Agence française de sécurité sanitaire
des produits de santé
Direction de l'Evaluation
des Médicaments et des Produits Biologiques

Saint-Denis, October 22nd 2008

Registration Procedures and
European Affairs Unit
[redacted]

[redacted]

Cc Company : [redacted]
Lilly

From: [redacted]

Re.: **PROZAC**
FR/H/242/01 and UK/H/0636/01,03
FOLLOW-UP MEASURE – NON-CLINICAL STUDIES (JUVENILE RAT STUDIES)
Joint Final Assessment Report

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,

[redacted]