

1 June 2004

The Chairman
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Dear Sir

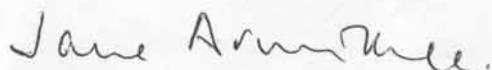
**MREC 03/8/087 – ASCEND: A Study of Cardiovascular Events in Diabetes
Notification of Protocol amendment and final questionnaires**

Please find enclosed a completed Notification of Amendment Form for ASCEND. The requested amendment is to allow a urine sample (in addition to a blood sample) to be collected during the pre-randomisation Run-in period, and at least once during follow-up in a random sample of participants.

Minor textual changes to the Protocol have been made to accommodate this amendment, some other textual clarifications have also been made. All changes are underlined and listed on the attached sheet. Changes needed to be made to Attachments B17-1, B17-2, B17-3 and B18-2.

As requested in the approval letter (29 December 2003), copies of the final version of the questionnaires (B15-2, B22-1 and B22-2) are also attached. Changes from the previous versions are highlighted.

Yours sincerely



Dr Jane Armitage

Enc: Annex 2: Notification of Amendment Form
Summary of Amendment
List of Attachments
Attachments 1 – 8 (including Protocol [V7_190504])