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NEVADA STATE BOARD OF PHARMACY
OFFICE OF THE GENERAL COUNSEL
WRITER'S DIRECT DIAL: (775) 850-1440 • E-MAIL: PEDWARDS@PHARMACY.NV.GOV • FAX: (775) 850-1444

August 7, 2018

COPY

BY CERTIFIED U.S. MAIL 9171 9690 0935 0157 4985 97

Roger Estevez, M.D.,
E. Desert Inn Road
Las Vegas, Nevada 89121

RE: Citation And Administrative Fine For Dispensing Without a Registration

Dear Dr. Estevez,

The Nevada State Board of Pharmacy (Board) received a complaint that you are engaged in dispensing dangerous drugs without a Nevada dispensing practitioner registration in violation of NAC 639.742. Board Staff, through its inspectors, verified those allegations during a visit to your office on July 5, 2018, where the inspectors confirmed that you are dispensing dangerous drugs to patients as part of a clinical trial.

This letter shall serve as a CITATION pursuant to NRS 639.2895(2), citing you for dispensing dangerous drugs to patients without a dispensing practitioner registration. *See* NAC 639.742 *et al.* For those violations, the Board has assessed an ADMINISTRATIVE FINE against you in the amount of five thousand dollars ($5,000.00). *See* NAC 639.2895(2), (3).

You shall pay this administrative fine within 30 days of receipt of this citation. Payment must be by *cashier's check*, *certified check* or *money order* made payable to the Nevada State Board of Pharmacy. Send all payments to the Board's Reno office, located at 431 W. Plumb Lane, Reno, NV 89509.

The Board is also authorized under NAC 639.2895(1) to issue an order directing you to cease and desist from all dispensing activities. The Board is holding that remedy in reserve anticipating that you will either voluntarily stop dispensing or come into compliance by applying for a dispensing practitioner registration immediately and by pursuing its approval. Your failure to pursue one of those courses may result in additional penalties.

You have the right to appeal this citation. *See* NRS 639.2895(2). To appeal you must submit a written request for a hearing to the Board's Executive Secretary, Dr. Larry Pinson, at the Board's Reno Office, located at 431 W. Plumb Lane, Reno, NV 89509, no later than 30 days after receipt of this letter. If you submit a request for a hearing, you may submit with your

request any evidence you wish the Board to consider. At a hearing, you would bear the burden to show that no violation occurred and that the Board issued this citation in error.

In the event that you apply to obtain a Nevada dispensing practitioner registration to allow you to continue the clinical trial in which you are engaged, please be aware that the Board may request that you attend a hearing to discuss this matter as part of its consideration of your application. An appeal of this citation and an application for a dispensing practitioner registration could be addressed at the same hearing at your request.

Feel free to contact me if you have questions.

Best regards,

S Paul Edwards

S. Paul Edwards
General Counsel
Nevada State Board of Pharmacy

Cc: Larry Pinson, Pharm.D. Executive Secretary, Nevada State Board of Pharmacy; David Wuest, R.Ph., Deputy Executive Director, Nevada State Board of Pharmacy

August 19, 2018 .

RE : Citation and administrative Fine for dispensing without a Registration .

Nevada State Board of Pharmacy.

Our office recently received the above- referenced citation Following a complain of dispensing dangerous drugs, This letters serves as our formal response, this citation is unreasonable based on the grounds that the patient was prescribed, desiccated thyroid extract (ARMOUR THYROID)with a valid prescription filled and dispensed by a license pharmacy by state of Nevada ,please see exhibit 1. This is a Pharmacy Delivery Service and they never got in touch with patient at the time of delivery, for patient's convenience they delivered to our Clinic , Patient picked bottle at the clinic .As you can see in the written protocol by sponsor, clearly state Item 6.5 .1 under treatment administered "No Medication will be provided as a part of study " . Instead physicians will prescribe a dose and brand of prescription DTE according to clinical Judgment. Please see Exhibit2.

As part of GCP (Good clinical Practice and regulatory requirements) our office Follow up industry Guidelines, please see exhibit 3.

Our office was never advise to request any stated license for dispensing medication as part of protocols in clinical research and this was discussed with the investigators during visit on July 5,2018 We had agree in pursuing dispensing practitioner registration , we are in the application process for this new license .

Base on the above mentioned reasons we appeal this citation and at the same time are requesting a Hearing to the Board's Executive Secretary , DR Larry Pinson, as this time pertinent clinical research trial is finished but we are determined in complying with Pharmacy state regulations as we have always done .

Sincerely

Dr. Roger Estevez

Aug/19/2018.

