U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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July 31, 2019

(b) (6)
(b) (4)

Dear (b) (6) :

The U.S. Food and Drug Administration (FDA) conducted an inspection at (b) (4) FDA has determined that the inspection classification of this facility is "no action indicated ("NAI").[1] Based on this inspection, this facility is considered to be in an acceptable state of compliance with regards to current good manufacturing practice (CGMP).

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 NAI 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.

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

If you have any questions regarding this letter, you may contact Margaret M. Sands, Supervisory Consumer Safety Officer via telephone at (781) 587-7483 or email at Margaret.Sands@fda.hhs.gov.

Sincerely,

Margaret
M. Sands -S

Margaret M. Sands
Supervisory Consumer Safety Officer
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Enclosure 1