risk sterile products with beyond use dates (BUDs) listed on the product label in excess of USP-797 guidelines. Assuming *arguendo* that this allegation is not also entirely derivative of 21 U.S.C. § 353a, and thus precluded from enforcement by the Board, the Accusation utterly fails to identify the alleged high-risk sterile products that were dispensed, when they were dispensed or how the dispensing was contrary to USP-797 guidelines.

Simply and summarily stated, the Accusation fails to pass due process muster under NRS 639.241(1), *Dutchess Business Services* and *Garrigus* and the Board should dismiss it.

IV. CONCLUSION

The Accusation is derivative of 21 U.S.C. § 353a, and for the reasons stated above, this Board lacks jurisdiction to enforce 21 U.S.C. § 353a, and per that lack of jurisdiction, NRCP 12(b) and NRCP 12(b)(5) require dismissal of the Accusation for failure to state a claim upon which relief can be granted. Additionally, the Accusation fails to satisfy the requirements for

administrative due process established by the Nevada Supreme Court and the federal courts.

Therefore, Revive respectfully moves the Board to dismiss the Accusation.

RESPECTFULY SUBMITTED this 7th day of November 2025.

DYER LAWRENCE, LLP

By: ***Francis C. Flaherty***
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Carson City, Nevada 89706
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By: ***Philip E. M. Crooker***
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CERTIFICATE OF SERVICE

I certify that I am an employee of Dyer Lawrence, LLP, and that on the 7th day of November 2025, I caused a true and correct copy of the foregoing document to be electronically served upon the parties listed below:

Brett Kandt, Esq.
Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, Nevada 89521
bkandt@pharmacy.nv.gov

Kelly Gilbert

EXHIBIT 1

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

REVIVE Rx,
Pharmacy License No. PH04215,

Respondent.

/

CASE NO. 23-411-PH-O

MOTION TO DISMISS

EXHIBIT 1

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Tuesday, October 10, 2023 4:04 PM
To: Mark I. Sedar <msedar@pharmacy.nv.gov>
Subject: FW: ReviveRx

Mark, who would I send this to?

From: Anthony Connors <[redacted]>
Sent: Sunday, October 8, 2023 2:40 PM
To: Pharmacy Board <pharmacy@pharmacy.nv.gov>; Maria Herrera <m.herrera@pharmacy.nv.gov>
Subject: ReviveRx

WARNING This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Greetings,

I write to bring your attention to the regulatory infractions being committed by ReviveRx, a compounding pharmacy licensed to operate in Nevada under Pharmacy License No.PH03016. These infractions include, *inter alia*, the manufacture and sale of performance enhancing drugs, and both the Misbranding of, and Introduction of, Unapproved Drugs into Interstate Commerce.

Some of these drugs were abandoned during clinical trials due to adverse reactions (including death). Others were abandoned due to a lack of efficacy and/or safety, and others simply have not successfully passed the FDA approval process or satisfied FDA as to propriety for use in bulk compounding. Accordingly, all are illegal for the purpose of compounding, all are performance enhancing drugs, and all are being produced and distributed by ReviveRx.

The drugs being illegally compounded and sold by ReviveRx are:

1. AOD-9604
2. BPC-157
3. CJC-1295
4. Dihexa
5. GHK-Cu
6. Ibutamoren Mesylate
7. IGF-I Lr3
8. Ipamorelin
9. Kisspeptin-10
10. Melanotan II
11. MOTs-C
12. Semax
13. Tesamorelin
14. Tesofensine

The Food and Drug Administration has classified AOD-9604, BPC-157, CJC1295, Dihexa, GHK-Cu, Ibutamoren Mesylate, Ipamorelin, Kisspeptin-10, Melanotan II, MOTs-C, Semax, as bulk drug substances in category 2. Therefore, each were nominated (and rejected) for use in compounding under sections 503A or 503B. These drugs were fully evaluated by FDA and rejected for posing significant safety risks. In the case of CJC-1295, clinical trials were halted due to a death in the test group. They are therefore illegal to compound. It should also be noted that most of the aforementioned substances are performance enhancing drugs, and accordingly banned by the United States Anti Doping Agency and World Anti Doping Agency, as well as every major professional and amateur sports league and federation. The remaining drugs, Tesamorelin, Tesofensine, and IGF-I Lr3, although not on the list of drugs specifically banned for compounding, are categorically banned for compounding through their status as biologics (discussed *infra*).

Archived screenshots taken from the ReviveRx.com website on 10/7/23 prove that the growth hormone secretagogues CJC-1295, Ipamorelin, Ibutamoren Mesylate, are still being sold (and advertised) despite the recent FDA decision making them invalid for compounding purposes. Screenshots of the ReviveRx.com site from 2022 and 2023, when compared to the attachments to this email (catalogs), confirm that while many of the illicit drugs were sold openly, others were shielded from public view through being offered for purchase in catalogs only.

In addition to those drugs being specifically listed as bulk drug substances in category 2, and not legal for compounding purposes, the entire list above is categorically banned under the regulations governing compounded biological products.

ReviveRx is a compounding pharmacy located at 3831 Golf Drive, Suite A, Houston, TX 77018, and operating pursuant to section 503A of the Federal Food, Drug, and Cosmetic Act ("FDCA"). While as a section 503A compounder, ReviveRx is exempt from certain requirements for drug manufacturers arising from section 505 of the FDCA, that extension is limited to the compounding of products subject to the FDCA. But ReviveRx has been marketing the aforementioned 13 biological products, which are approved pursuant to section 351 of the Public Health Service Act ("PHS Act") and therefore ineligible for the 503A exemption.

Under section 503A of the FDCA, a drug product compounded by a licensed professional is exempt from certain requirements as long as the drug product is compounded for an identified individual patient based on receipt of a valid prescription. 21 U.S.C. § 353a(a). Those exemptions, however, are limited, and no safe harbor exists for the infractions enumerated herein. Compounded drug products are exempt only from the adulteration and misbranding provisions of the FDCA, as well as the approval provisions for small molecule drug products in FDCA § 505. The exemption from approval requirements does not extend to biological products, which are approved under the PHS Act.

Certain products, like human chorionic gonadotropin ("hCG") and follicle stimulating hormone ("FSH"), were at one time eligible for compounding under the 503A exemption, but this changed in March 2020 when provisions of the Biologics Price Competition and Innovation Act of 2009, Pub. L. 111-148 (2010) (the "BPCIA"), went into effect. The BPCIA amended the definition of "biological product" under the PHS Act to include a "protein." By regulation, FDA subsequently defined "protein" to mean an alpha amino acid polymer with a specific, defined sequences greater than 40 amino acids in size. Definition of the Term "Biological Product," 85 Fed. Reg. 10,057 (Feb. 21, 2020). As a result of this definitional change, in March 2020, all proteins previously approved as New Drug Applications under the FDCA transitioned to Biologics License Applications ("BLA") under the PHS Act. Now, any and all alpha amino acid polymers with more than 40 amino acids are biological products subject to the PHS Act. Revive is additionally compounding hCG and FSH in violation of the applicable regulations.

Several previously compounded products transitioned to biologics in March 2020. Notice to Compounders: Changes That Affect Compounding as of March 23, 2020 (Mar. 5, 2020). In March 2020, FDA provided notice to compounders about the upcoming changes to the regulatory status of these products when it issued a Notice to Compounders. Id. Specifically, this Notice stated, "this transition affects compounding under sections 503A and 503B of the FD&C Act because, beginning on March 23, these transitioning biological products will not be eligible for the exemptions for compounded drugs under sections 503A and 503B of the FD&C Act." Id. (emphasis added). Indeed, FDA further explained in guidance, "a biological product that is mixed, diluted, or repackaged outside the scope of an approved BLA is an unlicensed biological product under section 351 of the PHS Act." FDA, Guidance for Industry: Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application, 5 (Jan. 2018). While that guidance does provide for "enforcement discretion" for the compounding of biologics, such discretion does not apply where the product at issue is a proscribed bulk substance. Id.

ReviveRx's October 2022 Catalog (attached)—published more than two-and-a-half years after the March 2020 transition —advertises hCG and FSH as medication available for "hormone" or "fertility" support (also viewable on the ReviveRx website as archived on 10/7/23). ReviveRx 2022 Catalog. These products are once again offered to its customers in the 2023 version of the Catalog. ReviveRx Catalog 2023. Additionally, ReviveRx offers several other compounded biologics on its website: chorionic gonadotropin— including a compounded follitropin alfa, and insulin lispro. Because these products are now—or always have been—biologics, they categorically are not eligible for the exemptions available for drugs compounded by 503A compounders. Accordingly, distribution of these unlicensed compounded biological products violates the PHS Act. And, because they are compounded from bulk substances, they are not entitled to enforcement discretion under FDA Guidance. FDA, Guidance for Industry:

Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application, 5 (Jan. 2018).

Further, 21 U.S.C.§ 353(1)(A)(B) precludes compounding of drugs, even if they are not biological products, if they are not either a component of a drug approved by FDA, the subject of a United States Pharmacopoeia or National Formulary Drug Monograph or included on FDA's interim or final bulk substance list. 21 U.S.C.§ 353(1)(A)(B). ReviveRx compounds multiple peptides and similar products that are not eligible for compounding under this provision generally, and as discussed previously, have been expressly and categorically prohibited by FDA. For the aforementioned reasons, Food and Drug Administration in 2020 declared AOD-9604, BPC-157, CJC-1295, GHK-Cu, IGF-I Lr3, Melanotan II, MOTs-C, and Semax, to be "ineligible drug products" for compounding. Yet for the next few years, ReviveRx continued to sell each of them.

ReviveRx similarly continues to compound several other unapproved peptides/drugs. These noncompliant compounded products raise significant safety and effectiveness concerns, as Revive is introducing into interstate commerce a new drug without any FDA review, and which can therefore not be labeled in any non-misleading manner. Compounding of these products is not only illegal, but it per the recent FDA decision and public announcement, is also dangerous.

Thank you for your prompt attention to this matter. Please do not hesitate to contact me if you have questions or require additional information.

Sincerely,

Anthony Connors, J.D.

Sent with Proton Mail secure email.

EXHIBIT 2

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,	**CASE NO. 23-411-PH-O**
Petitioner,	
v.	**MOTION TO DISMISS**
REVIVE Rx, **Pharmacy License No. PH04215,**	
Respondent.	

EXHIBIT 2

PHILIP E. M. CROOKER, ESQ.
ATTORNEY & COUNSELOR AT LAW AND PRESIDENT

PISTEVO LAW
LLC
AN FDA FOCUSED LAW & ADVISORY PRACTICE

December 14, 2023

Dena McClish
Investigator
Nevada State Board of Pharmacy
1140 N. Town Center Drive, Suite 300
Las Vegas Nevada 89144

Sent via electronic mail ("e-mail") to dmcclish@pharmacy.nv.gov and USPS Return Receipt Requested

CONFIDENTIAL INFORMATION RELATED TO INVESTIGATION [1]

Re: Revive Rx Pharmacy Response to Nevada State Board of Pharmacy Case 23-411.

Dear Investigator McClish:

This practice represents Revive RX LLC and Revive Rx Pharmacy (collectively "Revive") and acknowledges receiving your correspondence dated November 20, 2023. Although the correspondence did not include a copy of the complaint, the correspondence indicates that the Nevada State Board of Pharmacy (or "Board") has opened an investigation regarding allegations that Revive is advertising and dispensing compounded peptides. Revive also acknowledges the Boards's discretion to permit Revive's response to be received no later than December 18, 2023.

This letter and attachments are a complete response to those allegations. Please include me in all further communications regarding this matter until it has been resolved.

Although a copy of the complaint was not attached, the complaint received by the Board is very likely a duplicate of the same complaint written by "Anthony Connors, J.D." and submitted to dozens of state boards of pharmacy and regulatory agencies. Revive has received a copy of that complaint and it is included as an attachment to this response. Mr. Connors, in a manner and form strikingly similar to the complaint letter previously submitted to several state boards of pharmacy and regulatory agencies by Karla Palmer of the law firm of Hyman, Phelps & McNamara, P.C., (or "HPM") has apparently again engaged in mass letter writing campaign leveling allegations of unlawful conduct in an effort to disparage and harm the business interests of Revive. As you recall, the Board closed its investigation and dismissed that prior complaint from HPM.

[1] Unless exempted, any records or information obtained during the course of an investigation by the Nevada Board of Pharmacy are confidential. Nev. Rev. Stat. § 639.2485 (2021).

As this letter will establish, the written allegations leveled against Revive, very likely made at arm's length by a highly unreliable third party not residing in the State of Nevada and not as a party in any part of the supply chain to the consumer level related to the compounding operations of Revive, do not rise to the level of reasonable cause that a violation of state law or regulation has occurred. There are grave questions regarding the veracity and credibility of the complainant. The complaint appears to be moot, is precluded by the dismissal of a nearly identical prior complaint and appears to lack any minimally viable statement of any cause of action for violation of Colorado law or regulations. There are significant questions whether jurisdiction is appropriate and the role of federal preemption for enforcement of the federal Food, Drug and Cosmetic Act ("FFDCA"). The complaint consistently misapplies existing law regarding the federal regulation of compounded drugs and biologics and much of the supporting evidence is irrelevant.

For these reasons, Revive requests that the Board dismiss the complaint as soon as practically possible so that Revive is not tainted or forced to operate under a cloud of regulatory uncertainty. To make every effort to assist with an expedient review of the complaint, Revive is willing to meet informally with the Board to discuss this response and the myriad weaknesses contained in the complaint and to reinforce Revive's position that the allegations presented in the complaint lack merit and are not reasonable cause that a violation of any state law or regulation has been committed.

The complaint should be evaluated cautiously since it was very likely sent by a highly unreliable party who lacks credibility as part of an effort to harm and damage Revive's reputation and interfere with its financial interests, and the grave lack of credibility is sufficient to dismiss the complaint.

Introduction

On information and belief, Revive suspects that the Anthony Connors who initiated the complaint to the Division is the same Anthony Connors who has a history of targeting companies on behalf of industry competitors to defame them with false information, using misappropriated trade secrets to damage the companies' reputations. We hold this belief because the nature of the complaint made to the Division by Anthony Connors aligns with the nature of the complaints for which the Anthony Connors we identified previously faced civil penalties and injunctions. As is demonstrated below, Anthony Connors' actions have historically been related to performance enhancing drugs, and the Anthony Connors who wrote to the Division complained of Revive's purported infractions with "the manufacture and sale of performance enhancing drugs."[2] While Anthony Connors perceives himself to be "an expert on steroids,"[3] he admits that he has no such credentials[4] and is even referred to by the company that obtained a civil judgment against him as nothing more than a "con artist."[5] While we cannot definitely say that the Anthony Connors that wrote the complaint to the Division is the

[2] Letter from "Anthony Connors, J.D.", to Colorado Division of Professions and Occupations, (October 8, 2023) (copies on file with Division of Professions and Occupations, Revive, and PISTEVO LAW, LLC).
[3] The Basement Bomber, attached hereto as Appendix B.
[4] *Id.*
[5] Steroid.Com Forum -- Anthony Roberts is Fired, attached hereto as Appendix C.

same Anthony Connors who has several civil judgments entered against him, the evidence strongly suggests that they are one and the same person.[6]

On information and belief, Revive also suspects that Anthony Connors is working for an industry competitor to file complaints, such as the one sent to the Division, in an attempt to discredit Revive, force Revive to invest extensive time and monetary capital in response to those complaints, and inhibit its ability to compound certain drugs. As is explained in this response letter, Anthony Connors' complaints intentionally misconstrue the legality of compounding the drugs mentioned in his complaint. Based on the evidence linking the Anthony Connors who made the complaint to the Anthony Connors with a prior history of making similar unfounded complaints, we perceive the complaint to the Division made by Anthony Connors as nothing more than an empty attempt by a competitor to obtain a competitive advantage over Revive.

