ALPHAPHARM
PHARMACEUTICALS

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SB:3049/sjb

19 January 1998

Director
Drug Safety and Evaluation Branch
Therapeutic Goods Administration
P O Box 100
Woden ACT 2606

Dear Sir/Madam,

Re: Product information and marketing date for isosorbide mononitrate 60 mg sustained release tablets ("Duride")
File no. 96/31307, AN 97/016/3

Reference is made to your letter dated 15 October 1997 approving our application for registration of the above product. Alphapharm wishes to advise that we will begin marketing ***Duride*** on 1 February 1998, and that this product will also be listed as a pharmaceutical benefit item on that date.

Enclosed are two copies of the approved product information, annotated with a statement that it has been approved by the Therapeutic Goods Administration on the date of the approval letter.

Yours sincerely,
Alphapharm Pty Limited

Sonia J. Bennett B.Sc.(Hons)
Senior Regulatory Affairs Associate

Encl:

COMPUTER UPDATED
Date: 6-2-98
App. No. 97.016.3
WTAID: AS

Original copy - Admin 96/31308
Clin 96/31307

Anne
- Please wait – ring company on 2nd February '98 & confirm that supply date was as stated above.
- Then addon as per SOP's
- Update chart for both < supply dates PI.
- Action PI as per SOPs

TS02B
AUGUST 97