

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 6751 Steger Drive Cincinnati, OH 45237-3097 512-679-2700 Fax: 513-697-2772 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 09/09,10,12,13,16,17,18,23,27&30/2019
	FEI NUMBER 3015242029

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Robert J. Hirsh, President

FIRM NAME SBH Medical LTD.	STREET ADDRESS 655 Dearborn Park Lane
CITY, STATE AND ZIP CODE Worthington OH 43085	TYPE OF ESTABLISHMENT INSPECTED Producer of Sterile and non-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 (I) (WE) OBSERVED:

Observation 1

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically,

You do not have media fill for (b) (4), representing the most manipulative conditions in your firm.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Ucheabuchi C. Chudi-nwankwor -S Andrew J. Barrowcliff -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) Ucheabuchi C. Chudi-Nwankwor Investigator Andrew J. Barrowcliff Investigator	DATE ISSUED 09/30/2019
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