Revive understands that the Division and the Board must take each complaint seriously and investigate the veracity of the allegations contained therein. However, based on Anthony Connors' prior history making defamatory statements with false or misappropriated information and Revive's belief that this is the same Anthony Connors who is subject to civil judgments and injunctions for engaging in similar behavior, we believe his complaint should be taken with caution. Revive is providing the Division with the following information so that you review the complaint by Anthony Connors through the appropriate lens.

Background Information on Anthony Roberts Connors

A. ThermoLife Lawsuit

Under the alias of Anthony Roberts, a man named Anthony Connors owned and operated the website, "the source for underground steroid information," located at the internet address, anthonyroberts.info (the "Website").[7] Anthony Connors' website purported to expose lies and corruption in the supplement industry.[8]

On July 19, 2013, ThermoLife International, LLC ("ThermoLife") and Ron Cramer sued "Anthony Connors a/k/a Anthony Roberts" for defamation, tortious interference with business relations, and tortious interference with contracts.[9] In that lawsuit, ThermoLife alleged that supplement companies paid Anthony Connors to promote their products and to use his website to falsely attack ThermoLife's products and the raw materials included in those products.[10] Among other things, Anthony Connors allegedly asserted, based on false information, that patents for certain products requested by ThermoLife could not be issued.[11] ThermoLife further alleged that Anthony Connors contacted companies to which those products were marketed and informed them that ThermoLife's patents

[6] Anthony Roberts sent his complaint through "protonmail," which is a Swiss end-to-end encrypted email service to protect email content and user data, in an apparent attempt to further protect his identity.
[7] ThermoLife Complaint, attached hereto as Appendix D.
[8] *Id.*
[9] *Id.*
[10] *Id.*
[11] *Id.*

would not be issued.[12] ThermoLife alleged that Mr. Connors' actions caused it monetary damages and sought an injunction against Anthony Connors to prevent further misrepresentations.[13]

On March 17, 2014, the court entered a default judgment against Mr. Connors, ordering him to pay $530,000 in compensatory damages.[14] Further, the court enjoined Anthony Connors from making any statement on the internet that falsely disparaged either ThermoLife's patent applications or the then-president / CEO of ThermoLife.

B. Dynamic Sports Lawsuit.

In December of 2007, Anthony Connors began employment with Dynamic Sports Nutrition, Inc. ("Dynamic") as a senior editor.[15] Anthony Connors' position required that he assist with drafting promotional items, website content, and informational articles and videos for Dynamic's websites.[16] Anthony Connors wrote under the pseudonym Anthony Roberts. On May 1, 2008, Dynamic terminated Anthony Roberts for several reasons.[17]

On June 18, 2008, Dynamic sued "Anthony Roberts a/k/a Anthony Connors" for misappropriation of trade secrets, violations of the Texas Theft Liability Act, unfair competition, breach of fiduciary duty, conversion, and violations of the Computer Fraud and Abuse Act.[18] Among the allegations in the lawsuit, Dynamic alleged that Anthony Connors "incit[ed] others to file complaints with the FDA, DEA, and FTC" against Dynamic for false advertising and deceptive trade practices.[19] The United States District Court for the Southern District of Texas ultimately entered an injunction and a final judgment against Anthony Connors ordering Mr. Connors to pay $565,065 in lost profits and $6,090,000 in future lost profits to Dynamic.[20]

Anthony Connors was ultimately held in contempt of court for failing to comply with the court's orders.[21] In response, Anthony Roberts Connors filed a letter stating, among other things, that he had turned over the electronic information allegedly stolen from Dynamic to the FBI.[22] Moreover, the U.S. Marshal's office seized Mr. Connors' website (www.robertsblog.com) in connection with this lawsuit.

C. Anthony Connors' Manifesto

We have also located a document claiming to be authored by Anthony Connors dated December 17, 2010, entitled, "The Basement Bomber" in which he explained his modus operandi and the events leading up to the judgment against him by Dynamic. In that manifesto, Anthony Connors admits to

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[12] *Id.*
[13] *Id.*
[14] ThermoLife Order and Judgment, attached hereto as Appendix E.
[15] Dynamic Sports Complaint, attached hereto as Appendix F.
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] *Id.*
[20] Dynamic Sports Injunction and Order, attached hereto as Appendix G; *see also* Dynamic Sports Memorandum and Opinion, attached hereto as Appendix H.
[21] Dynamic Sports Contempt Motion, attached hereto as Exhibit K.
[22] Connors Letters to Court, attached hereto as Appendix L.

using "various names and pseudonyms" as digital avatars in online forums, names which he self-described as "alter ego[s]."[23] In that manifesto, Anthony Connors further admits that he is "an expert liar … a craft [he] has mastered."[24]

In retribution, Anthony Connors admitted that he "snitched on everyone in the community, exposing them to serious legal repercussions," to "teach [them] a lesson."[25] On information and belief, this is what led to the lawsuit filed by Dynamic. Finally, the manifesto ultimately admits that Mr. Connors was trying to "ruin [Brian Clapp's][26] reputation," "steal[ing] Brian's laptop . . . [and] spreading the contents of his hard drive across the internet," and "stealing [Dynamic's] trade secrets."[27]

D. Anthony Connors' Freedom of Information Act Quest

In 2016, Anthony Connors began sending Freedom of Information Requests to the DEA, FBI, and FDA, among many other organizations seeking documents regarding dietary supplements and other drugs.[28] This freedom of information request barrage continues to this day.

Anthony Roberts Connors' Connection to Revive

The Anthony Connors who is subject to civil judgments and injunctions in the ThermoLife and Dynamic lawsuits is strikingly similar to the actions of the Anthony Connors who wrote the complaint to the Division. Accordingly, these individuals appear to be one and the same.

On information and belief, Mr. Connors is working for a competitor to send letters to state pharmacy boards, in a format like the complaint sent to the Division, so that Revive is continually investigated by state agencies, faces the potential loss of its right to compound certain drugs, and invests enormous financial resources and time in response. Indeed, Revive has recently been investigated by two State Board of Pharmacies which have named Anthony Connors as a complainant, including North Carolina. In response to the complaint from Anthony Connors, the North Carolina State Board of Pharmacy closed its investigation and renewed Revive's non-resident compounding pharmacy license with no discipline or restrictions.

Revive has also retained the law firm of Bradley Arant Boult Cummings, LLP ("Bradley") to represent Revive regarding the actions by Anthony Connors and Bradley will continue to investigate the relationship between Mr. Connors and its competitor to put a stop to the damage caused to Revive with this complaint.

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[23] App'x B (The Basement Bomber). Mr. Connors admits that these alter egos were fueled by Sybil—a Greek Goddess with multiple personalities. *Id.*

[24] *Id.*

[25] *Id.*

[26] Brian Clapp was the Principal of Dynamic. *Id.*

[27] *Id.*

[28] *See* MuckRock, Anthony Roberts, *available at* https://www.muckrock.com/accounts/profile/anthonyroberts/, last visited November 8, 2023.

The Board may take notice of its earlier dismissal of a nearly identical complaint.

On June 7, 2022, Revive received correspondence from the Board notifying Revive of a complaint ("letter") from Hyman, Phelps & McNamara P.C. (or "HPM") alleging "unlawful marketing and sale of formulations including biologics compounded by Revive Rx Pharmacy." [29] In addition to raising nearly identical allegations as included in the complaint from "Anthony Connors, J.D.," the complaint from HPM also relied on various screenshots and copies of pages that were allegedly taken from the Revive website. This style and format was also used for the most recent complaint submitted by "Anthony Connors, J.D." For all intents and purposes, the complaints from HPM and "Anthony Connors, J.D." are virtually identical in form, content, and style.

The nearly identical complaint from HPM was closed by the Board. On August 29, 2022, the Board sent Revive a written confirmation that the "matter" of the NPM complaint is "now closed. " [30]

Nev. Rev. Stat. § 47.130 permits judicial notice of facts capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned. *Yellow Cab of Reno v. Second Judicial Dist. Court of Nev.*, 127 Nev. 583, 585. Nev. Rev. Stat. § 47.130(2) states that a judicially noticed fact must be generally known within the territorial jurisdiction of the trial court; or capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned so that the fact is not subject to reasonable dispute. *Cassinari v. Mapes*, 91 Nev. 778, 779. Because the Board is a well-known source whose accuracy is reliable, the communication from the Board closing the matter of the nearly identical complaint from HPM would be judicially noticed.

The powers conferred upon the official designated under the statute to supervise and administer the laws were, at most, quasi-judicial. *Vineyard Land & Stock Co. v. District Court of Fourth Judicial Dist.*, 42 Nev. 1, 18. The Supreme Court of the United States has held that judicial powers may be conferred upon administrative agencies. *Nevada Indus. Comm'n v. Reese*, 93 Nev. 115, 119. In fact, this court has recognized that administrative agencies from one branch can exercise functions linked to another branch without violating the separation of powers doctrine. *See Nevada Industrial Comm'n v. Reese*, 93 Nev. 115, 119-22, 560 P.2d 1352, 1354-56 (1977) (holding that appeals officers can exercise administrative powers "that are quasi-judicial in nature without violating the separation of powers doctrine"). "Such an overlapping or duplication of effort or function can be entirely valid so long as each can logically and legitimately trace its efforts or functions back to, and is derived from, its basic source of power." *Galloway*, 83 Nev. at 22, 422 P.2d at 243. *Comm'n on Ethics v. Hardy*, 125 Nev. 285, 297-298.

Given the Board's recognized quasi-judicial authority, there is an adequate basis in law now for the Board to take notice of its prior dismissal of a nearly identical complaint and likewise act to dismiss this complaint.

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[29] Letter from Karla L. Palmer, Hyman, Phelps & McNamara, P.C., to Colorado Division of Professions and Occupations, *Unlawful Marketing and Sale of Formulations Including Biologics Compounded by Revive Rx Pharmacy*, (May 24, 2022) (copy on file with Division of Professions and Occupations).

[30] E-mail from Dena McClish, Nevada State Board of Pharmacy to Revive Rx and PISTEVOI LAW LLC, (July 22, 2022) (copy on file with Revive and PISTEVO LAW LLC).

The dismissal of the nearly identical prior complaint acts to preclude the Board from litigating this complaint, and the complaint should be dismissed.

The Board previously dismissed and closed a nearly identical complaint.

The doctrine of res judicata is properly limited to the situation where there is a bar to or a merger of the former cause of action. It is a rule which precludes the parties from relitigating what is substantially the same cause of action. *Clark v. Clark*, 80 Nev. 52, 55-56. Generally, the doctrine of res judicata precludes parties or those in privity with them from relitigating a cause of action or an issue which has been finally determined by a court of competent jurisdiction. *Kuptz-Blinkinsop v. Blinkinsop*, 466 P.3d 1271. As a form of res judicata, collateral estoppel or issue preclusion may apply to administrative proceedings. Jerry's Nugget v. Keith, 111 Nev. 49, 50

Because this complaint raises the same claims with the same parties – Revive, the Division and Board – and the legal issue of compounding drugs that were allegedly prohibited was previously determined by the Board by dismissing the nearly identical previous complaint, re-litigation of the claims and issues in this complaint are prohibited in administrative proceedings. As a result, the complaint should be dismissed.

The complaint is moot since Revive has begun efforts to transition its portfolio and does not intend to compound many of the products alleged to be unlawful in the complaint.

Well before the complaint from "Anthony Connors, J.D." was received by the Board and Revive provided notice of the complaint, Revive had begun the process for planning significant changes to its portfolio of products offered to health care providers, patients and consumers, including individually compounded drugs. This process will accelerate during the first quarter of 2024 and is expected to be completed during the second quarter of 2024.

Revive has taken concrete and specific steps, including capital expenditures, in preparing for this shift. Revive has entered into purchase agreements with suppliers and ordered significant quantities of active pharmaceutical ingredients (or "API") for use in compounding drugs that are expected to be selected by health care providers when choosing alternatives to various compounded drugs that were previously dispensed by Revive. Some of the compounds expected to be included in Revive's refreshed portfolio will be alternatives to various products now classified by FDA as Category 2 bulk drug substances, including certain peptides that are identified in the complaint. [31]

Cases presenting real controversies at the time of their institution may become moot by the happening of subsequent events. *Degraw v. Eighth Judicial Dist. Court*, 134 Nev. 330, 332. Generally, we will not decide moot cases. *Nat'l Collegiate Athletic Ass'n v. Univ. of Nev., Reno*, 97 Nev. 56, 58, 624 P.2d 10, 11 (1981). A case is moot if it "seeks to determine an abstract question which does not rest upon existing facts or rights." *Id.* Mootness is a question of justiciability. *Personhood Nev. v. Bristol*, 126 Nev. 599, 602, 126 Nev. 599, 245 P.3d 572, 574 (2010). The dispute must continue through all of the controversy's phases. *Id.* A case may become moot due to later occurrences

[31] U.S. Food and Drug Administration, *Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, 503A Categories Update for September 2023 (fda.gov) (accessed November 14, 2023).

despite the existence of a "live controversy" at the beginning of the litigation. *Newman v. State*, 132 Nev. 340, 344.

Revive has made significant progress planning and implementing its portfolio changes and is not expected to compound and dispense products that products now classified by FDA as Category 2 bulk drug substances, including certain peptides that are identified in the complaint. What is now apparent is that the facts of the case have changed, and these subsequent events related to changes in Revive's portfolio have made the complaint moot and any dispute about the lawfulness of compounding peptides alleged in the complaint cannot continue. As a result, the Board should dismiss the complaint for mootness.

Such a change in business strategy is not an admission by Revive that its prior operations were unlawful, and the reorientation of its portfolio cannot be used as evidence that Revive was non-compliant with state or federal laws or regulations. Nev. Rev. Stat. 48.095 provides that subsequent remedial measures are not admissible to prove negligence or culpable conduct. *Robinson v. G.G.C., Inc.*, 107 Nev. 135, 136. Nev. Rev. Stat. § 48.095, patterned after Fed. R. Evid. 407, excludes evidence of subsequent remedial measures to prove negligence or culpable conduct. *Jacobson v. Manfredi*, 100 Nev. 226, 227.

The complaint should be dismissed since it fails to state a claim that Revive violated any Nevada law or regulation.

The complaint is devoid of any allegation made with sufficient specificity that Revive has violated any Nevada law or regulation. The allegations that are presented in the complaint are not well articulated facts but only conclusory statements and are merely the opinion of the complainant.

The mere use of the words "wrongful" and "unlawful" are mere conclusions of the pleader, and standing alone are not enough to show that the acts complained of were unlawful, in the absence of a statement of facts from which such conclusion legitimately may be drawn. *Dixon v. Reno*, 43 Nev. 413, 415.

Because the complaint lacks any specific factual allegation that Revive violated any Nevada law or regulation and consists of only the opinion of the complainant, the complaint is legally insufficient and should be dismissed.

The allegations in the complaint reach beyond the jurisdiction of the Board.

The complaint is essentially rooted in federal claims of misbranding and introduction of unapproved drugs into "interstate commerce." Initial approval or exemption of a drug is within the primary jurisdiction of the Federal Drug Administration ("FDA"). *Rutherford v. American Medical Asso.*, 379 F.2d 641, 642.

