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

August 22, 2017

Ben Kesner, R.Ph.
Executive Director/Chief Drug Inspector
Regulation and licensing Department
New Mexico State Board of Pharmacy
5500 San Antonio Drive NE, Suite C
Albuquerque, NM 87109

Dear Mr. Kesner:

The purpose of this letter is to refer to the New Mexico 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 New Mexico BOP, In Your Atmosphere Holdings, LLC dba Highland Pharmacy Santa Fe, located at 1676 Hospital Drive, Santa Fe, NM 87505-4754 (Pharmacy license# PH00003706; Controlled substance license #CS00220251).

FDA inspected the firm from January 9, 2017, to January 19, 2017. FDA investigators were accompanied by the New Mexico BOP state investigators for two days. A copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm542170.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), which contains additional information about our inspection, that FDA will provide to the firm. 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 investigators reviewed a small sample of records for products compounded by In Your Atmosphere Holdings, LLC dba Highland Pharmacy Santa Fe and determined, based on this sample, that this firm appeared to obtain valid prescriptions for individually-identified patients for the drug products that it compounded and distributed. During the inspection, the FDA investigators observed deviations from appropriate practice standards that, if not corrected, could lead to cross-contamination of compounded drugs, potentially putting patients at risk. For example, the firm handled hazardous drug products without adequate cleaning of work surfaces and utensils.

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

In Your Atmosphere Holdings, LLC dba Highland Pharmacy Santa Fe committed to FDA in its written responses, dated February 8, 2017, and March 30, 2017, to correct the deviations in the Form FDA 483 and provided documentation in support of those corrective actions. In May 2017 the firm informed FDA that it was closing permanently, effective May 26, 2017. We confirmed with you, the New Mexico State BOP, that the state licenses are in "Retired" status and that the facility has closed.

With this knowledge and after review of the record, FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtained prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act. Therefore, FDA is referring this matter to the New Mexico State BOP for follow up, as necessary.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact CDR Matthew Dionne, Compliance Officer, at (303) 236-3064, or by email at Matthew.Dionne@fda.hhs.gov.

Sincerely,

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

SP: mrd

Cc: Misty Appling, Owner
In Your Atmosphere Holdings, LLC dba Highland Pharmacy Santa Fe
1676 Hospital Drive
Santa Fe, NM 87505-4754
Tel. 505-983-7169
Email: mappling@highlandrxsf.com