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GLOBAL CLINICAL DEVELOPMENT

Dr. Daniel Brasseur
European Medicines Agency (EMEA)
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom

6 June 2006

Subject: **EMEA/H/C/625**
Withdrawal of Marketing Authorisation Application for SURFAXIN 30mg/mL, Endotracheopulmonary Instillation, Suspension

Dear Dr. Brasseur:

I would like to inform you, at this point in time, the applicant, PRA International, on behalf of the US sponsor, Discovery Laboratories, Inc. (Discovery) has taken the decision to withdraw the application for Marketing Authorisation of SURFAXIN, 30mg/mL, endotracheopulmonary instillation suspension, which was intended to be used for the prevention of respiratory distress syndrome (RDS) in premature neonates of less than 32 weeks of gestational age and for the treatment of RDS in premature neonates of less than 37 weeks of gestational age.

This withdrawal is based on identification of manufacturing and clinical issues which support the SURFAXIN application.

Discovery is addressing these issues and is committed to working with the EMEA to address the issues identified.

PRA and Discovery reserve the right to make further submissions at a future date in this or other therapeutic indication(s).

Both PRA and Discovery agree for this letter to be published on the EMEA website.

Yours sincerely,