



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Pharmaceutical Quality  
Office of Surveillance  
Division of Quality Surveillance Assessment  
10903 New Hampshire Avenue  
Building 51, Room 4316  
Silver Spring, MD 20993  
TELEPHONE: (301) 796-3254  
FAX: (301) 847-8742

11/04/2016

Mr. Michael Cheng  
Wuhan Biocause Pharmaceutical Development Co., Ltd.  
4th Floor, Zhuankou Economic Development  
Hi-Tech Industrial Park  
Wuhan, Hubei , CN

Reference: Inspection Date(s): 07/18/2016 - 07/22/2016

Location: Wuhan Biocause Pharmaceutical Development Co., Ltd.  
Hi-Tech Industrial Park, Building #1  
4th Floor, Zhuankou Economic Development  
Wuhan, 430056 , CN

Dear Mr. Michael Cheng

We are enclosing a copy of the establishment inspection report (EIR) for the inspection that the U.S. Food and Drug Administration (FDA) conducted at your premises on the referenced locale and date(s). When the Agency concludes that an inspection is "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment. This procedure is applicable to EIRs for inspections completed on or after April 1, 1997.

The Agency continually works to make its regulatory process and activities more transparent to the 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 CFR Part 20. This, however, does not preclude you from requesting additional information under FOIA.

If there is any question about the released information, feel free to contact me at the above address or number

For more information on the U.S. FDA, please visit our website at [www.fda.gov](http://www.fda.gov).

Sincerely,

Luis A.  
Carrion -A

Digitally signed by Luis A. Carrion  
-A  
DN: c=US, o=U.S. Government,  
ou=HHS, ou=FDA, ou=People,  
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Date: 2016.11.04 08:55:05 -04'00'

FEI: 3004202226

Enclosure: Establishment Inspection Report (EIR)