



Tel. direct: +41 22 791 37.17
Fax direct: +41 22 791 47.30
E-mail : stahlm@who.int

In reply please
refer to: CPH28/MS/AL

Your reference:

Mr. Rakesh Chaurasia
Deputy General Manager
Drug Regulatory Affairs
MacLeods Pharmaceuticals Limited
Atlanta Arcade, 3rd Floor,
Church Road, Near Leela Hotel,
Andheri-Kurla Road,
Andheri (East) Mumbai - 400 059
Inde

19 December 2005

Dear Mr Chaurasia,

**Procurement, Quality and Sourcing Project:
Access to Antimalarial, Antituberculosis and HIV/AIDS Drugs and
HIV/AIDS Diagnostics of Acceptable Quality**

Product Reference Number: **TB154** *Cycloserin 250mg Capsules*

This letter is for the **Efficacy/Safety** part of the above-mentioned dossier only.

Thank you for submitting the data and information requested for the assessment of the product dossier within the above-mentioned project of United Nations agencies. A team of evaluators recently assessed the dossier you submitted.

As a result of this assessment, you are informed that the Efficacy and Safety part of the above-mentioned product dossier TB154, is considered acceptable for prequalification.

Please ensure that all correspondence reflects the appropriate product reference number.

For further information, please contact Dr M. Stahl (stahlm@who.int),
Dr O. Gross (grosso@who.int) or Miss L. Oakes (oakesl@who.int).

Your cooperation is appreciated.

Yours sincerely,

Dr Matthias Stahl
Quality Assurance and Safety: Medicines
Department of Medicines Policy and Standards