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Pfizer

Global Research & Development

[redacted]

16th February 2012

CHMP Chairman
European Medicines Agency
7 Westferry Circus
Canary Wharf
London
E14 4HB
United Kingdom

Dear Dr Abadie,

RE: Somavert (pegvisomant) 25 and 30 mg Extension Application: EMEA/H/C/409/X/052, Withdrawal of Application

On 10th August 2011, Pfizer submitted an extension application for two higher strengths: Somavert (pegvisomant) 25 mg and 30 mg powder and solvent for solution for injection. The procedure start date was 21st September 2011 with the Day 120 List of Questions issued on 20th January 2012.

I would like to inform you that, at this point of time, Pfizer Limited has taken the decision to withdraw the Somavert (pegvisomant) 25 mg and 30 mg extension applications.

The withdrawal is based on the following reason:
The CHMP's Day 120 List of Questions requires the provision of specific data that cannot be generated within the timeframe allowed within the Centralised Procedure for the Day 120 responses.

[redacted]

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Following withdrawal, Pfizer intends to further evaluate the data when available and may make further submissions in the EU at a future date, in this area or other therapeutic indications.

I agree to this letter to be published on the EMA website.

If you have any questions regarding this withdrawal letter, please feel free to call me at [redacted]

Yours sincerely,

[redacted]

[redacted]