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In reply please
refer to: CPH30/MS/AL

Your reference:

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

12 April 2006

Dear Dr Chaurasia,

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

Product Reference Number: **TB168** *Rifampicin/Isoniazid/Pyrazinamide/Ethambutol*
150mg/75mg/400mg/275mg Tablets

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 programme of United Nations agencies. A team of evaluators recently assessed the dossier you submitted.

As a result of this assessment, we would like to inform you that the Efficacy and Safety part of this dossier is accepted. However, the identity regarding composition of the biobatch and commercial batches must be checked and verified by the quality reviewer. This will be done at the time of the Quality Assessment.

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