U.S. Food and Drug Administration
10 Waterview Boulevard, 3rd floor
Parsippany, NJ 07054
www.fda.gov

Via UPS
Return Receipt Requested

May 15, 2018

Mr. Jingming Wang,
General Manager
Hangzhou Huadong Medicine Group Zhejiang Huayi Pharmaceutical Co., Ltd.
NO. 15 Shuangfeng Rd., Fotang
Yiwu, Zhejiang, 322002, China

Dear Mr. Jingming Wang,

The U.S. Food and Drug Administration (FDA) conducted an inspection at Hangzhou Huadong Medicine Group Zhejiang Huayi Pharmaceutical Co., Ltd., 3003657871, located at NO. 15 Shuangfeng Rd., Fotang
Fotang, Yiwu, Zhejiang, China from 3/12/2018-3/16/2018. FDA has determined that the inspection classification of this facility is "voluntary action indicated" ("VAI").[1]

A VAI inspection classification indicates that, although investigators found and documented objectionable conditions during the inspection, FDA will not take or recommend regulatory or enforcement action because the objectionable conditions do not meet the threshold for action at this time. Despite this facility inspection classification, FDA recommends that you address any observations noted on the Form FDA 483 issued at the the conclusion of the inspection or otherwise conveyed to you following the inspection. If not corrected, the same or similar conditions could lead to a future inspection being classified as "official action indicated" ("OAI").

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to ensure continued compliance with CGMP.

An inspection classification of VAI for CGMP compliance will not directly negatively impact FDA's assessment of any pending marketing application referencing this facility. Please note, however, that application approval will depend on a product- and application-specific facility assessment conducted by CDER's Office of Pharmaceutical Quality. This letter does not address or reflect FDA's decision making with respect to any potential non-CGMP compliance issues.

FDA has concluded that this inspection is "closed" under 21 CFR 20.64(d)(3), and we are enclosing a copy of the narrative portion of the Establishment Inspection Report (EIR). It may reflect redactions made by FDA 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 you have any questions regarding this letter, you may contact Stephen Mottola via telephone at (732) 390-3805 or email at Stephen.Mottola@fda.hhs.gov

Sincerely,

Stephen Mottola
Supervisory Consumer Safety Officer
Pharmaceutical Division 1
629 Cranbury Road
East Brunswick, New Jersey 08816

[1] See Inspection Classification Definitions, at https://www.fda.gov/ICECI/Inspections/ucm223231.htm.