December 6, 2017

Larry Pinson
Executive Secretary
Nevada State Board of Pharmacy
431 West Plumb Lane
Reno, NV 89509

Dear Mr.Pinson :

The purpose of this letter is to refer to the Nevada State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor practices observed during an FDA inspection at a pharmacy licensed by the Nevada BOP, Meditech Laboratories, Inc., located at 3200 Polaris Ave Suite 27, Las Vegas, NV 89102-8379 (Pharmacy License number PHN01794; expires October 31, 2018).

FDA inspected the firm from May 9, 2017, to May 11, 2017. An FDA investigator was accompanied by Nevada State Board of Pharmacy investigators throughout the entire inspection (3 days). A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at: https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM567306.pdf with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that FDA will provide to the firm, which contains additional information about our inspection. If you are a Commissioned Official or if your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigator reviewed a sample of records for products compounded by Meditech Laboratories, Inc. and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

During the inspection, the FDA investigator observed a deviation from appropriate non-sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Specifically, drugs were produced without providing adequate containment and cleaning of utensils to prevent cross-contamination. The investigator observed visible white powder residue on a non-dedicated plastic scoop, stored in a bin with other utensils, used to portion out bulk drug substances to produce creams.

Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road, Irvine, CA 92612-2506
Telephone: (949) 608-2900; Fax: (949) 608-4417
www.fda.gov

Meditech Laboratories, Inc., committed to FDA in its response to the Form FDA 483, dated May 24, 2017, to correct the deviation in the Form FDA 483 and provided documentation in support of those corrective actions. In addition, the deviation identified appears to be readily correctable.

After review of the record, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Nevada State BOP for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law. In addition, please notify FDA if you become aware of this firm resuming production of sterile drug products.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Lance M. De Souza, Compliance Officer, at (510) 337-6873, or by email at lance.desouza@fda.hhs.gov.

Sincerely,

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV

SP:wvm(lmd)

Cc: Meditech Laboratories, Inc.
3200 Polaris Ave suite 27
Las Vegas, Nevada 89102-8379

FEI 3012200488
CMS WA 161152