



U.S. Food and Drug Administration  
Division of Pharmaceutical Quality Operations III  
300 River Place, Suite 5900  
Detroit, MI 48207  
Telephone: (313) 393-8100  
Fax: (313) 393-8139  
[www.fda.gov](http://www.fda.gov)

June 16, 2020

**UPS NEXT DAY**  
**SIGNATURE REQUIRED**

Robert J. Hirsh, President  
SBH Medical LTD  
655 Dearborn Park Lane  
Worthington, OH 43085

Dear Mr. Hirsh:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, SBH Medical LTD, located at 655 Dearborn Park Lane, Worthington, OH 43085, from September 9, 2019, to September 30, 2019, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the State of Ohio Board of Pharmacy for follow up.

When the Agency considers an inspection to be “closed” under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact Eric Mueller at (402) 331-8536 or by email at: [ORAPHARM3\\_RESPONSES@fda.hhs.gov](mailto:ORAPHARM3_RESPONSES@fda.hhs.gov).

Sincerely,

Nicholas F.  
Lyons -S

Digitally signed by Nicholas F. Lyons -S  
DN: c=US, o=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
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3, cn=Nicholas F. Lyons -S  
Date: 2020.06.16 10:22:08 -05'00'

Nicholas F. Lyons,  
Director Compliance Branch  
Division of Pharmaceutical Quality Operations III

Enclosure: Redacted 1<sup>st</sup> party EIR, State Referral Letter

CC: FMD-145 Cover Letter Only  
Steven W. Schierholt  
Executive Director  
Ohio State Board of Pharmacy  
77 S High Street, 17<sup>th</sup> Floor  
Columbus, OH 43215-6126