European Medicines Agency
Press office

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PRESS RELEASE
Fournier Laboratories withdraws its marketing authorisation application for Synordia

The European Medicines Agency (EMEA) has been formally notified by Fournier Laboratories Ireland Ltd of their decision to withdraw its application for a centralised marketing authorisation for the medicinal product Synordia (fenofibrate/metformin hydrochloride).

Synordia was expected to be used as an adjunct to changes to diet and exercise to improve glycaemic control and dyslipidaemia in patients with type 2 diabetes mellitus. It was intended for use in patients who require both fenofibrate and metformin and have already been stabilised on each drug.

The application for marketing authorisation for Synordia was submitted to the EMEA on 17 July 2006. At the time of the withdrawal, it was under review by the Agency's Committee for Medicinal Products for Human Use (CHMP).

In its official letter, the company stated that the withdrawal of Synordia was due to the fact that it is not able to respond to the request for additional information within the allowed timeframe.

More information about Synordia and the current state of the scientific assessment at the time of withdrawal will be made available in a question and answer document. This document, together with the withdrawal letter from the company, will be published on the EMEA website after the next meeting of the CHMP on 11-14 December 2006.

--ENDS--

NOTES

1. Withdrawal of an application does not prejudice the possibility of a company making a new application at a later stage.
2. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.europa.eu

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