Generally, states may not engage in impermissible extraterritorial regulation. *See Pharmaceutical Research and Manufacturers of America v. Walsh*, 538 U.S. 644 (2003). Nevada may not impermissibly regulate the flow of prescriptions from Revive that enter interstate commerce from Texas and beyond the borders of Nevada.

Because the allegations fall outside the jurisdiction of the Board, the complaint should be dismissed.

Even if the allegations are arguably within the jurisdiction of the Division, they are preempted by federal law.

The Nevada Revised Statues prohibit the sale of any drug that has not been authorized to move in interstate commerce under the *federal* Food, Drug and Cosmetic Act ("FFDCA") (emphasis added).[32]

A state law or requirement can be preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Arizona v United States*, 132 S Ct. 2492, 2501 (2012) (quoting *Hines v. Davidowitz*, 312 US 341, 349 n.4 (2001)). State requirements are preempted where they interfere with the delicate balance of policy objectives undertaken by Congress and/or a federal agency such as the FDA. *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001). State requirements are preempted where they undermine a federal policy favoring a uniform national approach – such as the federal regulation of drugs. *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.'").

This complaint is preempted by the FFDCA and should be dismissed because it "'impinge[s] on the FDA's sole authority' over enforcement of the FDCA's drug approval requirements." *Zyla Life Sciences, LLC*, 2023 WL 6301651 at *4 (quoting *Spano*, 65 F.4th at 264). The Supreme Court has recognized that the "FDCA invests the [FDA] with the power to enforce its requirements." *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362 (2002) (citing 21 U.S.C. § 371(a)). The FFDCA "includes a prohibition on private enforcement: all proceedings to enforce or restrain violations of the FDCA must be 'by and in the name of the United States,' except for certain proceedings by state governments." *Nexus Pharm., Inc.*, 48 F.4th at 1040 (quoting 21 U.S.C. § 337(a)).

This exclusive enforcement power provides the FDA with "discretion to temper enforcement or not to enforce in circumstances it deems appropriate." *Nexus Pharm., Inc.*, 48 F.4th at 1048. Indeed, the FDA has "absolute discretion" "not to prosecute or enforce" violations of the FDCA. *Heckler*, 470 U.S. at 831. As in *Zyla*, this complaint "'depend[s] on speculation' that the FDA would have taken regulatory action in response to Defendant's sale of compounded [drugs], as Plaintiff does not allege that Defendant violated the FDCA but asserts state law claims that hinge on FDCA compliance." *Zyla Life Sciences, LLC*, 2023 WL 6301651 at *4 (quoting *Spano*, 65 F.4th at 264). And like *Zyla*, the complaint "fails to plead any facts to support the assertion that Defendant is noncompliant with the compounding provisions of the FDCA, while relying on state laws that require compliance with the FDCA." *Id.* The complaint is therefore barred by implied conflict preemption. *Id.*

Other recent federal court cases have also "made it clear that § 337(a) preempts any state-law claim that exists solely by virtue of an FDCA infraction." *DiCroce v. McNeil Nutritionals, LLC*, 2023 WL 6056144, *4 (1st Cir. 2023) (internal quotation marks and citations omitted). In its decision, the court, relying on *Buckman*, explained that because the state law claims "exist solely by virtue of an FDA infraction," they were barred by implied conflict preemption. *Id.* (internal quotation marks and alterations omitted)

[32] Nev. Rev. Stat. § 585.490 (2022).

Here, the state law for the sale of any drug hinges on compliance with the federal FFDCA. The complaint alleges the misbranding and introduction of unapproved new drugs into interstate commerce that are premised on an alleged FFDCA violation, just as in *Zyla* and *Nexus*, which likewise involved drug compounding, and *DiCroce*. The complaint is barred by preemption and should be dismissed.

The complaint is an ill-fated end run around the federal law governing the review, approval and marketing of drugs and biologics.

On its face the complaint attempts to have a private party make an end-run around the enforcement of the FFDCA and Public Health Services Act (or "PHSA") by presenting the gloss of using the investigative capability of the Board but glaringly ignoring the insurmountable federal preemption barriers.

This is impermissible. The federal statutory scheme amply empowers the U.S. Food and Drug Administration (or "FDA") to punish and deter fraud against the agency, and that this authority is used by the agency to achieve a somewhat delicate balance of statutory objectives. The FDA has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud against the agency. The FFDCA leaves no doubt that it is the federal rather than private litigants who are authorized to file suit for noncompliance with the provisions of the FDCA. *Buckman v. Plaintiff's Legal Committee*, 531 U.S. 341, 349 (2001). There can be no state law cause of action if a plaintiff's true goal is to privately enforce alleged violations of the FDCA. *Exela Pharma Scis., LLC v. Sandoz, Inc.*, 486 F. Supp. 3d 1001 (W.D.N.C. 2020).

The FDA has inspected Revive twice and has only requested that Revive take voluntary actions rather than initiate any enforcement action related to the drugs mentioned in the complaint.

The FDA concluded inspections of Revive on August 6, 2021, and May 4, 2022. During those inspections, the FDA declined to issue either a verbal or written comment related to the compounding and dispensing of any drug identified in the complaint. The inspection observations are limited to a small number of events, many of which are based on a common set of facts. Inspection records also indicate that the FDA requested that Revive cease compounding and dispensing only Thymosin-Beta 4 and that Revive voluntarily complied with FDA's request. [33]

In fact, after the most recent inspection that ended May 4, 2022, the FDA notified Revive in an Untitled Letter that some of its corrective actions submitted to the FDA in response to the written observations from FDA following the inspections were adequate. FDA further advised Revive that it simply lacked additional information to make any judgments about other corrective actions and not that the corrective actions were inadequate.

[33] U.S. Food and Drug Administration, Compounding: Inspections, Recalls, and other Actions, Compounding: Inspections, Recalls, and other Actions | FDA (accessed December 13, 2023).

The observations included in Form FDA 483 are merely an investigator's judgment about potential problems and these observations are thoroughly reviewed by FDA management. Firms that are inspected and receive Form FDA 483 observations may be eligible for a satisfactory regulatory inspection classification by the FDA following management review. [34]

The FDA has implemented a deliberate and comprehensive process for the management review and assessment of inspection observations, and there are ample opportunities in that process for the FDA to take enforcement action. [35] FDA has declined to do so.

FDA Warning or Untitled Letters are merely an exercise of the agency's enforcement discretion for voluntary compliance and cannot be considered final agency action.

It is the FDA's practice to give individuals and firms an opportunity to take voluntary and prompt corrective action before it initiates an enforcement action. Warning and Untitled Letters are issued to achieve voluntary compliance and to establish prior notice. These letters are based on the expectation that most individuals and firms will voluntarily comply. A Warning or Untitled Letter is *informal and advisory* (emphasis added). It communicates the agency's position on a matter, but it does not commit FDA to taking enforcement action. For these reasons, FDA does not consider Warning or Untitled Letters to be final agency action. [36]

An Untitled Letter can be distinguished from a Warning Letter. An Untitled Letter cites violations that do not meet the threshold for significance of regulatory significance for a Warning Letter. An important difference is that an Untitled Letter *does not* include a warning statement that failure to take prompt correction may result in enforcement action (emphasis added). [37]

Furthermore, federal courts have routinely and consistently held that Warning Letters do not constitute final agency action. FDA's warning letters…neither mark the consummation of the agency's decision-making process nor determine the appellants' legal rights or obligations. FDA warning letters…giv[e] firms an opportunity to take voluntary and prompt corrective action before [the FDA] initiates an enforcement action…Nor do the letters represent a decision determining rights or obligations, or one from which legal consequences flow…[A] Warning Letter is the agency's principal means of achieving prompt voluntary compliance with the [FDCA]. Although a warning letter communicates the agency's position on a matter, it is only informal and advisory and does not commit FDA to taking enforcement action…In short, an FDA warning letter compels action by neither the recipient nor the agency. *Holistic Candlers & Consumers Ass'n v. FDA*, 664 F.3d 940, 943-44 (D.C. Cir. 2012).

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[34] U.S. Food and Drug Administration, Inspection Operations Manual, Reports of Observations, Section 5.2.3, 5 (fda.gov) (accessed December 13, 2023).
[35] U.S. Food and Drug Administration, *Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations*, Integration of FDA Facility Evaluation and Inspection Program for Human Drugs: A Concept of Operations | FDA (accessed December 13, 2023).
[36] U.S. Food and Drug Administration, *Regulatory Procedures Manual, Warning Letter Procedures*, §4.1.1 (Chapter 4 Advisory Actions (fda.gov) (accessed December 13, 2023).
[37] U.S. Food and Drug Administration, Regulatory Procedures Manual, 4-2-1, Regulatory Procedures Manual (CH. 4) (fda.gov) (accessed December 13, 2023).

Nor do Warning Letters contain or communicate any FDA imprimatur that unlawful or wrongful conduct has been determined. [A] warning letter is not "final agency action," it is not a "finding" that warrants negligence per se liability action…A trial court denied a defendant's request for judicial notice of an FDA warning letter sent to it regarding its Internet marketing. Warning letters, even as supplemented by FDA's Web site and the appellants' conversations with FDA officials, do not constitute final agency action, and so a judicial review complaint is not cognizable under the APA and must be dismissed for failure to state a claim. An FDA warning letter is not a final decision by the FDA and its position may change after further investigation. A warning letter does not constitute evidence in the record that the FDA has determined or will determine that a product's mark is deceptive…FDA warning letters have not been judicially reviewable "final action", but some cases will suggest a basis for such a review. [38]

And if Warning or Untitled Letters cannot be cited as a final action by the FDA that determines rights or obligations, or one from which legal consequences flow – such as a determination by the FDA that a firm has violated the law and is liable in an enforcement action – it is a grossly inaccurate and misleading reading and application of the law to conclude or infer that Revive has violated any portion of the FFDCA. [39] [40]

The FDA has lawfully exercised its enforcement discretion for compounded drugs now "deemed" to be biologics.

The FDA has broad prosecutorial discretion. The U.S. Supreme Court has held that "an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion," *Heckler v. Chaney*, 470 U.S. 821 (1985). It is also well established that a federal regulatory agency has the discretion to take enforcement action on a case-by-case basis. *See Moog Industries, Inc. v FTC*, 355 U.S.411 (1958).

An example of FDA's enforcement discretion with respect to compounding biologics was the publication of the document titled *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application - Guidance for Industry* in January 2018. [41] Contrary to the claims made in the complaint, a close reading of this guidance document reveals a policy position enacted by the FDA that would permit a drug now "deemed" to be a biologic to be compounded without running afoul of the FDCA and PHSA. In fact, these arguments have been raised with the FDA previously in a meeting held between the FDA and the Alliance for Pharmacy Compounding (or "APC") and the Outsourcing Facilities Association (or "OFA") on November 15, 2021.[42] At the meeting, the APC and OFA argued that in this guidance the FDA stated "*…the term biological product does* ***not*** *include products for which a marketing application can be or has been submitted under section 505 of the*

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[38] O'Reilly, *et al.*,1 Food & Drug Admin. §6:2 (2015).
[39] For a discussion of the definition of "legal consequence," *see U.S. Army Corps of Engineers v. Hawkes Co.*, 136 S. Ct. 1807, 1813-16 (2016).
[40] Agency letters describing inspectional observations or other communication such as Warning Letters do not subject a regulated party to potential liability in an enforcement action. *See Orton Motor, Inc. v. HHS*, 884 F.3d 1205, 1215 (D.C. Cir. 2018).
[41] U.S. Food and Drug Administration, *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application - Guidance for Industry*, Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application Guidance for Industry (fda.gov) (accessed December 13, 2023).
[42] U.S. Government, *Memorandum of Meeting from FDA/CDER*, Regulations.gov (accessed December 13, 2023).

FD&C Act" (emphasis added). [43] Thus, "deemed" or transitioned products are considered drugs for purposes of Section 503A of the FDCA because a marketing application was approved (or has [had] been submitted) under Section 505 of the FDCA.[44] For example, a quick search of the "Drugs@FDA" website that lists FDA product approvals reveals several marketing applications for human chorionic gonadotropin (or "HCG") and tesamorelin that have been approved under Section 505 of the FDCA prior to their transition or being "deemed" biologics.[45]

As the complaint acknowledges, drugs are eligible to be compounded from bulk drug substances by pharmacies operating under Section 503(A) of the FDCA if they meet three criteria: (1) comply with a United States Pharmacopoeia (or "USP") monograph if a monograph exists; (2) if a monograph does not exist, be a component of a drug approved by FDA, or (3) appear on the FDA list of substances that may be used in compounding.[46] The APC and OFDA further argued in the meeting with FDA that if a USP monograph exists for a transitioned or product "deemed" to be a biologic, then Section 503(A) of the FDCA permits compounding from bulk drug substance.

For example, both HCG and tesamorelin are components of a drug approved by FDA. Furthermore, a USP monograph exists for HCG. Neither HCG or tesamorelin is on the withdrawn or removed list available at 21 § C.F.R. 216.24, nor do they present "demonstrable difficulties" to compound. As a result, pharmacies may lawfully compound HCG from bulk drug substance. [47]

As the record of the meeting indicates, the FDA did not object to these arguments. Nor has the FDA at any time following the meeting publicly refuted these arguments or made any policy available to compounding pharmacies indicating that these arguments are an incorrect interpretation of how drugs now "deemed" or transitioned to biologics are classified for the purposes of the compounding exemptions found in Sections 503(A) and (B) of the FDCA.

Given that the FDA has promulgated policy that carves out an exemption for products now "deemed" to be a licensed biologic for which a marketing application had been submitted under Section 505 of the FDCA – which creates the statutory requirements for new *drugs* (emphasis added) – and the FDA has chosen to refrain from enforcement action consistent with its judicially permissible judgment for deciding how to allocate its resources and set priorities, Revive is operating well within a zone of acceptable regulatory discretion created by the FDA for these products.

The complaint makes significant errors in misstating and misapplying the law and FDA policy regarding compounding with bulk drug substances.

The complaint erroneously mentions – numerous times – that the bulk drug substances placed by FDA into "Category 2" on the list of substances nominated for use in compounding are "not legal

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[43] *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application - Guidance for Industry, supra,* n. 3.
[44] 21 U.S.C. § 355 (2022).
[45] U.S. Food and Drug Administration, *Drugs@FDA – FDA Approved Drugs,* Drugs@FDA: FDA-Approved Drugs (accessed December 13, 2023).
[46] 21 U.S.C. § 353(b)(1)(a) (2022) and Letter from "Anthony Connors, J.D.", *supra,* n. 2.
[47] Joint presentation, *Deemed to be a License Products,* Alliance for Pharmacy Compounding ("APC") & Outsourcing Facilities Association ("OFA") Meeting with FDA (July 20, 2021) (copy on file with PISTEVO LAW LLC).

for compounding." [48]An unambiguous reading of the plain language published by FDA on its website clearly contradicts this error. There are numerous substantive and procedural errors with this allegation.

