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Wyeth

07 January 2010

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

Subject: Withdrawal of Ibuprofen/Diphenhydramine Hydrochloride Wyeth 200 mg/25 mg soft capsules - EMEA/H/C/1108

Dear Dr. Abadie,

I would like to inform you that Wyeth Consumer Healthcare has taken the decision to withdraw the application for Marketing Authorisation of Ibuprofen/Diphenhydramine Hydrochloride Wyeth 200 mg/25 mg soft capsules, which were intended to be used for the short-term treatment of mild to moderate pain in adults who have a history of experiencing difficulty in getting to sleep and staying asleep as a result of the pain.

Wyeth Consumer Healthcare has taken this decision based on the CHMP's view that the data provided do not allow the committee to conclude on a positive benefit risk balance.

At the present time there are no ongoing clinical trials with Ibuprofen/Diphenhydramine Hydrochloride Wyeth 200 mg/25 mg soft capsules.

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,