
THE WELLNESS PHARMACY

Compliance Branch Director

6000 Metro Dr., Suite 101

Baltimore, MD 21215

On behalf of The Wellness Pharmacy, I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's website. 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 (b), 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: The Wellness Pharmacy's letter dated 03/16/2015 excluding attachments/exhibits which responds to FDA's Form 483 dated 03/12/2015.

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 The Wellness Pharmacy and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Sincerely,



Bruce K. Kowiatek, PharmD, MBA, BA

Pharmacist-in-Charge

The Wellness Pharmacy

2228 Papermill Rd Suite E

Winchester, VA 22601

Phone: (540) 723-6883

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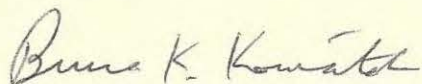
6000 Metro Suite 101

Baltimore, MD 21215

March 16, 2015

This letter serves as the submission from The Wellness Pharmacy in response to the 483 observations presented to us on March 12, 2015. As of that date, The Wellness Pharmacy has hereby agreed to cease and desist compounding sterile products altogether. Please accept this letter as authorization to post on the US FDA internet website.

Sincerely,



Bruce K. Kowiatek, PharmD, MBA, BA

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