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In reply please
refer to: P5-447-3/DC/EB/2

Dr Kamal Vashi
Mangalam Drugs and Organics Ltd, Unit 1
Plot No 187, 2nd Phase GIDC, Vapi
Gujarat, 396 195
Inde

Your reference:

5 February 2019

Dear Dr Vashi,

**WHO Prequalification Team – Inspection Services
Closing of Inspection**

I refer to the inspection that was performed by Dr Catsoulacos and Dr Slade the details of which are outlined below:

Name: Mangalam Drugs and Organics Ltd, Unit 1
Address: Plot No 187, 2nd Phase GIDC, Vapi Gujarat, 396 195, India
Date: 1-4 May 2018

Thank you for your correspondence dated 5 October and 23 July 2018 and the corrective actions to the observations listed in the inspection report. The actions taken, or proposed to be taken, to correct the deficiencies have been reviewed by the inspectors.

In general, they are considered acceptable and their satisfactory implementation will be verified during future inspections. On the basis of the findings of the inspection and these subsequent responses the inspectors have recommended that the APIs:

- APIMF 100 Lumefantrine
- APIMF 138 Artemether
- APIMF 134 Amodiaquine Hydrochloride
- APIMF 135 Artesunate
- APIMF 149 Piperaquine Phosphate
- APIMF 151 Dihydroartemisinin
- APIMF 204 Tenofovir Disoproxil Fumarate
- APIMF-2018-0028 Primaquine phosphate

are considered to be compliant with the standards of Good Manufacturing Practices (GMP) for APIs published by the World Health Organization (WHO), for the scope of activities listed below:

- Manufacture and packaging of APIs.
- Analytical and microbiological testing of raw materials and associated intermediates and API.

Furthermore, the inspection findings and your response allow us to recommend to the Prequalification Assessment Group that the site inspected may be named to be named as API manufacturing site in dossiers assessed within the WHO Prequalification Team.

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Please note that acceptance of compliance with WHO GMP does not necessarily mean that the API product has been prequalified by WHO. You will be notified of the outcome of the assessment of your prequalification application in due course.

Please do not hesitate to send an email to prequalinspection@who.int should you require any further information regarding the closing of this inspection.

Yours sincerely,



for
Dr Joey Gouws
Group Lead, Inspection Services
Prequalification Team
Regulation of Medicines and other Health Technologies