

European Commission Pharmaceuticals Unit

Att.: entr-pharmaceuticals@ec.europa.eu

Date 2009-09-08

Our ref ABLL_08092009

Your ref -

Position from H. Lundbeck A/S on

Detailed guidance for the request for authorisation of a clinical trial on a medicinal product for human use to the competent authorities, notification of substantial amendments and declaration of the end of the trial, Daft Revision 3

Dear Colleagues,

H. Lundbeck A/S welcomes this revised document and appreciates the possibility to provide comments. We have contributed to, and support, the comments submitted by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Kind regards,

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