

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT ADDRESS AND PHONE NUMBER 404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	DATE(S) OF INSPECTION 6/14/2016-6/30/2016* FEI NUMBER 1051570
--	--

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mark F. Binkley , Owner

FIRM NAME Health & Wellness Compounding Pharmacy	STREET ADDRESS 329 21st Ave N, Suite 3
CITY, STATE, ZIP CODE, COUNTRY Nashville, TN 37203-1839	TYPE ESTABLISHMENT INSPECTED Producer of Sterile Drugs

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 WE OBSERVED:

OBSERVATION 1

Drug product containers were not sterilized and processed to remove pyrogenic properties to assure that they are suitable for their intended use.

Specifically,

Your firm does not depyrogenate glassware used for mixing drug products intending to be sterile.

***DATES OF INSPECTION**

6/14/2016(Tue),6/15/2016(Wed),6/16/2016(Thu),6/20/2016(Mon),6/21/2016(Tue),6/29/2016(Wed),6/30/2016(Thu)

6/30/2016

Meocha V Whaley

Meocha V Whaley
Investigator
Signed by: Meocha V. Whaley -S

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Zada L Giles, Investigator Meocha V Whaley, Investigator	DATE ISSUED 6/30/2016 6/30/2016
	<input checked="" type="checkbox"/> Zada L Giles Zada L Giles Investigator Signed by: Zada L. Giles -S	