**DEPARTMENT OF HEALTH & HUMAN SERVICES**
Public Health Service
Food and Drug Administration
CENTER FOR DRUG EVALUATION AND RESEARCH

Office of Manufacturing and Product Quality
Division International Drug Quality
International Compliance Branch
10903 New Hampshire Avenue
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March 5, 2015

Mr. Ante Rasack, C.E.O.
Gfm Gesellschaft fur Micronisierung mbH
Lesumer Heerstrasse 30
Bremen, 28717
Germany

Reference: FEI 3003973558

Dear Mr. Rasack,

We have completed our review of the Establishment Inspection Report (EIR) for the inspection conducted at your active pharmaceutical ingredient manufacture ring and excipient micronizing facility in Bremen, Germany by Investigators Nebil A. Oumer and Junho Pak during the period of November 13 to November 14, 2014. A Form FDA-483, Inspectional Observations was issued at the conclusion of the inspection.

We have also reviewed your company's response dated December 1, 2014. Based on the profile classes covered during the inspection, we are classifying your facility as acceptable. The proposed commitments and corrective actions described in your response will be evaluated during the next FDA inspection. In addition, we highly recommend the following items, which were verbally discussed with you during the inspection:

- Your firm refer to USP growth promotion testing to ensure your purchased environmental monitoring (EM) media plates will support growth (Establishment Inspection Report general discussion item#3); and
- Your firm's EM plate incubation times should meet the minimum incubation requirements of 72 hours at 30-35 °C and 48 hours at 20-25 °C (Establishment Inspection Report general discussion item #4).

This letter is not intended as an endorsement or certification of the facility. It remains your responsibility to assure continued compliance with current good manufacturing practices (CGMP).

Please be advised that all manufacturers must register annually as required by 21 C.F.R. § 207.40. Information on how to register is available at http://www.fda.gov/cder/drls/registration_listing.htm.

Additionally, we enclose a copy of the establishment inspection report (EIR). Releasing this EIR to you is part of FDA's effort to make its regulatory process and activities more transparent to the regulated industry. It is being provided to you for information purposes only and may reflect some redactions made by the Agency in accordance with the Freedom of Information Act and 21 C.F.R. Part 20. Copies provided to other requestors may have additional redactions of trade secret and confidential commercial information.

If you have any questions regarding this letter, you may contact me at the above address or number.

Sincerely,

Xiaohui Shen
Compliance Officer
B-3/DIA/OPF/OPQ
on behalf of
Global Compliance Branch 1
Division of Drug Quality I
Office of Manufacturing Quality

Enclosure: EIR