

Prozac - FR/H/242/01 and UK/H/636/01,03 - Joint FAR onPreclinical studies

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Wed 22/10/2008

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Letter joint FAR - FUM preclinical 141008.doc
146 KB

Prozac FUM Pre-clinical studies - Joint FAR UK-FR 14-10-08.doc
1 MB

Dear colleagues,

Please find enclosed the Joint Final assessment report dealing with these studies.

The applicant is requested to provide a response document, as well as a variation dossier (in order to change section 5.3 of the SPC) within 3 months, i.e on January 23rd 2009 at the latest.

Best regards,

Registration Procedures and European Affairs Unit
AESSAPS - France

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