European Medicines Agency
Press office

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Press release
Alcon Laboratories (UK) Ltd withdraws its application to extend the marketing authorisation for Opatanol

The European Medicines Agency has been formally notified by Alcon Laboratories (UK) Ltd of its decision to withdraw its application for an extension of the marketing authorisation for the medicinal product Opatanol (Olopatadine hydrochloride).

Opatanol was first authorised in the European Union on 17 May 2002 as eye drops for the treatment of ocular signs and symptoms of seasonal allergic conjunctivitis. On 25 April 2005, Alcon Laboratories (UK) Ltd submitted an application for the extension of the marketing authorisation to add a new pharmaceutical form: a nasal spray intended for a new use in the treatment of the symptoms of seasonal and perennial allergic rhinitis.

The company's decision to withdraw the application was based on commercial reasons.
Information on the state of discussions at the level of the CHMP at the time of withdrawal are given in a question-and-answer document.

--ENDS--

NOTES

1. The legal basis for the publication of this withdrawal are Articles 11 and 80 of Regulation (EC) No 726/2004.
2. Withdrawal of an application does not prejudice the possibility of a company to make a new application at a later stage.
3. A question and answer document has been published and can be found here.
4. The withdrawal letter of the company has been published and can be found here.
3. 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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