

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations.

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Cincinnati District Office 6751 Steger Drive Cincinnati, OH 45237-3097 (513)679-2700 Fax:(513)679-2772 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 02/07/2019-02/14/2019*
	FEI NUMBER 3011838368

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Matthew J. Buderer, Owner and Pharmacist

FIRM NAME Buderer Drug Company	STREET ADDRESS 38530 Chester Road, Suite 400
CITY, STATE AND ZIP CODE Avon, Ohio 44011	TYPE OF ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1

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.

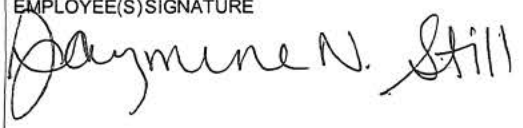
Specifically, your firm used EVERCLEAR 95% GRAIN ALCOHOL to produce approximately 200 prescriptions made in non-sterile drug production from 2012 to 2019.

For example:

- A. Ketoprofen 5% Gel was prepared using EVERCLEAR 95% GRAIN ALCOHOL for a total of (b)(4) times from 2012 to 2019.
- B. (b)(4) base, (b)(4), is used as a component in over (b)(4) different non-sterile drug formulas. Your firm prepared (b)(4) using EVERCLEAR 95% GRAIN ALCOHOL in (b)(4) prescriptions from 2012 to 2019.
- C. From 2013 to 2019, your firm formulated (b)(4) prescriptions of a cream, Ultracaine-Benzocaine 20%, Lidocaine 8%, Tetracaine 4%, Ibuprofen 2%, Bupivacaine 0.5%, that used EVERCLEAR 95% GRAIN ALCOHOL.

There is no evidence that EVERCLEAR 95% GRAIN ALCOHOL used to produce creams and liquid non-sterile drug products is of an appropriate quality for its intended use.

*Dates of the Inspection: 02/07/2019, 02/11/2019, 02/12/2019, and 02/14/2019

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Jazmine N. Still, Consumer Safety Officer	DATE ISSUED 02/14/2019
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