World Health Organization

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In reply please refer to: VAR-2020-0356/HY/MS/FV

Your reference:

Mr JagdishKumar Dobaria
DGM - Regulatory Affairs
Hetero Labs Ltd
7-2-A-2 Hetero Corporate Industrial Estates
Sanathnagar
Hyderabad 500 012
Telangana
Inde

6 January 2021

Dear Mr Dobaria,

WHO Prequalification Unit – Medicines Assessment Team
Variation application Acceptance Letter

Variation application number: VAR-2020-0356

Related FPP dossier: TB299

Variation category: Vmin

Thank you for submitting the data for the assessment of the variation to your prequalified product dossier for the WHO Prequalification Unit – Medicines, the receipt of which was acknowledged on 26 November 2020 and assigned the respective WHO Variation reference number: VAR-2020-0356.

A team of evaluators recently assessed the data submitted for:

- **TB299**: Linezolid Tablets, Film-coated 600mg

Nature of variation: #47b- Change in the shelf life of the FPP (as packaged for sale) involving- Extension in shelf life from 36 months to 48 months for 10 x 10's Alu/Alu blister pack

As a result of this assessment, you are informed that the variation submitted is considered acceptable. However, please you are requested to revise sections 2.3.P.8.2 (a), (b) and (c) of the QIS, under testing intervals to Initial, 3rd, 6th, 9th, 12th, 18th, 24th, 36th & 48th months for long term stability testing. The revised QIS can be submitted along future variation applications.

For further communication regarding the variations to your prequalified product dossier please use the email address – **prequalvariation@who.int** – ensuring that any such email mentions the corresponding WHO product reference number.

Your cooperation is appreciated.

Yours sincerely,

Digitally signed by Chirtoacă Iurie
Date: 2021.11.30 15:37:43 EET
Reason: MoldSign Signature
Location: Moldova

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