Alkermes

[redacted]

6 March 2012

Dr. Eric Abadie
Chairman, Committee for Medicinal Products for Human Use
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Subject: Withdrawal of the Marketing Authorisation Application for Megestrol Acetate Alkermes (Megestrol) 125 mg/ml Oral Suspension - EMEA/H/C/2177.

Dear Dr. Abadie,

I would like to inform you that, at this point of time, Alkermes Pharma Ireland Limited has taken the decision to withdraw the application for Marketing Authorisation for Megestrol Acetate Alkermes (Megestrol) 125 mg/ml Oral Suspension, which was intended to be used for the treatment of anorexia, cachexia or an unexplained significant weight loss in adult AIDS and oncology patients.

The application is being withdrawn as a consequence of portfolio prioritisation by Alkermes.

There are no ongoing clinical trials or compassionate use programmes for this medicinal product in Europe. Hence, this decision has no immediate impact upon patients 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 European Medicines Agency website.

Yours sincerely,

[redacted]
Director, Regulatory Affairs

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