- The list *Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act* published on the FDA website is different than the final regulation *List of Bulk Drug Substances That Can Be Used To Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act* published in the *Federal Register*. FDA can make changes to the list of nominated bulk drug substances without needing to comply with the legal requirements for creating a regulation. [49]
- Section 503A of the FFDCA does require that the FDA convene and consult with the advisory committee on pharmacy compounding and USP before publishing any notice of proposed final regulations that substances to the 503A bulks list. [50] The last such advisory committee meeting was held June 8, 2022, so it is impossible for FDA to have made a final determination that the tentative classification of any of these compounds in Category 2 remains permanent or that these compounds are ineligible for compounding. [51]
- However, when adding these compounds to Category 2 of the list of compounds nominated for use in compounding by 503A pharmacies, FDA is not taking any final regulatory action related to the bulks list that is published as a regulation. FDA had sufficient information to evaluate their nomination, but the FDA determined that there were significant safety risks when used in drugs compounded by 503A pharmacies. Here's **the key point** that has been omitted from the complaint – these substances *may ultimately be eligible for inclusion on the 503A bulks list published as a regulation, but they are pending further evaluation* (emphasis added). Unlike substances placed in Category 3, they do not need to be re-nominated. [52]
- Because FDA has only taken action to change the status of the evaluation of substances that were nominated and has not taken any action to change the regulation with any of the nominated substances on the list of bulk substances that can be used in compounding, FDA does not yet need to convene a meeting of the advisory committee. [53]

Copies of purported website catalogs and order forms are useless as evidence to confirm the dispensing and sale of any compounded products to Nevada patients.

The purported copies of the catalog and ordering information from the Revive website that were attached to the complaint are to be differentiated from a merchant's purchase order which had been accepted by Revive. These documents lack needed information to form a contract to dispense and

[48] U.S. Food and Drug Administration, Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act, 503A Categories Update for September 2023 (fda.gov) (accessed December 13, 2023).
[49] 84 Fed. Reg. 4696 (February 19, 2019).
[50] 21 U.S.C. §§ 353a(a)(C)(1) and (2).
[51] U.S. Food and Drug Administration, 2022 Meeting Materials, Pharmacy Compounding Advisory Committee, 2022 Meeting Materials, Pharmacy Compounding Advisory Committee | FDA (accessed December 13, 2023).
[52] U.S. Food and Drug Administration, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry, 7, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry (fda.gov) (accessed December 13, 2023).
[53] 84 Fed. Reg. 4696, 4697 (February 19, 2019).

sell any compounded products in Nevada since there are no terms for quantity, price, a description, delivery date and signature of any responsible official from Revive.[54] Since there is no evidence of a purchase order which had been accepted by Revive, then no contract was formed to dispense and sell any compounded products even presuming that the myriad issues discussed above with the complaint could be overcome.

Instead, these catalog forms and the purported screenshots of product promotions constitute nothing more than mere advertising. Generally, courts have held that documents such as blank order forms are considered advertisements that are only a statement of the intention to sell or a preliminary proposal inviting offers because they do not state any quantity and there is no language of commitment. *See Morrill v. Tehama Consol. Mill & Mining Co.*, 10 Nev. 125.

What little, if any, relevant information can be garnered from these advertisements hardly constitutes incontrovertible evidence of actual compounding and dispensing to patients located in Colorado. Because the purported website and catalog pages are only advertisements that fail to demonstrate that Revive definitively entered into any agreements with Colorado licensed health care providers to compound and dispense products to patients located in Colorado, and the catalog forms are merely advertising limited to healthcare practitioners, these documents are irrelevant to the complaint and should be excluded.

The complaint fails to rebut the presumption of compliance.

It is fair to argue there is a strong presumption that a regulated party will comply with the law. *Int'l Ladies' Garment Workers' Union v. Donovan (ILGWU)*, 722 F.2d 795, 811 (D.C. Cir. 1983). This presumption is conclusive absent contrary evidence. As discussed above, no evidence proffered in the complaint is sufficient to overcome this presumption that Revive is operating its compounding activities in compliance with applicable federal and state laws.

Conclusions

This response to the complaint has thoroughly and definitively demonstrated that there are numerous and adequate reasons to dismiss the complaint, namely:

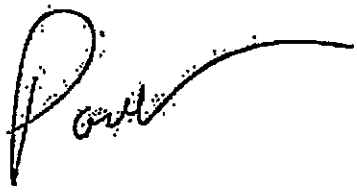
- There are grave concerns regarding the credibility of the complainant.
- The complaint is an impermissible, coordinated attempt to re-litigate issues that were presented in the HPM complaint and dismissed by the Board previously.
- The allegations of regulatory "infractions" are preempted by federal law and the FDA has chosen not to take enforcement action against Revive.
- Any of the numerous purported pages from the Revive website cannot be used as evidence of illegal conduct within the State's borders since they are irrelevant.
- Since Revive has taken steps to re-balance its portfolio subsequent to the complaint, the allegations are now moot.
- The preponderance of the evidence fails to mee the threshold of any reasonable cause that a violation of state law or regulation has occurred.

[54] Nev. Rev. Stat. § 104.2205 (2022).

As it was for the case of the nearly identical complaint from HPM, the careful and systematic refutation of the misleading legal arguments raised in this complaint clearly supports the proposition that Revive is operating lawfully as a non-resident (out-of-state) compounding pharmacy. Revive requests that the Board dismiss the complaint and demur on further investigating the baseless allegations contained in the complaint.

Please contact me for any additional information or with further questions related to this matter.

Sincerely,



Philip E. M. Crooker, Esq.
President and Managing Member

Enc: *Appendices (B) – (L).*
Letter from "Anthony Connors, J.D." to multiple state boards of pharmacy.

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

January 2025
Compounding and Related Documents

EXHIBIT 3

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

REVIVE Rx,
Pharmacy License No. PH04215,

Respondent.

_____/

CASE NO. 23-411-PH-O

MOTION TO DISMISS

EXHIBIT 3

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act

Guidance for Industry

Additional copies are available from:

Office of Communications, Division of Drug Information
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Food and Drug Administration
10001 New Hampshire Ave., Hillandale Bldg., 4th Floor
Silver Spring, MD 20993-0002
Phone: 855-543-3784 or 301-796-3400; Fax: 301-431-6353
Email: druginfo@fda.hhs.gov
https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

January 2025
Compounding and Related Documents

Contains Nonbinding Recommendations

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Contains Nonbinding Recommendations

Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION AND SCOPE

This guidance sets forth the Food and Drug Administration's (FDA or Agency) interim regulatory policy concerning compounding using bulk drug substances under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a). Section 503A of the FD&C Act includes certain restrictions on the bulk drug substances that can be used in compounding and directs FDA to develop a list of bulk drug substances that can be used in compounding under that section. FDA is developing this list of bulk drug substances (the 503A bulks list), and this guidance describes FDA's interim regulatory policy for licensed pharmacists in State-licensed pharmacies and Federal facilities and for licensed physicians who compound human drug products using bulk drug substances while the list is being developed.[2,3]

This guidance revises and replaces the guidance for industry *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act* issued in January 2017 (2017 503A Interim Policy Guidance).[4] This revision does not change FDA's policy with respect to bulk drug substances that were nominated for inclusion on the 503A bulks list before the publication date of this guidance, January 7, 2025. In contrast, bulk

[1] This guidance has been prepared by multiple offices in the Center for Drug Evaluation and Research at the Food and Drug Administration.

[2] Drug products compounded for use in animals are not within the scope of this guidance.

[3] FDA is developing a separate list of bulk drug substances that can be used in compounding under section 503B of the FD&C Act (the 503B bulks list). Because section 503B contains different criteria for the 503B bulks list and provides for a different process for its development, the 503B bulks list is discussed in a separate guidance (see the guidance for industry *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act* (January 2025). We update guidances periodically. To make sure you have the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[4] The 2017 version of the guidance revised the original guidance published in 2016, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (June 2016) (2016 503A Interim Policy Guidance).

drug substances that are nominated on or after the date of publication of this guidance are not within the scope of the policy described in section III.A of this guidance. FDA intends to continue to receive and evaluate new nominations of bulk drug substances for inclusion on the 503A bulks list consistent with the process and criteria established in the FD&C Act and FDA regulations.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

A. Compounding From Bulk Drug Substances Under Section 503A of the FD&C Act

Section 503A of the FD&C Act describes the conditions that must be satisfied for human drug products compounded by a licensed pharmacist in a State-licensed pharmacy or Federal facility, or by a licensed physician, to be exempt from the following three sections of the FD&C Act: (1) section 505 (21 U.S.C. 355) (concerning the approval of drugs under new drug applications or abbreviated new drug applications); (2) section 502(f)(1) (21 U.S.C. 352(f)(1)) (concerning the labeling of drugs with adequate directions for use); and (3) section 501(a)(2)(B) (21 U.S.C. 351(a)(2)(B)) (concerning current good manufacturing practice requirements).

One of the conditions that must be met for a compounded drug product to qualify for these exemptions is that a licensed pharmacist or licensed physician compounds the drug product using bulk drug substances that:

(1) Comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding;

(2) If such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary of the Department of Health and Human Services (Secretary); or

(3) If such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appears on a list developed by the Secretary through regulations issued by the Secretary under subsection (c) of section 503A.[5]

[5] See section 503A(b)(1)(A)(i) of the FD&C Act.

A *bulk drug substance* is defined as meaning "the same as 'active pharmaceutical ingredient' as defined in [21 CFR] 207.1."[6] *Active pharmaceutical ingredient* is defined as "any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body," but the term "does not include intermediates used in the synthesis of the substance."[7,8] FDA has interpreted "an applicable USP or NF monograph" to mean an official USP or NF *drug substance* monograph.[9] Accordingly, FDA does not consider USP monographs for dietary supplements to be *applicable* USP or NF monographs within the meaning of section 503A(b)(1)(A)(i)(I).

Under section 503A(c)(1), before developing this list through regulation, FDA must convene and consult an advisory committee on compounding unless FDA determines that the issuance of such regulation before consultation with the advisory committee is necessary to protect the public health. FDA must also consult with USP when promulgating the regulations.[10] The criteria for determining which bulk drug substances should appear on the section 503A bulks list "shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify."[11]

Bulk drug substances used in compounding under section 503A must also meet certain other requirements, including: (1) the bulk drug substance must be manufactured by an establishment registered under section 510 of the FD&C Act (21 U.S.C. 360) and (2) the bulk drug substance must be accompanied by a valid certificate of analysis (COA).[12]

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[6] 21 CFR 207.3.

[7] See section 503A(b)(1)(A) and 21 CFR 207.3. Section 503A references the definition of *bulk drug substance* in FDA's drug establishment registration and listing regulations, which was codified at 21 CFR 207.3(a)(4) when section 503A was enacted. In August 2016, FDA published a final rule, "Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application and Animal Drugs" (81 FR 60170, Aug 31, 2016), to update its registration and listing regulations in 21 CFR part 207, which made minor changes to the definition of bulk drug substance and moved the definition to 21 CFR 207.3. The definition is also found in 21 CFR 207.1. Under the previous definition, *bulk drug substance* was defined to mean "any substance that is represented for use in a drug and that, when used in the manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug, but the term does not include intermediates used in the synthesis of such substances."

[8] Inactive ingredients are not subject to section 503A(b)(1)(A)(i) or the policies described in this guidance because they are not included within the definition of a bulk drug substance. See 21 CFR 207.3. Pursuant to section 503A(b)(1)(B), inactive ingredients used in compounding must comply with the standards of an applicable USP or NF monograph, if a monograph exists, and the USP chapter on pharmacy compounding.

[9] See the preamble of the final rule "List of Bulk Drug Substances That Can Be Used to Compound Drug Products in Accordance With Section 503A of the Federal Food, Drug, and Cosmetic Act" (84 FR 4696 at 4705, Feb 19, 2019).

[10] See section 503A(c)(2) of the FD&C Act.

[11] Section 503A(c)(2) of the FD&C Act.

[12] See section 503A(b)(1)(A) of the FD&C Act.

In July 2014, FDA issued a guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act*, that stated:

> Until a bulk drug substances list is published in the *Federal Register* as a final rule, human drug products should be compounded using only bulk drug substances that are components of drugs approved under section 505 of the FD&C Act, or are the subject of USP or NF monographs.[13]

FDA received comments that this policy could be causing unnecessary and inappropriate disruptions in patient care because there are patients receiving drug products compounded with bulk drug substances that are not components of FDA-approved drug products, or the subject of an applicable USP or NF monograph, but that may ultimately be included on the 503A bulks list, and those patients' care should not be disrupted while the list is under development. After considering this issue, FDA decided to use the 2016 503A Interim Policy Guidance to describe its interim policy concerning compounding with bulk drug substances while the 503A bulks list is being developed. In 2016, FDA also revised the July 2014 guidance to state:

> FDA's interim policy concerning bulk drug substances that are not components of drugs approved under section 505 of the FD&C Act or that are not the subject of applicable USP or NF monographs can be found in the guidance, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug and Cosmetic Act*.[14]

FDA seeks to avoid unnecessary disruption to patient treatment while the Agency considers the bulk drug substances that were nominated with sufficient support to permit FDA to evaluate them and promulgates the regulations required under section 503A. Therefore, as described further below, FDA does not intend to take regulatory action for compounding drug products under section 503A using a bulk drug substance when an applicable USP or NF monograph does not exist and the substance is not a component of an FDA-approved drug product if, among other conditions, the bulk drug substance appears on Category 1 on FDA's website.[15]

B. Efforts to Develop the List of Bulk Drug Substances Under Section 503A

1. Section 503A Bulks List — Early History

Section 503A of the FD&C Act was enacted in 1997 as part of the Food and Drug Administration Modernization Act. In the *Federal Register* of April 7, 1998 (63 FR 17011), FDA invited all interested persons to nominate bulk drug substances for inclusion on the list of

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[13] FDA, guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (July 2014) at 5, available at https://www.regulations.gov/document/FDA-2013-D-1444-0038.

[14] FDA, guidance, *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act* (June 2016) at section III.B.2.

[15] *See* Bulk Drug Substances Used in Compounding Under Section 503A of the FD&C Act, available on the Human Drug Compounding web page at https://www.fda.gov/drugs/human-drug-compounding/bulk-drug-substances-used-compounding-under-section-503a-fdc-act.

bulk drug substances that can be used in compounding under section 503A and received nominations for 41 different drug substances. In November 1998, FDA published a guidance for industry, *Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act.* In this guidance, FDA announced that it would not normally take regulatory action relating to a drug product that had been compounded with a bulk drug substance that had been nominated for inclusion on the bulk drug substances list on or before November 21, 1999, while the substance was being evaluated, as long as the compounding complied with the other effective requirements in section 503A and did not appear to present a significant safety risk.[16]

In January 1999, after evaluating the nominated bulk drug substances and consulting with the Pharmacy Compounding Advisory Committee (PCAC) as required by section 503A, FDA published a proposed rule listing 20 drug substances on the section 503A bulks list (64 FR 996, January 7, 1999). The preamble to the proposed rule indicated that 10 of the 41 nominated drug substances were the subject of a USP or NF monograph, or components of FDA-approved drug products and did not need to be considered for inclusion on the list.[17] The proposed rule also described 10 nominated drug substances that were still under consideration for the bulk drug substances list and stated that one of the substances was withdrawn by its nominator at the first meeting of the PCAC. The PCAC reconvened in May 1999 to discuss bulk drug substances included in the proposed rule, in addition to other bulk drug substances.[18]

However, after a 2002 U.S. Supreme Court decision holding that certain provisions of section 503A were unconstitutional,[19] FDA suspended its efforts to develop the 503A bulks list.

Because of the amount of time that had passed between the publication of the proposed rule and the enactment of the 2013 Drug Quality and Security Act (DQSA), which removed the provisions of the FD&C Act that the U.S. Supreme Court held to be unconstitutional in 2002, FDA felt it was necessary to begin again to develop the 503A bulks list. In the December 4, 2013, *Federal Register* (78 FR 72841), FDA published a notice withdrawing the 1999 proposed rule and inviting all interested persons to nominate bulk drug substances for inclusion on a list of bulk drug substances that can be used for compounding under section 503A of the FD&C Act.

