FOURNIER PHARMA

Date: 07 December 2006

Dr Daniel Brasseur
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of Synordia®, (fenofibrate/metformin fixed combination), 54mg/850 mg, 80 mg/500 mg, 80 mg/850 mg , film-coated tablets
EMEA/H/C/000768

Dear Dr. Brasseur,

I would like to inform you that, at this point of time, Fournier Laboratories Ireland acting as applicant, has taken the decision to withdraw the application for Marketing Authorisation of Synordia®, (fenofibrate/metformin fixed combination), 54mg/850 mg, 80 mg/500 mg, 80 mg/850 mg, film-coated tablets.

The proposed indication for Synordia as submitted in the Marketing Authorisation Application was as an adjunct to diet and exercise to improve glycaemic control and dyslipidemia in patients with type 2 diabetes mellitus who require both drugs and have already been stabilised on each drug.

This withdrawal is based on the request for additional information that can not be responded within the timeframe allowed under the Centralised Procedure.

We reserve the right to make further submission at a future date in this or other therapeutic indication(s).

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

Yours sincerely,

FOURNIER LABORATORIES IRELAND, LTD.
A member of the Sulvay Group

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