152

Sok Central

Till: Wändel-Liminga Ulla; Melander Hans
Ämne: VB: UK/H/0636/001,003; Post-licensing commitment to assess sexual maturation in children
Prioritet: Hög
Bifogade filer: RFI 12 March 2007.doc

Från: uk-h.mrve [mailto:uk-h.mrve@uk-h.eudra.org]
1994-0112, Fontex®, 4 mg/ml, Oral lösning, UK/H/636/03, FUM 02; EMEA/H/A-6(12)/671, 2111:2006/63256

Clock stop -> IVB -> 0
/Eva P

Skickat: den 12 mars 2007 15:46
Till: List-H-MRVE (EUDRA); List-H-MRFG (EUDRA)
Kopia: Riegl, Martina; Dunne, Dr Julia
Ämne: UK/H/0636/001,003; Post-licensing commitment to assess sexual maturation in children
Prioritet: Hög

Dear Colleagues,

Please find the third clock stop and RFI for the above mentioned procedure.
<<RFI 12 March 2007.doc>>
Please do not hesitate to contact me should you require any further information.

Kind regards

Rahul Verma
MR/DC Team
Licensing Division

Safeguarding public health

MHRA

Dr Carly Anderson
Lilly UK
Erl Wood Manor
Windleham
Surrey
GU20 6PH
UNITED KINGDOM

12 March 2007

Dear Dr Anderson

REQUEST FOR FURTHER INFORMATION

Product:	Prozac 20mg capsules (PL 0006/0195) and Prozac Oral Liquid 20mg/5ml (PL 0006/0272)
Type of Procedure:	Mutual Recognition
Submission Type:	**Follow up Measure no. 2**
EU Procedure Number:	UK/H/636/01, 03
Reason:	**Post-licensing commitment to assess sexual maturation in children**

With reference to the above submission, further information is needed as follows:

Taking into consideration your responses of 31 January 2007, the points made by the investigators, the Letter of Undertaking accepted by the European Commission and CPMP guidance CPMP/EWP/462/95, and feasibility, it is considered that the following amendments to the proposed Protocol Addendum B1Y-MC-HCLU would be acceptable:

- Total duration of Follow-Up: 104 weeks after double-blind period.
- Hormone measurements are required.
- Assessment of Tanner staging by nurse practitioners would be acceptable, provided that these nurses have documented and substantial specialised training. Interrater reliability should be tested. Tanner staging should be conducted at 6-monthly intervals for 104 weeks after the end of double-blind treatment.
- Height and weight should be monitored at the same time as Tanner staging is performed.
- The primary analysis variable should be amended to reflect the scientific rationale of the trial.

Please amend the protocol addendum B1Y-MC-HCLU in line with the above points.

In addition, please provide any data that you may have obtained or can obtain from the TADS investigators regarding the 18-week and 36-week efficacy and safety data from the TADS trial.

The information should be received within 15 calendar days of the date of this letter.

Please quote our reference in all future correspondence regarding this submission. Do not hesitate to contact me if you wish to discuss any issues further.

Yours sincerely,

Dr Martina Riegl