2. *Current Nominations for the 503A Bulks List*

In response to the December 2013, *Federal Register* notice, over 2,000 substances were nominated for the 503A bulks list. However, many of the substances nominated for the 503A bulks list were for substances that can be compounded without being on the list because they are

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[16] The 1998 guidance was withdrawn in the *Federal Register* notice announcing the availability of the draft guidance *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.* See 78 FR 72901 (Dec 4, 2013). The final guidance was published in July 2014.

[17] See 64 FR 996 at 997 (Jan 7, 1999).

[18] See 64 FR 19791 (Apr 22, 1999).

[19] For additional legal history of section 503A, see the guidance *Pharmacy Compounding of Human Drug Products Under Section 503A of the Federal Food, Drug, and Cosmetic Act.*

the subject of an applicable USP or NF monograph or are a component of an FDA-approved drug product. In addition, many of the nominations were not for bulk drug substances used in compounding as active ingredients, or did not include sufficient information for FDA to evaluate the nominated substances for inclusion on the list. To improve the efficiency of the process for developing the 503A bulks list, FDA reopened the nomination process in July 2014 (79 FR 37747) and provided more detailed information on what it needs to evaluate nominations for the 503A bulks list (July 2014 docket). FDA stated that bulk drug substances that were previously nominated would not be considered further unless they were renominated with adequate support to permit a meaningful evaluation. Substances that were already eligible for use in compounding or that were not adequately supported would not be evaluated for placement on the 503A bulks list.

In the *Federal Register* of October 27, 2015 (80 FR 65765), FDA established a docket (October 2015 docket) where new nominations for these substances can be submitted with sufficient supporting information or where nominations for substances that were not previously nominated can be submitted.

In response to this request for nominations, as of publication of the 2016 503A Interim Policy Guidance, approximately 740 unique substances were nominated. Of those nominated substances:

- Approximately 315 substances are already eligible for use in compounding under section 503A.

  These are the subject of an applicable USP or NF monograph or components of an FDA-approved drug product, which can be used in compounding pursuant to sections 503A(b)(1)(A)(i)(I) and (II) and, therefore, can be used in compounding without being included on the 503A bulks list. To determine if a bulk drug substance is the subject of an applicable USP or NF monograph, see the *USP-NF* available at https://www.uspnf.com. To determine if a bulk drug substance is a component of an FDA-approved drug product, see the FDA's *Orange Book: Approved Drug Products With Therapeutic Equivalence Evaluations*, available at https://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.[20]

- At least one[21] of the nominated substances is not a bulk drug substance.

[20] Biological products subject to approval in a biologics license application (BLA) under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262) are not eligible for the exemptions in section 503A of the FD&C Act (21 U.S.C. 353a). Biological products subject to approval in a BLA under section 351 of the PHS Act will not be considered for the 503A bulks list. See the guidance for industry *Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application* (January 2018) for FDA's policies regarding State-licensed pharmacies, Federal facilities, and outsourcing facilities that mix, dilute, or repackage biological products outside the scope of an approved BLA.

[21] The nonprescription finished drug product Maalox was nominated. Maalox is not a bulk drug substance.

This is a finished drug product that was nominated by its brand name. Finished drug products are not eligible for the 503A bulks list because they do not meet the definition of a bulk drug substance in 21 CFR 207.3.

- At least four of the nominated substances appear on the list published by FDA of substances that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective (withdrawn or removed list).[22]

  Such substances cannot be used in compounding under section 503A of the FD&C Act and, therefore, are not eligible for inclusion on the 503A bulks list.

- One of the nominated substances has no currently accepted medical use and is included on Schedule I of the Controlled Substances Act (CSA) (21 U.S.C. 812(c)).[23]

  The CSA does not allow possession or distribution of Schedule I substances (21 U.S.C. 841(a)(1) and 829), except for research purposes (21 U.S.C. 823(f)), and these substances will not be considered for the 503A bulks list at this time. Those desiring to do research on a Schedule I substance can apply to do so under an investigational new drug application (IND).

- Of the substances that are not components of an FDA-approved drug product or the subject of an applicable USP or NF monograph, that are not included on Schedule I of the CSA, and do not appear on the withdrawn or removed list, approximately 350 substances were nominated without sufficient supporting evidence for FDA to evaluate them.

- The remaining substances may be eligible for inclusion on the 503A bulks list and were nominated with sufficient supporting information for FDA to evaluate them. However, FDA has identified significant safety risks relating to the use of some of these bulk drug substances in compounded drug products.

FDA's website identifies the following categories of substances nominated for the 503A bulks list:[24]

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[22] See section 503A(b)(1)(C) of the FD&C Act. See also 21 CFR 216.24.

[23] An extract of cannabidiol (CBD) and tetrahydrocannabinol (THC) derived from marijuana (marihuana) was nominated. This is a Schedule I substance.

[24] See Bulk Drug Substances Nominated for Use in Compounding Under Section 503A of the Federal Food, Drug, and Cosmetic Act, updated September 19, 2024, available at https://www.fda.gov/drugs/human-drug-compounding/bulk-drug-substances-used-compounding-under-section-503a-fdc-act. As discussed in the July 2014 *Federal Register* notice requesting nominations for the 503A bulks list (79 FR 37747), nominators were to confirm that all substances nominated for the list are active ingredients that meet the definition of a bulk drug substance. Inclusion of a substance in any of these categories does not reflect a determination by FDA that the substance is a bulk drug substance. Whether a substance is a bulk drug substance subject to the conditions in section 503A(b)(1)(A) depends on whether it meets the definition of a bulk drug substance in 21 CFR 207.3. If the substance is used in a compounded drug-product as an inactive ingredient, then it does not meet the definition of a

503A Category 1 – Substances Nominated for the Bulks List Currently Under Evaluation: These substances may be eligible for inclusion on the 503A bulks list, were nominated with sufficient supporting information for FDA to evaluate them, and do not appear on any other list.

503A Category 2 – Substances Nominated for the Bulks List That Raise Significant Safety Risks: These substances were nominated with sufficient supporting information to permit FDA to evaluate them, and they may be eligible for inclusion on the 503A bulks list. However, FDA has identified significant safety risks relating to the use of these substances in compounding pending further evaluation and, therefore, does not intend to adopt the policy described for the substances in Category 1. If FDA adds a substance to Category 2, it will publish a public communication (e.g., a safety alert) describing the safety risks and will post the communication on FDA's human drug compounding website,[25] advising that the substance has been added to Category 2 and is not within the scope of the policies regarding substances in Category 1.

503A Category 3 – Substances Nominated for the Bulks List Without Adequate Support: These substances may be eligible for inclusion on the 503A bulks list but were nominated with insufficient supporting information for FDA to evaluate them. These substances can be renominated with sufficient supporting information through a docket that FDA has established, as discussed below in section III.B.

3. Process for Developing the 503A Bulks List

FDA is currently evaluating the substances that were nominated for the 503A bulks list with sufficient supporting information to permit evaluation. FDA is considering a number of factors in prioritizing the order in which it reviews the nominated bulk drug substances, including but not limited to the following:

- Safety concerns about use of the bulk drug substance in compounding
- Whether the bulk drug substance was nominated by multiple parties or identified as necessary by medical professional organizations
- The efficiency with which the evaluation can be completed, based on ease of acquiring the necessary information to conduct the review, available resources, and other logistical issues

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bulk drug substance in 21 CFR 207.3, is not subject to the conditions in section 503A(b)(1)(A), and need not appear on the 503A bulks list to be eligible for use in compounding. Instead, when used as an inactive ingredient, the substance is subject to the conditions in section 503A(b)(1)(B), which applies to ingredients other than bulk drug substances used in compounded drug products.

[25] See https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding. FDA also encourages compounding facilities to subscribe to FDA's list serve to receive updates at https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding#subscribe.

FDA may also group some nominated drug substances to facilitate efficient review and discussion. These include drug substances that raise similar issues (e.g., vitamins, botanicals) or have been nominated for the treatment of the same condition (e.g., warts).

In conducting its evaluations, FDA reviews the information provided in support of the nomination and other available information to assess each bulk drug substance according to the following four criteria:[26]

- The physical and chemical characterization of the substance
- Any safety issues raised by the use of the substance in compounded drug products
- Historical use of the substance in compounded drug products, including information about the medical condition(s) the substance has been used to treat and any references in peer-reviewed medical literature
- The available evidence of effectiveness or lack of effectiveness of a drug product compounded with the substance, if any such evidence exists

In evaluating nominated bulk drug substances for the 503A bulks list under these criteria, FDA is using a balancing test. No single one of these criteria is dispositive; rather, FDA is considering each criterion in the context of the others and balancing them, on a substance-by-substance basis, to evaluate whether a particular substance is appropriate for inclusion on the 503A bulks list.

Once the evaluation of a substance is complete, FDA will present the results of its review to the PCAC to obtain its advice on whether to include the substance on the 503A bulks list.[27]

Section 503A requires that FDA create the 503A bulks list by regulation in consultation with the USP. To this end, FDA has been periodically meeting with USP and discussing the list. FDA will publish a notice of proposed rulemaking (NPRM) that identifies substances FDA proposes for placement on the 503A bulks list and the substances FDA has evaluated but is not proposing to include on the 503A bulks list. After publication of the NPRM, the public will have an opportunity to comment on the proposed rule. After considering the comments submitted to the docket, FDA will publish a final rule that establishes the 503A bulks list and identifies the substances that were considered and will not be placed on the list. FDA does not intend to evaluate all of the sufficiently supported nominations before publishing the first NPRM. Instead, after FDA has made a decision on whether to propose a group of substances (e.g., 10 substances), it intends to publish an NPRM with respect to that group of substances and continue to prepare the 503A bulks list on a rolling basis.

[26] See 21 CFR 216.23(c).

[27] See section 503A(c)(1) of the FD&C Act.

A final rule will list the substances that FDA has determined can be used in compounding under section 503A and those substances that have been evaluated and not placed on the 503A bulks list, if any.

After a final rule is published, drug products compounded using the bulk drug substances on the 503A bulks list will be eligible for the section 503A exemptions, provided the drug product meets the other conditions of section 503A. Those substances that have been evaluated and not placed on the 503A bulks list will no longer be within the scope of policies described in this guidance.

C. Categorization Under FDA's Interim Policy

Section 503A of the FD&C Act directs FDA to establish a list of bulk drug substances that can be used in compounding under that section. After enactment of the DQSA in 2013, FDA engaged in renewed efforts to implement section 503A, including the condition concerning bulk drug substances. However, because FDA had not yet promulgated regulations to develop the 503A bulks list, compounded drug products containing such bulk drug substances were not eligible for the exemptions in section 503A. Stakeholders advised FDA that some of these compounded drug products, which patients may have received prior to the DQSA's enactment, were important for patient care. In 2016, FDA issued the 2016 503A Interim Policy Guidance setting forth its interim policy on compounding using bulk drug substances by State-licensed pharmacies, Federal facilities, and physicians (not registered as outsourcing facilities). The guidance explained that the purpose of the interim policy was to "avoid unnecessary disruption to patient treatment while the Agency considers the bulk drug substances that were nominated with sufficient support to permit FDA to evaluate them."[28] As described in the 2016 503A Interim Policy Guidance, FDA categorized bulk drug substances that had been nominated by a certain date and explained an interim policy under which the Agency did not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician for compounding drug products using those bulk drug substances if certain conditions were met. However, stakeholders advised FDA that, less than 3 years after DQSA was enacted, certain compounded drug products containing bulk drug substances that had not yet been nominated were important for patient care. Accordingly, in 2017, FDA published the 2017 503A Interim Policy Guidance to provide for ongoing categorization of newly nominated bulk drug substances.

As discussed further below, since FDA developed the 2017 503A Interim Policy Guidance, stakeholders have had substantial opportunity to nominate new bulk drug substances for categorization. As reflected in the updated policy described in section III below, FDA has determined that ongoing categorization of newly nominated substances, as described in the 2017 503A Interim Policy Guidance, no longer serves the interim policy's stated objective of avoiding unnecessary disruption to patient treatment and does not otherwise benefit public health. Categorizing substances nominated on or after the publication date of this guidance January 7, 2025, would unnecessarily expose patients to the risks associated with drug products compounded from such bulk drug substances.

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[28] 2016 503A Interim Policy Guidance at 3, available at https://www.regulations.gov/document/FDA-2015-D-3517-0017.

Drug products compounded from bulk drug substances nominated for inclusion on the 503A bulks list may present particular risks when FDA has not yet completed the process to conclude whether they will be placed on the 503A bulks list, and because they are not the subject of an applicable USP or NF monograph or components of an FDA-approved drug product. When FDA evaluates bulk drug substances nominated for the list, Agency medical and scientific experts examine the physical and chemical characterization of the substance; any safety issues raised by the use of the substance in compounded drug products; historical use of the substance in compounded drug products; and available evidence of effectiveness or lack of effectiveness of a drug product compounded with the substance, if any such evidence exists. FDA considers whether these criteria, on balance, weigh in favor or against inclusion of the bulk drug substance on the 503A bulks list. An advisory committee and the USP provide expert advice, and FDA engages in notice-and-comment rulemaking, taking into consideration any public comments received. Although FDA's evaluation of a substance for the 503A bulks list is, necessarily, far less rigorous and less comprehensive than the Agency's review of drugs as part of the new drug approval process, this evaluation process is important to reduce the risk of patient harm and the risk of patients receiving ineffective treatments.

In the early days of DQSA implementation, FDA recognized that patients may have a medical need for treatment with certain drugs that they may have received prior to enactment of the DQSA, but that were compounded from bulk drug substances that the Agency had not yet evaluated for inclusion on the 503A bulks list. In developing the 2017 503A Interim Policy Guidance, FDA weighed these public health interests and concluded that, at that early stage of section 503A implementation, the potential patient benefits of such a policy outweighed the risks. Importantly, FDA characterized the guidance as an *interim* policy because the Agency intended for it to be temporary. For the reasons that follow, FDA is now ending categorization of newly nominated substances because the Agency believes such a policy no longer serves the guidance's stated objective of preventing unnecessary disruption to patient treatment and, therefore, the balance of public health interests supporting the policy has changed.

In the approximately 7 years since FDA issued the 2017 503A Interim Policy Guidance providing for ongoing categorization of bulk drug substances newly nominated to the October 2015 docket, nominators have had substantial opportunity to nominate bulk drug substances with sufficient supporting information for placement in Category 1. A substance that has not been used to compound drug products during that period cannot reasonably be considered necessary to avoid disruption to patient treatment. Nor do we expect the policy in section III.B of this guidance to adversely affect market stability because, among other reasons, FDA intends to retain the policy, described in section III.A of this guidance, for bulk drug substances already categorized. In addition, FDA intends to continue to receive and evaluate new nominations for inclusion on the 503A bulks list consistent with the process and criteria established in the FD&C Act and FDA regulations.

Accordingly, the balance of public health interests relating to categorization of newly nominated bulk drug substances has changed. As discussed above, the statutory and regulatory process for evaluating such bulk drug substances ensures that FDA, independent medical and scientific experts, and the public can carefully consider a bulk drug substance before it may appear on the 503A bulks list. During this process, FDA may, for example, uncover safety risks or

effectiveness concerns, or concerns about the physical and chemical characterization of the substance, that could place patients at risk. These concerns may not be apparent until FDA and other experts conduct the evaluation of the substance under consideration for the 503A bulks list.[29] FDA also believes that the public health is best served by FDA leveraging its limited resources to develop the 503A bulks list rather than to categorize newly nominated substances.

