BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Eli Lilly Nederland B.V. submitted on 31 May 2001 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for FORSTEO, in accordance with the centralised procedure falling within the scope of Part A of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Dr I. Hudson Co-Rapporteur: Dr E. Abadie

Scientific Advice:

The company Eli Lilly Nederland B.V. received Scientific Advice from the CPMP on 22 April 1999. The Scientific Advice pertained to IV of the dossier.

Licensing status:

The product was not licensed in any country at the time of submission of the application.

2. Steps taken for the assessment of the product

- The procedure started on 19 June 2001
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 13 September 2001. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 12 September 2001.
- During the meeting on 16 - 18 October 2001, the CPMP agreed on the consolidated List of Questions to be sent to the company. The final consolidated List of Questions was sent to the company on 18 October 2001.
- The company submitted the responses to the CPMP consolidated List of Questions on 16 July 2002.
- The Rapporteur circulated the response Assessment Report on the company's responses to the List of Questions to all CPMP members on 3 September 2002.
- During the meeting on 17 – 19 September 2002 the CPMP adopted a list of outstanding issues to be addressed by the company in writing. The list of outstanding issues was sent to the company on 20 September 2002.
- The company provided written information on these outstanding issues to all CPMP members on 16 October 2002. The Rapporteur/Co-Rapporteurs' joint review on the responses to the list of outstanding issues was circulated to all CPMP members on 7 November 2002.
- During the CPMP meeting on 19 – 21 November 2002, outstanding issues were addressed by the company during a hearing before the CPMP.
- During the meeting on 17 – 18 December 2002 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to FORSTEO on 18 December 2002.
- In February 2003, the European Commission, during the Standing Committee phase, referred the CPMP opinion back to the CPMP since according to Article 51(1)(a) all batch release testing has to be performed in the EU.

- During the meeting on 18 - 19 March 2003 the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee~~,~~ issued a revised positive opinion for granting a Marketing Authorization to FORSTEO on 19 March 2003.
- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 10 June 2003.