# Huron Pharmaceuticals, Inc. 4/20/17

Detroit District
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Detroit, MI 48207
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**WARNING LETTER**
**2017-DET-04**

**April 20, 2017**
**VIA UPS**

Hassan A. Ghoul, President
Huron Pharmaceuticals, Inc.
24071 Research Drive
Farmington Hills, MI 48335

Dear Mr. Ghoul:

The U.S. Food and Drug Administration (FDA) inspected your drug manufacturing facility, Huron Pharmaceuticals, Inc., at 24071 Research Drive Farmington Hills, Michigan, from December 13 to 22, 2016.

This warning letter summarizes significant deviations from current good manufacturing practice (CGMP) for active pharmaceutical ingredients (API).

Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your API are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B).

We reviewed your January 20, 2017, response in detail. Your response was inadequate. Although you committed to address deficiencies regarding quality systems and cleaning validation, your overall response lacked details. You also did not perform a retrospective review of the impact of CGMP deficiencies on the quality of distributed products.

During our inspection, our investigators observed specific deviations including, but not limited to, the following.

**1. Failure to transfer all quality or regulatory information received from the API manufacturer to your customers.**

You repeatedly omitted the name and address of the original API manufacturer on the certificates of analysis (COA) you issued to your customers and did not include a copy of the original batch certificate. Additionally, your firm did not conduct a secondary review of COA you generated to ensure the information presented to your customers was accurate.

Regulators and customers rely on the COA to provide accurate information about the quality and sourcing of drugs and their components. Omitting information on a COA compromises supply chain accountability and traceability, and may put consumers at risk.

**2. Failure to establish, document, and implement an effective system for managing quality.**

Your firm had no written procedures for supplier qualification, relabeling and repackaging operations, sampling, product release, stability, and document retention. You failed to maintain master production batch records for any of the API you repackaged and distributed. Additionally, you released API for distribution before you received and reviewed records from your drug testing lab.

**3. Failure to have adequate cleaning procedures to prevent contamination or carry-over of a material that would alter the quality of the API.**

Your firm uses shared equipment for the API you manufacture. The Repacking Procedure in your Standard Operating Procedures Manual includes brief instructions on cleaning surfaces in the repacking room and scoopers used to handle API. You have not performed any validation tests to determine whether your cleaning procedure is able to remove drug residues to prevent cross-contamination.

**CGMP consultant recommended**

Based upon the nature of the deviations we identified at your firm, we strongly recommend engaging a consultant qualified to evaluate your operations and assist your firm in meeting CGMP requirements. Your use of a consultant does not relieve your obligation to comply with CGMP. Your firm's executive management remains responsible for fully resolving all deficiencies and ensuring ongoing CGMP compliance.

**Additional API CGMP guidance**

FDA considers the expectations outlined in ICH Q7 in determining whether API are manufactured in conformance with CGMP. See FDA's guidance document, *Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients*, for guidance regarding CGMP for the manufacture of API, at **http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryinformation/Guidances/UCM073497.pdf (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryinformation/Guidances/UCM073497.pdf**

**Conclusion**

Deviations cited in this letter are not intended as an all-inclusive list. You are responsible for investigating these deviations, for determining the causes, for preventing their recurrence, and for preventing other deviations.

Correct the deviations cited in this letter promptly. Failure to promptly correct these deviations may result in legal action without further notice including, without limitation, seizure and injunction. Unresolved deviations in this warning letter may also prevent other Federal agencies from awarding contracts.

Until these deviations are corrected, we may withhold approval of pending drug applications listing your facility. We may re-inspect to verify that you have completed your corrective actions. We may also refuse your requests for export certificates.

After you receive this letter, respond to this office in writing within 15 working days. Specify what you have done since our inspection to correct your deviations and to prevent their recurrence. If you cannot complete corrective actions within 15 working days, state your reasons for delay and your schedule for completion.

Please address all correspondence to Tina M. Pawlowski, Compliance Officer, at the address above. If you have questions regarding the contents of this letter, please contact Compliance Officer Pawlowski at (313) 393-8217.

Sincerely,
/S/
Art O. Czabaniuk
District Director
Detroit District Office

**More in 2017 (/ICECI/EnforcementActions/WarningLetters/2017/default.htm)**