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In reply please refer to: CPH64/MS/HA526E

Your reference:

Mr Rakesh Chaurasia  
General Manager – Drug Regulatory Affairs  
Macleods Pharmaceutical Limited  
304 Atlanta Arcade  
Marol-Church Road  
Andheri (East)  
Mumbai 400 059  
Inde

6 December 2011

Dear Mr Chaurasia,

**WHO Prequalification of Medicines Programme  
Efficacy/safety part of a product dossier**

Thank you for submitting the data and information requested for the assessment of the product dossier within the WHO Prequalification of Medicines Programme.

A team of evaluators recently assessed the dossier

**HA526 Zidovudine 10mg/ml oral solution**

As a result of this assessment, you are kindly informed that the efficacy/safety part of the dossier is considered acceptable. Please note, that the outcome of the assessment of quality part of the dossier may affect the final acceptability of the efficacy/safety part of the dossier.

Your cooperation is appreciated.

Yours sincerely,

  
Dr Matthias Stahl  
Head of Assessments  
Prequalification of Medicines Programme  
Quality Assurance and Safety: Medicines