B&B Pharmacy
10244 Rosecrans Ave
Bellflower, CA 90706

October 26, 2016

Dr. Raymond W. Brullo, DPM
Compliance Officer/Doctor of Podiatric Medicine
Office of Regulatory Affairs/Los Angeles District Office
U.S. Food and Drug Administration
19701 Fairchild/Irvine, CA 92612

Re: Warning letter - Pacific Healthcare dba B&B Pharmacy - posting of 483 response

Dear Dr. Brullo,

On behalf of Pacific Healthcare dba B&B Pharmacy, I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's web site. I understand that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331, and 5 U.S.C. § 552(b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Information to be disclosed: Pacific Healthcare dba B&B Pharmacy's letter dated September 03, 2015 excluding attachments/exhibits, which responds to FDA's Form 483 dated August 18, 2015.

Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of Pacific Healthcare dba B&B Pharmacy and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Sincerely,

Hyun Joon Ro, R.Ph.
FORMER OWNER
B&B PHARMACY
10244 Rosecrans Ave
Bellflower, CA 90706
Ph) 562.866.8363
Fax) 562.925.6208

Mr. Alonza Cruse
District Director
U.S. Food and Drug Administration
19701 Fairchild Rd
Irvine, CA 92612

Dear Mr. Cruse,

My name is Hyun Joon Ro and I am the President and owner of Pacific Healthcare, Inc. On behalf of Pacific Healthcare, Inc dba B&B Pharmacy ("BBP"), I hereby authorize the United States Food and Drug Administration ("FDA") to publicly disclose the information described below on FDA's website. I agree to hold FDA harmless for any injury caused by FDA's sharing of this information with the public.

This is a response to the FDA Form 483 issued on August 18, 2015.

Introduction

B&B Pharmacy has been a successfully run and well-established business since 1957. It has been a staple of the local community as a neighborhood pharmacy as well a U.S. postal contract unit to serve our community. We have been providing sterile compounded preparations to the local community for over a decade and we have performed rigorous testing for sterility and endotoxin consistently without incident. Our products have experienced neither contamination nor potency issues, nor issues concerning assurance of sterility. During our history, we have been fully compliant with our regulatory body, the California State Board of Pharmacy. The California State Board of Pharmacy inspects sterile compounding pharmacies annually at a minimum and maintains strict standards of safety. We maintain an active retail pharmacy license as well as a separate sterile compounding pharmacy license with the Board. As they exercise licensing authority over our pharmacy, we abide by the Board's rules and regulations.

B&B Pharmacy's Response to FDA's Form 483

There were 11 observations noted in the issued Form 483 and we found that some of the observations were valid and applicable as we had not properly followed our stated policies such as:

Observation 1E: "Section 5.5.2 states to 'place the glassware inside the convection oven and heated to 170degrees Celsius for 3 hours to remove pyrogens.' According to the technician (CC), they heat the glassware to 250 degrees Celsius for for two and a half hours to sterilize it. There were no records kept by the firm while they do sterilization."

Response: In this case, although we believe the infraction to be minor as our actual degree of heat applied was much higher than our policy stated figure, we do acknowledge that we did not follow our policy and procedure. This is a case in which staff retraining as well as an update of the policy procedure was necessary.

Other observations include minor structural deficiencies such as **Observation 6b**(small portion of wood on corner exposed). These issues have already been repaired and addressed. We have also prohibited the use of the restroom noted in **Observation 11** and will be reforming into a storage area.

The remainder of the observations pertains to cGMP guidelines, a set of guidelines not applicable to the practice of pharmacy. These cGMP requirements are designed for the repeated manufacturing of single, specific products, where large pharmaceutical manufacturers can meet the time requirements. Enforcing these types of requirements on compounding pharmacies, where individualized preparations are made and dispensed on a daily or emergency basis, not only adversely affects patient care, it is unworkable for pharmacies that are asked to provide individualized medications in a timely or exigent manner. For example, we have compounded antibiotic eyedrops for patients walking in with severely infected and inflamed eyes and the application of cGMP guidelines would have made a timely dispensing of such immediate medications impossible.

cGMP's rigorous validation process makes sense for a single product made repeatedly on a manufacturing line. These validations, which, under cGMP, must be performed for every drug formulation, can take days to weeks to complete. A compounding pharmacy cannot comply with these elements of cGMP and extemporaneously compound drug products to meet the needs of patients that day. The cGMP requirements rest upon a model of repeatedly testing a relatively small number of products. That model does not fit the model of a pharmacy that compounds a variety of products, many of which are newly formulated to meet emerging needs including commercial drug shortages.

In the healthcare professions, we are often called on to make risk vs benefit decisions in various scenarios. In certain circumstances, if no other options are available or other options exhausted, while the process may not quite be up to cGMP standards, dispensing a sterility-confirmed compounded preparation for immediate use can be in the patient's benefit and the public's best interest. While I commend and understand the FDA's mission to uphold public health and safety, I would venture to say that this practice of broadly applying cGMP guidelines to all compounding pharmacies nationwide may not always be in the public's best interest.

Conflict and Confusion

Regarding the differences in enforcement standards of the FDA on 503a vs 503b, we inquired of the lead FDA inspector whether a 503a pharmacy would be inspected differently from a 503b pharmacy. We were informed that there would be no change or difference in the standards to be enforced by the FDA; the FDA applies cGMP standards universally to all pharmacies.

I am not an attorney but I find this either borderline unlawful and, at a minimum, needs further exploration. If there is no difference in enforcement standards, why is there a distinction between 503a and 503b pharmacies? Congress made that distinction for a reason and the FDA actually posts information about 503a and 503b on its website even delineating the criteria of each category.

The fact that cGMP is not applicable to 503a pharmacies is further explained on the FDA's own website:

http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm2007064.htm

"Title I of this new law, the Compounding Quality Act, removes certain provisions from section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) that were found to be unconstitutional by the U.S. Supreme Court in 2002. Section 503A describes the conditions under which certain compounded human drug products are entitled to exemptions from three sections of the FDCA requiring: Compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B)); Labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505)."

This language clearly states that 503a pharmacies are exempt from cGMP application.

Based on this, I do not understand why the FDA does not make provisions for their inspectors to inspect 503a pharmacies based on a separate, non-cGMP set of guidelines that can realistically commingle with the practice of pharmacy. Instead, the FDA sends its agents to blindly enforce a set of standards incompatible with pharmacy.

Conclusion

In any case, we have made a business decision to close down the preparation of sterile compounds at our pharmacy. This decision is not based on an unwillingness to improve our processes; we will continually do so to ensure the well-being and safety of our patients. We simply cannot justify the enormous costs required to maintain cGMP standards as we are not a large scale manufacturer of pharmaceutical goods. We abide by rules and regulations set forth by various agencies such as the Board of Pharmacy, Medicare, the Drug Enforcement Agency, California State Law as well as Federal Law (CFR) while also following certain recommendations of USP as well as other standards of good practices. It is difficult to maneuver and achieve compliance with pull from so many different bodies. However, we have successfully complied because the rules and regulations they lay out are actually what is enforced. In contrast, we object to the FDA's stance on indiscriminately applying cGMP on 503a as well as 503b pharmacies when clearly, there is a reason for the delineation. While we understand that the FDA has the public's best interest at heart, we hope that the FDA addresses the serious conflicts that still remain in its enforcement policy.

Sincerely,

HR 9/3/2015

Hyun Joon Ro, R.Ph.
President, Owner

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