DEPARTMENT OF HEALTH AND HUMAN SERVICES  
FOOD AND DRUG ADMINISTRATION  

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  

DATE(S) OF INSPECTION  
6/14/2016-6/30/2016*  

FEINUMBER  
1051570  

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  

X Meocha V Whaley  
Meocha V Whaley  
Investigator  
Signed by: Meocha V. Whaley -5  

SEE REVERSE OF THIS PAGE  
Zada L Giles, Investigator  
Meocha V Whaley, Investigator  

DATE ISSUED  
6/30/2016  

EMPLOYEE(S) SIGNATURE  
Zada L Giles  
Meocha V Whaley  

FORM FDA 483 (09/08)  
PREVIOUS EDITION OBSOLETE  
INSPECTIONAL OBSERVATIONS  
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