CLOSEOUT LETTER

Zhejiang Huahai Pharmaceutical

MARCS-CMS 566685 — NOVEMBER 04, 2021

Product:

Drugs

Recipient:

Mr. Baohua Chen

Chairman and President

Zhejiang Huahai Pharmaceutical

Xunqiao Xin Street
Linhai Shi Taizhou Shi Zhejiang Sheng, 317024
China

Issuing Office:

Center for Drug Evaluation and Research | CDER

United States

Dear Mr. Chen:

The Food and Drug Administration (FDA) has completed an evaluation of your firm's corrective actions in response to our Warning Letter 320-19-04 dated November 29, 2018.

Based on our evaluation, it appears that you have addressed the deviations contained in this Warning Letter. Future FDA inspections and regulatory activities will further assess the adequacy and sustainability of these corrections.

This letter does not relieve you or your firm from the responsibility of taking all necessary steps to assure sustained compliance with the Federal Food, Drug, and Cosmetic Act and its implementing regulations or with other relevant legal authority.

The FDA expects you and your firm to maintain compliance and will continue to monitor your state of compliance. This letter will not preclude any future regulatory action should deviations be observed during a subsequent inspection or through other means.

Sincerely,
/S/
Rory K. Geyer
Compliance Officer
Division of Drug Quality II
Office of Manufacturing Quality
Office of Compliance
Center for Drug Evaluation and Research FDA

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