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In reply please refer to: APIMF448-0/AF/MS/EG

Mr. Komarely Udata  
MSN Life Sciences Private Limited  
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Chandampet (Village)  
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28 June 2024

Dear Mr. Udata,

**World Health Organization Prequalification Unit – Medicines  
API Master File Procedure - Letter of Acceptance**

**Application number: APIMF448-0**

**Related APIMF dossier: APIMF448**

Thank you for your company's APIMF application for Bedaquiline fumarate to the WHO Prequalification Unit.

A team of evaluators recently completed the assessment of your APIMF. As a result of this assessment, you are informed that the present APIMF information for Bedaquiline fumarate is acceptable.

The API starting material accepted as a result of this assessment are:

- 3-phenylpropanoic acid
- 4-Bromoaniline
- 1-Acetyl naphthalene

Please note that the API starting material represents the point in the preparation of the API where GMP should be applied and detailed in your APIMF. Similarly, this also represents the point where changes to preparation or control of the API should be notified to the WHO including changes to the suppliers of the API starting material.

Please note that the outcome of the assessment of this APIMF is an important step towards the final acceptability of the quality part of any product dossier submitted to the WHO Prequalification Unit.

ENCL: (1)

**Information/notification/commitment noted**

- a. At present, blending is not conducted. The Applicant commits to inform the Agency if blending will be performed.
- b. Recovery of solvents and materials does not occur.
- c. The applicant committed to update and to provide all the data / documents related to recovery of solvents & materials to the Agency provided they are developed and employed in future.
- d. The applicant committed to analyze N-nitroso desmethyl bedaquine impurity for the on-going stability batches at the end of the retest period of the API.

Your cooperation is appreciated.

Yours sincerely,



Dr Matthias Stahl  
Team Lead  
Prequalification Unit - Medicines Assessment Team  
Regulation and Prequalification Department