European Medicines Agency
Press office

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PRESS RELEASE
Pharm Research Associates (UK) Ltd withdraws marketing authorisation application for Surfaxin

The European Medicines Agency has been formally notified by Pharm Research Associates (UK) Limited of their decision to withdraw the application for a centralised marketing authorisation for the medicinal product Surfaxin.

Surfaxin is a designated orphan medicinal product. The indication applied for was prevention and treatment of respiratory distress syndrome in premature babies.

The application for marketing authorisation for Surfaxin was submitted to the EMEA on 18 October 2004. 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 withdrawal letter, the company stated that the withdrawal of Surfaxin was due to manufacturing and clinical issues.

More information about Surfaxin 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 26-29 June 2006.

--ENDS--

NOTES

1. The active substances of Surfaxin are sinapultide, dipalmitoylphosphatidylcholine, palmitoyl-oleoyl phosphatidylglycerol and palmitic acid.
2. The legal basis for the publication of this withdrawal is Regulation (EC) No 726/2004, Articles 11 and 80.
3. Withdrawal of an application does not prejudice the possibility of a company to make a new application at a later stage.
4. This press release, together with other information about the work of the EMEA, may be found on the EMEA website: http://www.emea.eu.int

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