Exhibit-1

First Class Rx Pharmacy
8846 S Eastern Ave # 100
LAS VEGAS, NV 89123
702-534-0325

Patient History Report

From: 12/1/2017 To: 8/16/2018

JOHNSON,FRANCINE

RX#	RX Date	Doctor Name	Drug Name	Qty	Plan	PatPay	Price
167611	01/30/2018	ESTEVEZ,ROGER	ARMOUR THYROID 60 MG TABLET	130		90	$124.35
			Totals:			**$90.00**	**$124.35**

6.4.3.2 Evaluations at the Time of Study Withdrawal

For any patient who is withdrawn from the study early, the physician will ensure that all appropriate eCRF pages are completed, including the date of and explanation for the patient's withdrawal from the study.

6.4.3.3 Replacement of Patients

Patients who enroll in the study but do not switch from L-T4 to DTE will be replaced

6.5 Treatment

6.5.1 Treatments Administered

No medication will be provided as part of this study. Instead, physicians will prescribe a dose and brand of prescription DTE according to their clinical judgment, and patients will obtain their medication as they usually do.

6.5.2 Study Treatment Formulation

Several brands of DTE are commercially available, and each physician will prescribe the most appropriate prescription product for each patient, based on clinical judgment.

6.5.3 Dose Adjustments and Dose Escalation

Physicians will make dose adjustments according to their clinical judgment, and will record dose adjustments and any associated thyroid hormone results in the eCRF.

6.5.4 Previous and Concomitant Therapy

The physician or designee will record the patient's previous and concomitant medications (only those medications prescribed for hypothyroidism, depression, or cholesterol management will be recorded), including the drug name, dosage, and dates of administration, in the eCRF. Patients currently taking any prescription or nonprescription thyroid extracts or thyroid hormone-containing supplements are not eligible to participate in the study.

6.5.5 Treatment Adherence

The physician or designee will determine patient adherence with treatment by their usual methods, if this is part of their standard practice.

6.5.6 Assignment to Treatment

Physicians will select a dose and brand of prescription DTE for each patient according to their clinical judgment.

6.6 Variables

6.6.1 Primary Variable - Effectiveness

- The percentage of patients who have a normal TSH at approximately Week 18 or at the time of study withdrawal

Exhibit-3

If significant changes are made in the formulation of the investigational or comparator product during the course of the trial, the results of additional studies (e.g. on the stability, comparative dissolution rate or, as appropriate, comparative bioavailability) should be made available before the new formulation is used in the trial. The studies would demonstrate that the changes would not be expected to alter the pharmacokinetic profile or other clinical characteristics of the product.

10.1 ***Supply and storage***

The arrangements made by the sponsor to supply the investigator with pharmaceutical products for the trial should be described in the protocol. The manner in which study products are to be recorded, delivered, dispensed and stored should be detailed.

The principles of Good Manufacturing Practice*(1)* should be applied not only by the supplier of the pharmaceutical product(s), but also by any intermediaries responsible for storing the product(s) temporarily.

Records must be kept of information about the shipment, delivery, receipt, storage, return and destruction of any remaining pharmaceutical products. The investigator should not supply the investigational product to any person not targeted to receive it. Preferably a local pharmacy or the pharmacy department of the local hospital should assume responsibility for storage, delivery, return and keeping records of the investigational and, when appropriate, comparator product(s). If so, these procedures must be documented to make auditing possible.

10.2 ***Investigational labelling and packaging***

The sponsor is responsible for the proper packaging and investigational labelling of the pharmaceutical products used. Study products should be labelled in compliance with the protocol and any applicable national regulations. The investigational label should state that the product is for clinical research purposes only. Investigational label information should be accurate and in a language that is understandable to the subject.

In blinded trials, the package should be labelled in a way that does not reveal the identity of the product. A coding system should be used to allow for the proper identification of the blinded products given to individual subjects (in case of emergency). In addition, all study products, including comparator products, should be indistinguishable by appearance, taste, smell, weight and other physical characteristics.

10.3 ***Responsibilities of the investigator***

The investigator is responsible for ensuring:

- Proper and safe handling of the investigational and, when appropriate, comparator products during and after the clinical trial, preferably in cooperation with a pharmacy (see Section 10.1);
- That the investigational product is used only in accordance with the protocol, which implies use only for subjects included in the trial and by designated staff responsible to the investigator, and that this use is documented in such a way as to ensure appropriate dosage;
- That the dosage and instructions for use are correct and that every subject involved understands them properly;
- That unused investigational and, when appropriate, comparator products are returned in accordance with the protocol to the pharmacy or sponsor or destroyed, and that proper records of these activities are kept.

10.4 ***Responsibilities of the sponsor and monitor (see also Sections 5 and 6)***

The sponsor is responsible for: