Please reply to:

Senior Director, EC Registration Authorised Representative (MDD)



ALCON LABORATORIES (U.K.) LIMITED, PENTAGON PARK, BOUNDARY WAY, HEMEL HEMPSTEAD, HERTS, ENGLAND HP2 7UD TEL 01442 (Int +44 1442) 341234 FAX 01442 (Int +44 1442) 341200 http://www.alconlabs.com/gb

Direct Line:

Date: 14th February 2006

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

Subject: Withdrawal of Opatanol (Olopatadine hydrochloride) 6 mg/ml nasal spray, EMEA/H/C/407/X/04

Dear Dr Brasseur,

I would like to inform you that Alcon Laboratories (UK) Ltd has taken the decision to withdraw the application for Marketing Authorisation of Opatanol (Olopatadine hydrochloride) 6 mg/ml nasal spray, which was intended to be used for the treatment of the symptoms of season and perennial allergic rhinitis, at this point of time.

This withdrawal is based on the following reasons:

Alcon's marketing strategy

It is confirmed that there are no ongoing clinical trials nor compassionate use programmes with Opatanol nasal in the EU.

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

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

Yours sincerely,



