DEPARTMENT OF HEALTH AND HUMAN SERVICES

DATE(S) OF INSPECTION

FEI NUMBER

3015242029

09/09.10.12.13.16.17.18.23.27&30/2019

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

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO. Robert J. Hirsh, President

2.611	
FIRM NAME	STREET ADDRESS
SBH Medical LTD.	655 Dearborn Park Lane
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Worthington OH 43085	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. Chudinwankwor -S

Andrew J. Barrowcliff -S

Digitally signed by Uchnebuchi C Chadt mentioner 5
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EMPLOYEE(S) NAME AND TITLE (Print or Type)

Ucheabuchi C. Chudi-Nwankwor Investigator

Andrew J. Barroweliff Investigator

DATE ISSUED

09/30/2019