I. BACKGROUND INFORMATION ON THE PROCEDURE

1.1. Submission of the dossier

Further to the submission of a letter of intent by Pfizer Ltd. on 25 January 2005, the Committee for Veterinary Medicinal Products (CVMP) accepted on 8-10 February 2005 that Cerenia was eligible for the submission of a dossier for granting of a Community marketing authorisation via the centralised system as provided for under Part B of the Annex to Council Regulation (EEC) No 2309/93.

The CVMP appointed Prof. Christian Friis from Denmark as Rapporteur and Dr Eva Johnsson from Sweden as Co-Rapporteur for the assessment of the application for Cerenia during its meeting of 8-10 February 2005. E. Johnson was later replaced by Dr. Karolina Törneke as Co-Rapporteur.

Pfizer Ltd. submitted an application to the EMEA on on 28 June 2005 for the granting of a Community marketing authorisation in accordance with Council Regulation (EEC) No 2309/93.
The application was validated on 12 July 2005.

1.2. Steps taken for the assessment of the product

- The Rapporteur's and Co-Rapporteur's assessment reports were circulated to all CVMP Members on 20 September 2005 and 5 October 2005, respectively.
- A consolidated list of questions was agreed by the CVMP during its plenary meeting on 9 November 2005 and the clock stopped.
- The Applicant circulated the responses to the CVMP list of questions on 16 February 2006 and the clock was restarted on 17 February 2006.
- The joint Rapporteur and Co-Rapporteur's assessment report on the responses to the consolidated list of questions, the overview of the scientific data and the overall conclusions were circulated to all CVMP Members on 17 March 2006.
- A list of outstanding issues was adopted by the CVMP on 19 April 2006 and the clock stopped.
- The Applicant provided written explanations on the outstanding issues and the clock restarted on 22 June 2006.
- The CVMP, in the light of the agreed scientific standards and methods for evaluating veterinary medicinal products at the time of submission of the dossier, issued on 19 July 2006 a positive opinion for the granting of a Community Marketing Authorisation for Cerenia.

1.3 The European Commission granted a marketing authorisation valid throughout the European Union for Cerenia on 29 September 2006.