However, FDA does recognize that certain substances that currently appear in Category 1 may be important for patient care and that the Agency has not yet made a final determination as to whether these substances will appear on the 503A bulks list. Thus, at this time, FDA is retaining the policy outlined in section III.A of this guidance, which concerns substances nominated prior to the date of publication of this guidance, until the Agency addresses these substances in a final rule, or unless the Agency removes the substances from Category 1 based on, for example, information about safety risks.

III. POLICY

As discussed below, FDA does not intend to categorize bulk drug substances that the public nominates for inclusion on the 503A bulks list on or after the publication date of this guidance January 7, 2025. Although the Agency intends to continue to receive and evaluate new nominations of bulk drug substances for possible inclusion on the 503A bulks list, FDA does not intend to place such bulk drug substances in categories published on FDA's website prior to evaluating them in accordance with section 503A(c). FDA is evaluating bulk drug substances nominated for the 503A bulks list on a rolling basis.

A. Compounding From Bulk Drug Substances Nominated for the 503A Bulks List

Under section 503A of the FD&C Act, a bulk drug substance that is not the subject of an applicable USP or NF monograph or is not a component of an FDA-approved drug product cannot be used in compounding unless it appears on a list promulgated as a regulation[30] pursuant to section 503A(b)(1)(A)(i)(III) of the FD&C Act.[31] A drug product compounded from a bulk drug substance that does not meet any of these three conditions is not eligible for the exemptions in section 503A and may violate the FD&C Act.[32]

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[29] Prior to placing an adequately supported substance in Category 1, it has been FDA's practice to preliminarily assess whether the substance appears to present significant safety risks such that it should be placed in Category 2. However, some risks may not be apparent until FDA conducts the evaluation in accordance with the established criteria, consults with the advisory committee and USP, obtains public comment, and makes a determination as to whether the substances meet the statutory and regulatory standard for placement on the 503A bulks list.

[30] See 21 CFR 216.23. This regulation identifies bulk drug substances that have been added, as well as those that FDA has determined will not be added, to the 503A bulks list to date.

[31] See section 503A(b)(1)(A)(i).

[32] Such compounded drug products would not be eligible for the exemptions in section 503A from sections 505, 502(f)(1), and 501(a)(2)(B). Drug products distributed in violation of these or other provisions of the FD&C Act are subject to enforcement action.

However, at this time, until a substance has been evaluated and is identified in a final rule as being included or not included on the 503A bulks list, FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician compounding a drug product using a bulk drug substance that is not a component of an FDA-approved drug product, the subject of an applicable USP or NF monograph, or on the 503A bulks list codified at 21 CFR 216.23(a), if all of the following circumstances are present:

(1) The bulk drug substance appears in 503A Category 1 on FDA's website at https://www.fda.gov/media/94155/download. A Category 1 substance may be eligible for inclusion on the 503A bulks list, was nominated before the publication date of this guidance with sufficient supporting information for FDA to evaluate the substance, and has not been identified by FDA as a substance that presents a significant safety risk in compounding prior to the publication of a final rule;

(2) The original manufacturer and all subsequent manufacturers of the bulk drug substance are establishments that are registered under section 510 (including foreign establishments that are registered under section 510(i) of the FD&C Act);

(3) The bulk drug substance is accompanied by a valid COA; and

(4) The drug product compounded using the bulk drug substance is compounded in compliance with all other conditions of section 503A of the FD&C Act.

Original manufacturer means the entity that originally produced the bulk drug substance and not a subsequent packer, repacker, labeler, or distributor.

Drug products compounded using a bulk drug substance for which each of the above circumstances are not present are not within the scope of the policy described in this guidance. For example, drug products compounded from the following bulk drug substances are not within the scope of the policy: (1) substances not nominated for the 503A bulks list or that were nominated on or after the publication date of this guidance January 7, 2025; (2) substances that are the subject of a final rule concluding that they will be included, or not included, on the 503A bulks list;[33] and (3) substances that are the subject of an applicable USP or NF monograph or a component of an FDA-approved drug.[34]

B. Substances Not Nominated, Nominated Without Adequate Support, or Nominated On or After the Publication Date of this Guidance January 7, 2025

As stated above, one of the categories of bulk drug substances FDA has identified on its website contains nominated substances that may be eligible for inclusion on the 503A bulks list, but that

[33] See section 503A(b)(1)(A)(i)(III) of the FD&C Act.

[34] These substances are eligible for use in compounding under section 503A without appearing on the 503A bulks list. See section 503A(b)(1)(A)(i)(I), (II) of the FD&C Act.

FDA is unable to evaluate for inclusion on the list at this time because the substances were nominated with insufficient supporting evidence for FDA to evaluate them (503A Category 3). New nominations for these substances with sufficient supporting information or nominations for substances that were not previously nominated can be submitted to the October 2015 docket.

After a substance is nominated to the October 2015 docket,[35] FDA will determine whether the nomination is supported with sufficient information to allow FDA to evaluate it.

Previously, after FDA made that determination, the nominated substance was placed in one of the three categories described in section II.B.2 above, and the categorization was published on the FDA website. Section III.A of this guidance sets forth a policy that addresses substances once they have been categorized. This guidance retains the policy described in section III.A with respect to substances that currently appear in the categories described in section II.B.2.

However, with respect to substances nominated on or after the publication date of this guidance, including new nominations of substances that currently appear in Category 3,[36] FDA does not intend to place such substances into the categories described in section II.B.2. Accordingly, substances nominated on or after the publication date of this guidance are not within the scope of the policy described in section III.A of this guidance. FDA intends to continue to evaluate such substances, provided they are nominated with sufficient supporting information to permit an evaluation, for inclusion on the 503A bulks list pursuant to section 503A(a)(2)(b)(1)(A)(i)(III) of the FD&C Act.

C. Comments About Nominated Bulk Drug Substances

If a nominator feels that a substance that it nominated prior to the publication date of this guidance does not appear on the appropriate category as described in this guidance, the nominator can submit a comment to docket number FDA-2015-N-3534. If the nominator has additional information on a previously nominated substance that was placed in Category 3, the nominator can submit a new nomination for the substance that includes the additional information. As described in section III.B of this guidance, FDA does not intend to categorize a substance nominated on or after the publication date of this guidance. However, provided the new nomination includes sufficient supporting information to permit an evaluation, FDA intends to consider the substance for inclusion on the 503A bulks list.

A nominator may also submit a comment to the docket requesting withdrawal of any of its nominations. If the substance that is the subject of such nomination appears in one of the categories, and the party nominating the substance was the sole nominator, FDA will update the categories described in this guidance to reflect the withdrawn nomination.[37] FDA intends to

[35] This includes new nominations of substances submitted with sufficient supporting information.

[36] This includes new nominations of substances in Category 3 that include sufficient supporting information to permit FDA evaluation for the 503A bulks list.

[37] If multiple parties nominated the same substance, each party that nominated the substance must withdraw its nomination for the nominated substance to be considered withdrawn and for the categories to be updated, if applicable, to reflect that withdrawal.

provide notice to the public before removing any nominated substances from Category 1 or Category 2.

Withdrawal of a nomination upon the nominator's request, and if applicable, a resulting update to the categories described in this guidance, do not reflect a determination by FDA regarding the validity of the nomination or of any reasons given by the nominator for requesting withdrawal. In addition, FDA may continue to evaluate a substance at its discretion even if the nominator submits a comment requesting withdrawal of the nomination.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE Rx,** **Pharmacy License No. PH04215,** **Respondent.**	**CASE NO. 23-411-PH-O** **OPPOSITION TO MOTION TO DISMISS**

The Nevada State Board of Pharmacy (Board), by and through counsel prosecuting this matter, Brett Kandt, General Counsel, files this opposition to Respondent Revive Rx's Motion to Dismiss filed November 7, 2025 (Motion). This opposition is submitted pursuant to NRS 622A.360(3) and based upon the following points and authorities and the pleadings on file herein.

MEMORANDUM OF POINTS AND AUTHORITIES

I. PROCEDURAL BACKGROUND

The Notice of Intended Action and Accusation was filed and served on or about March 12, 2025. The entire bate-stamped case file was produced in response to Respondent's discovery request on July 3, 2025.

II. LEGAL STANDARD

Respondent seeks dismissal of the Accusation "for failure to state facts which, if true, would form a sufficient basis for discipline." NRS 622A.360(2)(e). Respondent faces a high bar. *See Buzz Stew, Ltd. Liab. Co. v. City of N. Las Vegas*, 124 Nev. 224, 227-28, 181 P.3d 670, 672 (2008) (standard for a motion to dismiss for failure to state a claim under NRCP 12(b)(5)).

On a motion to dismiss for failure to state a claim, the Board must construe the Accusation liberally and draw every fair inference in favor of the State. *See Brown v. Kellar*, 97 Nev. 582, 583, 636 P.2d 874, 874 (1981). All factual allegations must be accepted as true. *See Hynds Plumbing & Heating Co. v. Clark Cty. Sch. Dist.*, 94 Nev. 776, 777, 587 P.2d 1331, 1332 (1978).

Dismissal may result only if the prosecution can prove no set of facts that support the charges. *See Simpson v. Mars Inc.*, 113 Nev. 188, 190, 929 P.2d 966, 967 (1997).

III. ARGUMENT

Respondent's Motion must be denied since it relies upon matters outside the pleadings and other extrinsic evidence that cannot be considered, and is predicated upon erroneous application of the law, and because the Accusation states facts which, accepted as true, form a sufficient basis for discipline.

A. Respondent's Motion Is Not Permitted Under Nevada Administrative Law.

Respondent's Motion relies upon matters outside the pleadings and other extrinsic evidence that is attached to the Motion and/or incorporated by reference in the Motion. In Nevada civil practice, when matters outside the pleadings are presented in a motion to dismiss, the motion must be treated as one for summary judgment under NRCP 56. *See* NRCP 12(d); *Kopicko v. Young*, 114 Nev. 1333, 1335-36, 971 P.2d 789, 790 (1998); *MacDonald v. Kassel*, 97 Nev. 305, 307, 629 P.2d 1200, 1200 (1981).

However, Nevada law governing administrative procedure before the Board makes no provision for summary judgment in a disciplinary proceeding. *See* NRS 233B.121; NRS 622A.360; NAC 639.120. The Board's powers as an administrative adjudicator are limited to those specifically set forth in statute. *See Andrews v. Nevada State Board of Cosmetology*, 86 Nev. 207, 208, 467 P.2d 96, 96-97 (2007). "The grant of authority to the agency must be clear." *Id. **The Board has no authority to grant summary judgment.*** Matters outside the pleadings and other extrinsic evidence submitted in support of Respondent's Motion should be excluded from the record, and the Motion evaluated under the standard for a motion to dismiss.

Furthermore, Respondent on page 2 raises material issues of fact that are not resolvable on a motion to dismiss. *See, e.g., Pennymac Holdings, LLC v. Fid. Nat'l Ins. Co.*, 134 Nev. 995, 423 P.3d 608 (2018); *Malfabon v. Garcia*, 111 Nev. 793, 798, 898 P.2d 107, 110 (1995).

B. The Accusation States a Cognizable Basis for Discipline.

In a contested case, "[o]pportunity must be afforded all parties to respond and present evidence and argument on all issues involved." NRS 233B.121 (4). The accusation "is a written statement of the charges alleged and must set forth in ordinary and concise language the acts or omissions with which the respondent is charged to the end that the respondent will be able to prepare a defense." NRS 639.241(2). The accusation in part "must specify the statutes and regulations which the respondent is alleged to have violated." *Id.*

The Accusation states a single count against Respondent, violation of federal and state law and unprofessional conduct based upon the factual allegations set forth in paragraphs 2-3. Paragraph 2 alleges that from October 10, 2023, through January 10, 2024, Respondent compounded and dispensed drug products to Nevada patients using active ingredients that (1) do not have a United States Pharmacopoeia-National Formulary monograph; (2) are not a part of an FDA approved drug product, or (3) are not authorized to be used in pharmacy compounding pursuant to 21 USC § 353a(b)(1) or the regulations adopted pursuant thereto. Specifically, Respondent is alleged to have dispensed compounded injectable peptides, including, without limitation, AOD9604, Ipamorelin, Kisspeptin, and MOTs-C Acetate, KPV 500mcg/BPX-157 20mcg and Dihexa in capsule form and Selank 7.5mg in a nasal spray. Paragraph 3 alleges that Respondent compounded and dispensed high-risk sterile products to Nevada patients with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD.

The Accusation sufficiently alleges the facts necessary to establish the single count against Respondent. Paragraphs 4-8 recite applicable law for the basic premise that a pharmacy engaged in the practice of compounding and dispensing compounded drug products in Nevada may be subject to discipline for failure to comply with the provisions of NAC 639.661-.690, inclusive, and related federal law, 21 U.S.C. § 353a, establishing national standards for compounding medications. Count One (Paragraph 9) cites the statutes and regulations Respondent is charged with violating by the conduct alleged in Paragraphs 2-3: Revive Rx, its owner(s), and/or personnel

engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated various provisions of 21 U.S.C. § 353a, NAC 639.67019, NAC 639.67067, NAC 639.67071 and/or NAC 639.757.

The factual allegations, taken as true, establish that Respondent is responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3) and subject to discipline pursuant to NRS 639.210(4), (11) and/or (12).

C. The Board has Jurisdiction to Discipline Respondent.

Respondent argues that the Board lacks authority to discipline a Nevada-licensed pharmacy engaged in compounding and dispensing drug products to Nevada patients that do not comply with 21 U.S.C. § 353a. However, the Nevada Supreme Court has emphasized that "[t]he Board has jurisdiction to discipline Nevada license holders under NRS 639.210." *Dutchess Business Services, Inc. v. Nevada State Bd. of Pharmacy*, 124 Nev. 701, 709, 191 P.3d 1159, 1165 (2008). That statute in pertinent part authorizes the Board to discipline licensees for unprofessional conduct (subsection 4), violation of federal law (subsection 11), and violation of state law (subsection 12), the basis for the charges in this case. NRS 639.210(11) expressly states that the Board may suspend or revoke a license if the holder has violated "***any provision of the Federal Food, Drug and Cosmetic Act.***" Respondent's preemption argument is without merit.

D. Respondent is Not Being Denied Due Process.

Respondent attempts to advance an argument that compounding and dispensing drug products to Nevada patients that do not comply with national standards for compounding cannot constitute unprofessional conduct, and that Respondent is therefore without sufficient notice of what it did wrong and being denied due process. *See* Motion at page 6. This argument stretches the limits of credulity. Furthermore, even as Respondent argues that the charges lack the specificity to enable Revive Rx to prepare a defense, the Motion puts forth extensive substantive arguments and offers extrinsic evidence ***in Revive Rx's defense.***

"Nevada is a notice-pleading jurisdiction and pleadings should be liberally construed to allow issues that are fairly noticed to the adverse party." *Nevada State Bank v. Jamison Family Partnership*, 106 Nev. 792, 801, 801 P.2 1377, 1383 (1990). "[I]n the context of administrative pleadings, 'due process requirements of notice are satisfied where the parties are sufficiently apprised of the nature of the proceedings so that there is no unfair surprise.'" *Dutchess Business Services*, 124 Nev. at 712, 191 P.3d at 1167 (citations omitted). Due process is not violated unless an administrative proceeding is so fundamentally unfair that a party is prevented from reasonably presenting his case and prejudiced as a result. *Manufactured Home Cmtys., Inc. v. Cty. of San Luis Obispo*, 167 Cal. App. 4th 705, 711 (2008) (citations omitted).

