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KENNETH WATSON *dec.*

# BUDERER DRUG CO.

COR. HANCOCK & MONROE • SANDUSKY, OHIO 44870
419-627-2800 • 800-259-6662 • FAX 419-626-0494
*26611 N. DIXIE HIGHWAY, SUITE 119 • PERRYSBURG, OH 43551
419-873-2800 • 800-318-3408 • FAX 419-873-0494
38530 CHESTER ROAD, SUITE 400 • AVON, OH 44011
440-934-3100 • 866-697-1231 • FAX 440-934-3103

*EST. 1878*

JAMES W. BUDERER, R.PH., PRESIDENT
MATTHEW J. BUDERER, R.PH., FIACP, VICE PRESIDENT

Tina M. Pawlowski, Compliance Officer
Food and Drug Administration
Division of Pharmaceutical Quality Operations III

15 March 2019

RE: FDA Disclosure of 483 Response on FDA's Web Site

Dear Dr Pawlowski,

It is my understanding that it is the policy of the United States Food and Drug Administration (FDA) to, at its discretion, electronically publish Form 483s issued to compounding pharmacies on its webpage called, "Compounding: Inspections, Recalls, and other Actions" and/or to the ORA FOIA Electronic Reading Room. I hereby request that the Agency **not** publish the 483 issued to Buderer Drug Company on this website, as any such publicity could have an unfavorable impact on our business.

If you are unable to refrain from publishing our 483 on the webpage, then on behalf of Buderer Drug Company Inc, I authorize FDA to publicly disclose the information in our Response Letter in the accompanying attachment on all pertinent web pages on www.FDA.gov. I understand that the information that is disclosed in our Response Letter may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331 U), and 5 U.S.C. § 552(b)(4) and that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any such injury caused by FDA's posting the information to the public.

Information to be disclosed: Buderer Drug Company's letter dated March 15, 2019, which responds to FDA's Form 483 issued to Buderer Drug Company at 38530 CHESTER ROAD, SUITE 400, AVON, OH 44011 (FEI Number 3011838368) on 14 February 2019.

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 Buderer Drug Company and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Respectfully yours,

Matthew J. Buderer, R.Ph., FIACP
Owner and Vice-president
Buderer Drug Company 38530 Chester Rd. Suite 400 Avon, Ohio 44011
(440) 934-3100 fascimile (440) 934-3103

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Food and Drug Administration
Division of Pharmaceutical Quality Operations III

15 March 2019

RE: Form 483 issued on 2/14/2019 to Buderer Drug Company's Avon, Ohio Pharmacy
FEI: 3011838368

Dear Dr. Pawlowski,

I am Matthew Buderer, R.Ph., FIACP, owner and Vice-president of Buderer Drug Company ("BDC"). BDC has three locations that are licensed by the State of Ohio as a terminal distributor of dangerous drugs.

This Letter is BDC's Response Letter to the single Observation in the Form 483 issued to our Avon location. (FEI Number: 3011838368).

Thank you for the opportunity to respond to the inspectional observation made during the inspection period of 7 February 2019 through 14 February 2019. I have reviewed this observation with our pharmacists and Quality Assurance Manager. Our plan of correction for the inspectional observation is found below, but first I would like to note that CSO Jazmine Still was professional, thorough, and pleasant during this inspection. Our staff and I found her to be knowledgeable and helpful in our pursuit of the quality assurance of compounded medications prepared at our 503A traditional compounding pharmacy. Her insightful suggestions will undoubtedly help us as we continuously strive to improve our performance.

***Observation 1***

Criteria: Non-pharmaceutical grade component, EVERCLEAR 95% GRAIN ALCOHOL, is used in the formulations of 19 non- sterile drug products, i.e. topical creams used to treat severe muscular pain.

Observation: "Specifically, your firm used EVERCLEAR 95% GRAIN ALCOHOL to produce approximately 200 prescriptions made in non-sterile drug production from 2012 to 2019. "

Even as the inspection was ongoing, we initiated our Quality Related Event (QRE) investigation. In summary, while the inspector was on site, we discontinued the use of Everclear 190 proof grain alcohol and removed it from the facility. Any prescriptions prepared with the Everclear and on site were quarantined and remade with Ethanol 190 proof, USP purchased from Letco. We altered our SOPs to exclude Everclear or any other food grade component used in compounding and instead, to use only USP grade alcohol and other USP grade components whenever such components are available for purchase.

The following exhibits are in support of the statement above and included as attachments to the email:

- Exhibit 1: Quality Related Event reporting form on the use of Everclear in compounding, Peer Review Process Worksheet and Plan-Do-Study-Act Worksheet.

- Exhibit 2: Employee training attestation signature sheets

- Exhibit 3: Purchase record of Ethanol 190 proof alcohol, USP and Certificate of Analysis from Letco

***Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act.***

CSO Still asked us to respond to your request for supporting information to validate compliance with the Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act. One week after her departure, the Final Rule on the list of bulk substances allowed for compounding by 503A pharmacies was published. Our response includes compliance with the new ruling.

We believe this request was due to CSO Still's finding of a formula containing Bromelain when she was investigating the use of the Everclear. These formulations were not current formulations. When the bulk list was published in July, Bromelain was identified as a substance not to be used in compounding by 503A pharmacies. Buderer Drug pharmacists contacted the physicians who used this formulation and requested their permission to discontinue use of bromelain. We removed the bromelain from inventory and archived the formulas that contained it. We have performed this same action on drugs removed from Bulk List 1.

The doctors who used the Bromelain requested that it be substituted with another mild digestive enzyme. We found that Papain carried a USP monograph and substituted that for the Bromelain. CSO Still was interested in the Papain used for this purpose. We did further investigation into the use of Papain topically and have decided to remove it from inventory and let physicians know that we will no longer be using Papain in compounded preparations.

We are pleased to provide you with following exhibits of our policy on the use of Bulk Drug substances, which are included in this email as attachments.

- Exhibit 4: SOP 6.030: 503A FDA Bulk Substance List, with revisions
- Exhibit 5: Employee training attestation signature sheets

***Final Comments***

Buderer Drug Company is committed to continuously improve the quality of the compounded prescriptions we dispense to patients. We appreciate the inspectional observations as a way to develop methods to improve our quality. Please do not hesitate to contact me should you have any further questions or concerns.

Best regards,

Matthew J. Buderer, R.Ph., FIACP
Vice president

cc: Katie Stabi, PharmD, R.Ph., Compliance Specialist, State of Ohio Board of Pharmacy