European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom
Attn.: Dr. Daniel Brasseur, CHMP Chairman

12 October 2006

NovoNorm®/Prandin® (repaglinide) 0.5 mg, 1 mg, 2 mg tablets.
Withdrawal of EMEA/H/C/0187/II-65 and EMEA/H/C/0362/II-40

Dear Dr. Daniel Brasseur,

I would like to inform you that, at this point of time, Novo Nordisk A/S has taken the decision to withdraw the application for an extension of the indication to include the use of repaglinide in combination with thiazolidinediones (TZD).

This withdrawal is based on the following reason:
The CHMP considers that the data provided do not allow the committee to conclude on a positive benefit risk balance of the concomitant use of repaglinide and TZD.

We reserve the right to make further submissions at a future date in this or other therapeutic indications.

I agree for this letter to be published on the EMEA website.

Yours sincerely,

Associate Product Manager, NovoNorm/Prandin
RAMP, Solid Dosage Forms

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