Based upon the arguments made in the Motion it is self-evident that Respondent has notice of the charges. Moreover, Respondent was provided bate-stamped copies of the entire case file in response to its discovery request, and therefore has possession of all of the documentary evidence that will be introduced against it. Respondent is receiving a hearing, including the opportunity to present evidence, call witnesses and cross-examine opposing witnesses in conformance with NRS 233B.121(4), NRS 233B.123(4) and NRS 622A.380. Respondent has been accorded all necessary due process guarantees of fundamental fairness.

IV. CONCLUSION

For the foregoing reasons, the prosecution respectfully requests that the Board deny Respondent's Motion and proceed with a hearing on the merits.

RESPECTFULLY SUBMITTED this 13th day of November 2025.

By: 

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CERTIFICATE OF SERVICE

I certify that I am an counsel for the Nevada State Board of Pharmacy, and that on this 14th day of November 2025, I served a true and correct copy of the foregoing document by electronic mail to the following:

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BRETT KANDT

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **REVIVE Rx,** **Pharmacy License No. PH04215,** **Respondent.**	**CASE NO. 23-411-PH-O** **STIPULATION AND ORDER**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Revive Rx, Pharmacy License No. PH04215, by and through counsel, Philip E. M. Crooker, Esq. and Francis C. Flaherty, Esq., **HEREBY STIPULATE AND AGREE THAT:**

1. On or about March 11, 2025, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. Respondent is entering into this Stipulation in lieu of filing an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights

to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent contests the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. From October 10, 2023, through January 10, 2024, Respondent compounded and dispensed drug products to Nevada patients using active ingredients that (1) do not have a United States Pharmacopoeia-National Formulary monograph; (2) are not a part of an FDA approved drug product, or (3) are not authorized to be used in pharmacy compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto. Specifically, Respondent dispensed compounded injectable peptides, including, without limitation, AOD9604, Ipamorelin, Kisspeptin, and MOTs-C Acetate. Respondent also dispensed KPV 500mcg/BPX-157 20mcg and Dihexa in capsule form and Selank 7.5mg in a nasal spray; and

B. Respondent, Respondent's owner(s), and/or their personnel engaged in unprofessional conduct as defined in NAC 639.945(1)(i) and violated various provisions of 21 U.S.C. § 353a and/or Nevada law, and Respondent is responsible for those violations, including all errors and omissions of pharmacy personnel, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

7. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Revive Rx, Pharmacy License No. PH04215, stipulate to the following penalties. The Board is suspending judgment pursuant to NRS 639.255(1)(a), and Respondent is placed on probation for a period of one (1) year pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent shall pay a fine of Five Thousand Dollars ($5,000.00) for the violations by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by January 2, 2026;

B. Pursuant to NRS 622.400, Respondent shall pay Four Thousand Dollars ($4,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by January 2, 2026;

C. Consistent with NAC 639.67013, the managing pharmacist and every pharmacist and pharmaceutical technician engaged in the practice of compounding sterile drug products shall complete sufficient training to maintain competency and proficiency. Respondent will provide Board staff with training records for every pharmacist and pharmaceutical technician engaged in the practice of compounding sterile drugs within thirty (30) days of the effective date of this Order, and if Board staff identifies a pharmacist or pharmaceutical technician in need of additional training, Respondent will send such identified individual(s) to Sterile Compounding Certification training provided by the National Pharmacy Technician Association (NPTA): https://cpht.org/advanced-certifications-old/sterile-compounding-certification/;

D. During the probation period, Respondent shall be subject to quarterly inspections by Board staff pursuant to NRS 639.090 and NRS 639.289 at Respondent's expense;

E. Respondent shall undergo one (1) inspection by the National Association of Boards of Pharmacy (NABP), with all findings provided directly to Board staff;

F. Respondent shall establish and put into practice any necessary policies and procedures for compounding and dispensing drug products in conformance with federal and state law; and

G. Respondent shall have no new charges filed against Revive Rx while on probation.

Upon successful completion of probation, Respondent's License No. PH04215 will be fully restored.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may immediately suspend or revoke Respondent's License No. PH04215 and may impose additional discipline upon that Respondent not inconsistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on December 3, 2025. Respondent will appear in person or through counsel at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60, and shall be further reported pursuant to NAC 639.960.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in

the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2025

REVIVE Rx
Pharmacy License No. PH04215

Signed this ___ day of _____ 2025

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT
this ___ day of _____ 2025

PHILIP E. M. CROOKER, ESQ.
FRANCIS C. FLAHERTY, ESQ.
Counsel for Respondent

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Revive Rx, Pharmacy License No. PH04215, in Case No. 23-411-PH-O, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of December 2025.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

17A

Nevada State Board of
NURSING

October 1, 2021

Eliab Munyehirwe
[redacted]
Henderson, NV [redacted]

Dear Mr. Munyehirwe:

Congratulations! The Nevada State Board of Nursing has approved your request for successful completion of probation. You may review the current status of your license, including your expiration date, through nvbn.boardsofnursing.org/licenselookup. It may take several days to update your status on NURSYS.com.

Please call me with any questions you may have.

Sincerely,
Nevada State Board of Nursing

Sherri Twedt, BSN, RN
Compliance Coordinator
[redacted]
stwedt@nsbn.state.nv.us

To: The Nevada Board of Pharmacy, Date: 12/03/2025

My name is Eliab "Eli" Munyehirwe, I am a recent graduate Psychiatric Nurse practitioner and I work at Desert Parkway Behavioral Healthcare Hospital here in Las Vegas. I am here today to request the board to grant me the prescribing privileges.

I understand this Board's mission which is to protect the public's health, safety, and welfare by carrying out and enforcing Nevada law in the regulation of the practice of pharmacy. I am here today to reassure you that I honor the responsibility you have, and that I also honor the responsibility I am requesting from you.

I ask that you evaluate me on what I've become over the past few years rather than who I was. I have grown so much over the past years, not only in my ability to understand and accept responsibility, but also in making efforts to grow both personally and professionally. I successfully completed my probation with the Nevada State Board of Nursing, I went back to school to advance my knowledge and understanding of mental health and chemical dependency problems and I have been working as a charge nurse for nearly six years in an acute mental health and chemical dependency Hospital where I work with a team of Psychiatrists, Social workers and other mental health professionals to provide the services to our population dealing with mental health and chemical dependency.

This work gave me a deep appreciation and understanding of the nature of these conditions. I sought professional counseling, I took responsibility of my actions, I am now more mature, more focused, and more grateful for the opportunity to serve the community I have been part of for the past 22 years. I made mistakes in my past, and I was on the wrong path, but I have found my footing. I've provided documents showing the completion of my probation and a character letter

from my director, and I ask that you take these into consideration in making your decision. I have worked hard to set myself into a position to be the best Nurse I can be, and I set that as my daily goal every morning.

In the end, I have worked hard to become the nurse that is before you today, and I'm asking that you grant a permission to this person, rather than withholding it from a person that no longer exists.

I'd be happy to answer any questions you have for me.

Thank you.

Eliab Munyehirwe

DESERT PARKWAY
Behavioral Healthcare Hospital

December 2, 2025

NV State Board of Pharmacy,

Thank you for allowing me to provide a written character reference for Eli Munyehirwe, an employee of mine for the last six years.

My name is Kristine Fisher, and I have had the privilege of providing supervision to Mr. Munyehirwe for the previous six years, as the Director of Assessment and Referral for Desert Parkway Behavioral Healthcare Hospital for the last 9 years.

Eli has served as a Charge RN during this time frame, for the department I provide oversight. Eli is an employee that has shown significant and profound growth throughout these years, and there has never been a moment's hesitation in supporting and encouraging his growth professionally.

As Eli continues to pursue his professional career, I feel privileged to be able to provide the necessary character reference and testimony. Eli is by far, one of the most dedicated, dependable, and trustworthy human beings I have been blessed to work with. Eli demonstrates impeccable decision-making skills, and has shown an ability to balance ethics and daily operational needs, excelling in finding strategies to accomplish both simultaneously. Eli consistently, without fail, has shown patient care to be his highest priority.

Eli consistently utilizes the resources he has been given, to promote appropriate and desired outcomes, and never hesitates to advocate when additional resources may be required. Eli treats every human being he comes in contact with, with the respect and dignity they deserve; the patient's he treats, remember him for his kindness and his desire to see positive results. Eli shows thoroughness even amongst the chaos, and never fails to address every aspect required to provide excellent care.

Eli is able to provide a solid foundation for the employees around him, and models the behavior he expects of himself. He is a leader that truly leads; in the roughest of times, he stands firm, confident, and positive, and will take on any task required to get a job done. Eli's ability to work with all disciplines within his daily job tasks, speaks to his skill set, and never once has he been unreceptive to any feedback or redirection. Eli is humble, but willing to provide the necessary guidance required to accomplish goals. Eli leads by his own behavior, and never fails to affect change when necessary. Eli is additionally a team player, understanding intuitively the dynamics of what makes a team successful.

I would trust Eli with my life, and I feel that speaks volumes on the type of human being he is. He will be a phenomenal health care provider, and his integrity and the quality of care I have seen him provide already, will go unmatched. I would recommend him for any type of consideration he will require, and I am very cautious when recommending individuals, as I take my professional oath very seriously. It is a pleasure to be able to support and provide reference for this very amazing young man in his career path. I welcome any additional questions if you have them.

Thank you for allowing me this opportunity. I can be reached at the following number, if additional information is needed: 702-370-9617, work cellular.

Kristine Fisher, MSW
Director of Assessment and Referral
Desert Parkway Behavioral Healthcare Hospital
3247 So. Maryland Parkway
Las Vegas, NV 89109

18A

Gerber Medical Clinic

www.gerbermedical.com

December 2, 2025

Via email and fax

Nevada State Board of Pharmacy
985 Damonte Rance Pkwy, Ste. 206
Reno NV 89521
pharmacy@pharmacy.nv.gov
Fax: 775-850-1444

Re: Workshop related to proposed regulation impacting homeopathic physicians

Dear members of the Board:

I am writing to provide my comments related to a proposed regulation which is scheduled for a workshop during your meeting on December 4, 2025. Unfortunately, I am unable to attend the meeting due to professional commitments, but I wanted to ensure that I provided my comments to the Board regarding the proposed regulation as I am one of only two homeopathic physicians in the state of Nevada which this regulation would disproportionately impact.

I am writing in both my capacity as a practicing homeopathic physician and as the current president of the Nevada Homeopathic and Integrative Medical Association. I have been licensed as a homeopathic physician in Nevada for 40 years and have provided care to patients in Northern Nevada since 1985. I do not currently hold a license to practice medicine in the state of Nevada as an allopathic or osteopathic physician and practice solely as a homeopathic physician.

The proposed regulation which is before the Board for consideration serves no purpose but to harm patients. As I noted above, I am one of only two actively practicing homeopathic physicians in the state that does not hold a license as an allopathic or osteopathic physician in the state. To my knowledge, there have been no concerns raised regarding the care my colleague or myself provide to patients. We both completed our medical schooling and have extensive experience and expertise in treating patients with therapies and treatments which are considered within the scope of a homeopathic physician under NRS and NAC Chapter 630A which governs my practice as a homeopathic physician.

Under NRS 630A.040 homeopathic medicine/homeopathy is defined as:

A system of medicine employing substances of animal, vegetable, chemical or mineral origin, including:

1. Nosodes and sarcodes, which are:

(a) Given in micro-dosage, except that sarcodes may be given in macro-dosage;

(b) Prepared according to homeopathic pharmacology by which the formulation of homeopathic preparations is accomplished by the methods of Hahnemannian dilution and succussion or magnetically energized geometric patterns applicable in potencies above 30X, as defined in the official *Homeopathic Pharmacopoeia of the United States*; and

(c) Prescribed by homeopathic physicians or advanced practitioners of homeopathy according to the medicines and dosages in the *Homeopathic Pharmacopoeia of the United States*, in accordance with the principle that a substance which produces symptoms in a healthy person can eliminate those symptoms in an ill person.

2. Noninvasive electrodiagnosis, cell therapy, neural therapy, herbal therapy, neuromuscular integration, orthomolecular therapy and nutrition.

Additionally, NAC 630A, which was originally adopted in 1998, further defines terms used in NRS Chapter 630A including therapies and modalities of treatments which a homeopathic physician is legally allowed to utilize. A copy of NAC 630A.014 is attached to this letter.

The proposed regulation attempts to prohibit the use of treatments that have been used by homeopathic physicians for decades without issue. This proposed regulation improperly attempts to regulate the practice of homeopathy which is the purview of the Nevada Board of Homeopathic Medical Examiners which also holds the expertise in the interpretation of the Homeopathic Pharmacopoeia of the United States.

Should this draft regulation be approved by the Board it would pose a great burden to current patients who would suffer both physically and financially from disruption of their medical care and I ask the Board to carefully consider the ramifications of approving such a regulation when there is clearly no need for such a regulation.

Sincerely,

Michael L. Gerber

Michael Gerber, HMD

cc: Nevada Homeopathic Examiners Board

NAC 630A.014 Interpretation of terms used in NRS 630A.040. (NRS 630A.040, 630A.155, 630A.200)

1. As used in NRS 630A.040, unless the context otherwise requires, the Board will interpret:

(a) "Herbal therapy" to mean a system of healing art that places the chief emphasis on the flow and balance of dynamic force or energy in the body mechanism as being the most important single factor in maintaining the natural health and well-being of the living organism and includes, without limitation, the prescribing and use of plants or plant extracts or a combination thereof to treat an ailment or disease of the mind, emotions or body, or for the cure or relief of any wound, bodily injury or deformity. As used in this paragraph:

(1) "Plant" includes, without limitation, any tree, vine, shrub, vegetable or herb or any part of a tree, vine, shrub, vegetable or herb.

(2) "Plant extract" means a substance removed from a plant by physical or chemical means for medicinal purposes.

(b) "Neural therapy" to mean dry needling, the use of an electronic testing and treatment device and the injection of vitamins, minerals, homeopathic medications, herbal extracts, enzymes, orthomolecular substances or other medicinal or pharmaceutical preparations into the:

(1) Acupuncture, acupressure or trigger points;

(2) Ganglia; or

(3) Subcutaneous tissue, intracutaneous tissue, intra-articular tissue or periosteal tissue,

Ê of a patient to control pain or produce other beneficial clinical effects.

(c) "Neuromuscular integration" to mean the progressive harmonization of the endocrine system, immune system, autonomic nervous system, skeletal system and smooth muscle system of a patient with the cognitive and noncognitive faculties of a patient by the use of:

(1) Manipulation of the soft tissues of the body to balance the body, including, without limitation:

(I) Aquastretch exercising or any other form of aquatic therapy; and

(II) Cranio-sacral manipulation; and

(2) Thought field therapy to recondition the endocrine system, immune system, autonomic nervous system and central nervous system.

(d) "Nutrition" to include, without limitation, applied kinesiology or any other modality or method used for the recognition, evaluation, treatment and correction of the unique dietary needs of a patient.

(e) "Orthomolecular therapy" to mean the treatment and prevention of disease, including, without limitation, infection, malignancy and degenerative illness, by adjusting the natural chemical constituents of the body on the molecular level. The term includes, without limitation:

(1) The prescription of topical and oral supplements, medicines and pharmaceutical preparations; and

(2) The intravenous infusion, intramuscular injection, subcutaneous injection and intradermal injection of vitamins, amino acids, peptides, polypeptides, enzymes, sarcodes, medicines and pharmaceutical preparations, homeopathic medications, ozone, bio-oxidative substances or chelating agents,

Ê to detoxify and remove harmful substances from the body, including, without limitation, heavy metals, the buildup of vascular and arterial plaque and toxic environmental factors, including, without limitation, pesticides, xenobiotics, bacteria and fungi.

2. As used in this section:

(a) "Aquastretch exercising" means a method of personal or assisted exercise used as a form of aquatic or nonaquatic therapy which enables stretching of the body to encourage dynamic intuitive movement, usually in various depths of water and with various weights attached to the body, to increase systemic flexibility and improve vascular, nerve and muscular functions.

(b) "Bio-oxidative substances" means substances that are used to promote healing at the cellular level by the use of oxygen in its various forms.

(c) "Chelating agents" means substances that are used to remove heavy metals and other toxins from the body, including, without limitation:

(1) Sodium 2,3-dimercaptopropane-1-sulfonate (DMPS);

(2) Dimercaptosuccinic acid (DMSA);

(3) Ethylene diamine tetra-acetic acid (EDTA);

(4) Penicillamine;

(5) Diethylene triamine penta-acetic acid (DTPA);

(6) Deferoxamine mesylate; and

(7) Clathration agents.

(d) "Cranio-sacral manipulation" means the manipulation of muscles, ligaments, fascia or other connective tissues, and any anatomical structures relating to those tissues, to improve the function of cranial nerves and systemic neurological dynamics.

(e) "Dry needling" means a procedure that involves inserting acupuncture needles under the skin at trigger points and, while those needles are inserted, rotating the needles or connecting the needles to a low current electrical supply.

(f) "Pharmaceutical preparations" includes narcotic drugs or opiates that are listed as schedule II controlled substances pursuant to chapter 453 of NRS.

(g) "Thought field therapy" means a technique that uses the energy meridians of the body which are used in acupuncture and acupressure to treat abnormal patterns of thought that cause emotional and psychophysiological distress.

(h) "Trigger point" means a hyperirritable spot within the skeletal muscle or the fascia of that muscle that, upon compression, causes pain, tenderness and autonomic nervous system phenomena.

(i) "Xenobiotics" means chemical compounds that, under normal circumstances, are foreign to living organisms.

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National Nurses Organizing Committee
National Nurses United
OUR PATIENTS. OUR UNION. OUR VOICE.

OAKLAND
155 Grand Avenue
Suite 100
Oakland CA 94612
phone: 800-504-7859

LAS VEGAS
8485 West Sunset Road
Suite 301
Las Vegas NV 89113
phone: 702-407-1119
fax: 702-766-5170

Via Email: teambc@pharmacy.nv.gov

December 4, 2025

Helen Park, President
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

RE: Proposed regulation relating to the possession and administration of dangerous drugs by an advanced emergency medical technician or paramedic (LCB File No. R004-25)

Dear President Park,

On behalf of more than 3,000 registered nurse (RN) members in Nevada, National Nurses Organizing Committee - Nevada (NNOC-NV), submits these comments in response to the State Board of Pharmacy's public hearing for possible action on the proposed regulation relating to the possession and administration of dangerous drugs by an advanced emergency medical technician or paramedic (LCB File No. R004-25). **NNOC-NV objects to the proposed regulation and strongly urges the Board to withdraw it and not to proceed with further rulemaking** for the following reasons: (1) allowing paramedics to provide services in hospital settings, including administration of controlled substances, would endanger patients because paramedics do not have the clinical education and experience required for treating patients in hospital settings; (2) paramedics have no authorization to provide services in hospital settings once a hospital takes responsibility of a patient and legislation that proposed such authorization, SB 495, failed to pass during the 83rd (2025) session; (3) notwithstanding the Board's authority to regulate the possession and administration of controlled substances by paramedics, the Board lacks the authority to permit paramedics to provide services in hospital settings; (4) rather than shift care to paramedics, state agencies should focus on strengthening nursing retention and recruitment.

I. Allowing paramedics to provide services in hospital settings would endanger patients based on differences in education and training requirements for emergency medical service personnel and registered nurses.

NNOC-NV objects to the proposed regulation because authorizing paramedics to treat patients in hospital settings, including administering controlled substances, would endanger patients. Paramedics, while valuable emergency responders, do not have the education and clinical experience required for treating patients in hospital settings, including intensive care units, emergency departments (ED), and other areas for acute or specialty care. Unlike registered nurses, paramedics are specifically trained to provide *pre-hospital* emergency care and then hand off patients to nurses or physicians when they arrive at the hospital.

19D

Hospital patients in need of acute care may have multiple underlying medical conditions, and ongoing assessment by an RN ensures patients receive the appropriate level of care. The regulations governing nursing practice expressly authorize RNs to make patient assessments: "A registered nurse shall perform … [t]he assessment and evaluation of the health of each patient under the care of the registered nurse based on his or her knowledge or understanding of the biological, psychological, social and cultural factors affecting the patient's condition." RNs monitor changes in a patient's condition hour by hour, often minute by minute, to determine whether their condition is improving and to anticipate potential complications. This ongoing evaluation enables the nurse to modify the patient's care plan when needed.[1]

Ongoing nursing assessment is especially critical when administering controlled substances to patients. Medication administration is one of the principal duties of professional registered nursing practice and is heavily regulated. The laws and regulations governing nursing practice expressly include "the administration of medications and treatments" in the definition of nursing practice.[2] Generally, administration of controlled substances is a high-risk procedure that is prone to complications and errors that may prove fatal. The nursing practice regulations currently protect patients from risk of medication errors by heavily restricting delegation of medication administration and prohibiting delegation of any medication administered by intravenous push, as well as administration of any medication used for purposes of sedation or any experimental drug.[3]

To perform patient assessments and provide direct care in hospital inpatient settings, RNs must complete robust clinical education and experience requirements. Nursing education programs require RNs to complete at least two years of clinical education and experience in hospital settings, including in medical-surgical nursing, maternal and child nursing, and psychiatric nursing.[4] In addition, registered nurses must have the relevant clinical competency for the patient care units in which they work such as intensive care, obstetrics, cardiology, or neurology.

In contrast, advanced EMT or paramedic training certification programs vary in length from four to twelve months, and specifically train individuals to stabilize patients, provide basic life support, and other pre-hospital care.[5] In addition, our state has recently weakened the training requirements for paramedic certification. Previously, certification required advanced EMT training before becoming a paramedic but now EMTs can skip the advanced EMT training and go straight to paramedic training.[6] In sum, paramedics do not have the education and clinical experience needed to safely and competently provide care in the inpatient hospital setting.

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[1] *See* NAC 632.026, 632.212, 632.214, 632.216, and R019-22 § 1.
[2] NRS 632.018; NAC 632.212.
[3] NAC 632.455.
[4] NAC 632.150.
[5] NAC 450B.360.
[6] Nevada Department of Public and Behavioral Health. (2025). *Emergency Medical System (EMS) - Training & Education: Changes to Nevada EMS Training Requirements*. https://www.dpbh.nv.gov/regulatory/emergency-medical-systems-ems/ems-home/dta/emergency-medical-system-ems-training-education/

II. As emergency responders, paramedics have no authorization to provide services in hospital settings, rather the law restricts authorized services by paramedics to pre-hospital settings.

Existing law does not authorize paramedics to provide services in hospitals generally. The Legislature acknowledged that paramedics lack this authorization but **failed to pass S.B. 495 this past session, a bill that proposed authorizing services by paramedics in hospitals.**[7] Currently, the laws and regulations governing emergency medical services heavily restrict the settings where paramedics can provide services:

- ***Services by paramedics restricted to scene of the emergency and during transport to hospital.*** Statute restricts services by paramedics to the scene of an emergency or while transporting sick or injured persons to a medical facility. Specifically, the law prohibits a fire-fighting agency from "provid[ing] the level of medical care provided by an advanced emergency medical technician or paramedic to sick or injured persons *at the scene of an emergency or while transporting those persons to a medical facility.*"[8]
- ***Community paramedicine services by paramedics restricted to individuals who do not require transport to hospital.*** Statute restricts community paramedicine services by paramedics to patients who do not require emergency medical transportation. Specifically, the law defines community paramedicine services as "services provided by an emergency medical technician, advanced emergency medical technician or paramedic to *patients who do not require emergency medical transportation.*"[9]
- ***Services by paramedics in hospitals restricted to period before patient hand-off.*** Regulations restrict hospitals' use of paramedics to provide emergency services to the period until hospital staff take responsibility for the care of the patient after transport and transfer. Consistent with statute, NAC section 450B.450 only allows hospitals to use services by paramedics under three circumstances: "(a) At the scene of an emergency and during transport to a hospital; (b) During transfer of a patient from a hospital to another medical facility or other location; and (c) *While in an emergency department of a hospital until responsibility for care is assumed by the regular staff of the hospital.*"[10]

III. Notwithstanding the Board's authority to regulate the possession and administration of controlled substances by paramedics, the Board lacks the authority to permit paramedics to provide services to patients in hospitals.

Notwithstanding the Board's authority to regulate the possession and administration of controlled substances by paramedics, the proposed regulation is an unauthorized expansion of the Board's authority and conflicts with the designated authorities under emergency medical

[7] S.B. 495, 83rd Leg. (Nev. 2025).
[8] NRS 450B.240. Emphasis added.
[9] NRS 450B.0615. Emphasis added.
[10] NAC 450B.450. Emphasis added.

services law. Under chapter 450B of the Nevada Revised Statutes, only district boards of health and the Division of Public and Behavioral Health have the authority to authorize services by paramedics pursuant to permits issued to certain entities.[11] Without authorization by these designated health authorities, the law prohibits services by paramedics:

- ***Services by paramedics prohibited without authorization by health authorities.*** The law prohibits fire-fighting agencies from using paramedics to provide services without permits issued by the designated health authorities: "A fire-fighting agency shall not provide the level of medical care provided by an advanced emergency medical technician or paramedic to sick or injured persons at the scene of an emergency or while transporting those persons to a medical facility *without a currently valid permit for that care issued by the health authority.*"[12]
- ***Community paramedicine services by paramedics prohibited without authorization by health authorities.*** The law prohibits persons or governmental entities from "provid[ing] community paramedicine services … *without a currently valid permit with an endorsement ... by the health authority.*"[13]

Thus, only designated health authorities in chapter 450B have the authority to authorize the settings and services that paramedics can provide, not the Board. As discussed above, legislators failed to expand the role of paramedics by authorizing their services in hospitals.[14] The Board cannot bypass the legislative process and promulgate regulations for which it has no authority.

IV. Nevada must strengthen nurse retention, not shift care to paramedics.

Our state does not have a shortage of registered nurses, yet proponents claim that there are not enough RNs to justify allowing non-nursing personnel to provide nursing care, including administering controlled substances, in hospitals. **To the contrary, the supply of RNs with active licenses is robust and outpacing state population growth:** the current number of active RN licenses in our state has increased by more than 17,000 or 38% since the beginning of 2020, a change from 45,254 to 62,806 active RN licenses.[15] In contrast, Nevada's population in 2024, the most recent year available, has increased by less than 5 percent since 2020.[16] **NNOC-NV urges**

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[11] NRS 450B.077 and NRS 450B.240.
[12] NRS 450B.240. Emphasis added.
[13] NRS 450B.240.
[14] S.B. 495, 83rd Leg. (Nev. 2025).
[15] National Council of State Boards of Nursing. Number of Active RN Licenses by State: December 31, 2019 and May 26, 2025. Available at: https://www.ncsbn.org/NND/Statistics/Archive/Aggregate-RNActiveLicensesTable2019.pdf and https://www.ncsbn.org/NND/Statistics/Aggregate-RNActiveLicensesTable.pdf - accessed 12/3/2025.
[16] Nevada Governor's Office of Economic Development: 2019 and 2024. Nevada Economic Highlights. Available at https://goed.nv.gov/data-portal/ - accessed 12/3/2025.

state agencies to focus instead on measures that retain and educate more registered nurses rather than shifting care to paramedics.

V. Conclusion: The Board should withdraw the proposed regulation to protect patients and safeguard nursing practice.

For the reasons above, NNOC-NV objects to the proposed regulation and strongly urges the Board to withdraw this rulemaking. First, the proposed regulations would endanger patients by allowing paramedics to provide services in hospital settings for which they do not have the clinical education and experience. Second, paramedics have no authorization under existing law to provide services in hospital settings once a hospital takes responsibility for a patient. Third, notwithstanding the Board's authority to regulate the possession and administration of controlled substances by paramedics, the Board lacks the authority to authorize services by paramedics in hospital settings. Finally, state agencies should focus on strengthening nursing retention and recruitment, rather than shift care to paramedics.

Sincerely,

Michelle Grisat

Michelle Grisat
National Director of Health and Regulatory Policy
National Nurses Organizing Committee/National Nurses United

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SFY26 BUDGET REPORT
NEVADA STATE BOARD OF PHARMACY
CURRENT MONTH: 10/31/2025

REVENUES	APPROVED BUDGET	BUDGET AMMENDMENTS	REVISED BUDGET	CURRNET MONTH REVENUE/EXPENSE	YTD REVENUE/EXPENSE	PROJECTIONS THROUGH 6/30/2026	TOTAL REVENUE/EXPENSE SFY26	DIFFERENCE
Beginning Balance	$ 7,680,671		$ 7,680,671	$ -	$ -	$ 7,680,671	$ 7,680,671	$ -
Renewal Fees	$ 1,800,000		$ 1,800,000	$ 867,290	$ 855,710	$ 77,000	$ 1,800,000	$ -
Registration Fees	$ 1,209,020		$ 1,209,020	$ 114,045	$ 391,980	$ 702,995	$ 1,209,020	$ -
Recovered Costs	$ 30,000		$ 30,000	$ 4,000	$ 10,000	$ 16,000	$ 30,000	$ -
CC Processing Fees	$ 155,000		$ 155,000	$ 46,487	$ 51,919	$ 56,595	$ 155,000	$ -
Change MGR RPh	$ 22,800		$ 22,800	$ 1,600	$ 4,600	$ 16,600	$ 22,800	$ -
Inspections	$ 5,000		$ 5,000	$ 286	$ 3,750	$ 965	$ 5,000	$ -
Interest Income	$ 20,000		$ 20,000	$ -	$ 37,882	$ -	$ 37,882	$ 17,882
Late Fees	$ 15,000		$ 15,000	$ 1,445	$ 4,655	$ 8,900	$ 15,000	$ -
Total Revenues	**$ 10,937,491**	$ -	**$ 10,937,491**	**$ 1,035,152**	**$ 1,360,495**	**$ 8,559,725**	**$ 10,955,373**	**$ 17,882**

EXPENSES								
Payroll	$ 4,299,317		$ 4,299,317	$ 335,161	$ 1,002,483	$ 2,961,673	$ 4,299,317	$ -
Operating	$ 1,442,170		$ 1,442,170	$ 182,028	$ 285,464	$ 974,678	$ 1,442,170	$ -
Equipment	$ 25,000		$ 25,000	$ 1,243	$ 2,216	$ 21,540	$ 25,000	$ -
In-State Travel	$ 110,000		$ 110,000	$ 10,999	$ 18,457	$ 80,544	$ 110,000	$ -
Out-of-State Travel	$ 65,000		$ 65,000	$ -	$ -	$ 65,000	$ 65,000	$ -
DAG Cost	$ 40,000		$ 40,000	$ -	$ 5,544	$ 34,456	$ 40,000	$ -
Reserve	$ 4,956,004		$ 4,956,004	$ -	$ -	$ -	$ 4,973,886	$ 17,882
Total Expenses	**$ 10,937,491**	$ -	**$ 10,937,491**	**$ 529,431**	**$ 1,314,164**	**$ 4,137,892**	**$ 10,955,373**	**$ 17,882**
Balance	$ -	$ -	$ -				$ -	$ -