I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The applicant Orion Corporation submitted on 29 August 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Stalevo, through the centralised procedure. After agreement by the CPMP on 30 May 2002, this medicinal product has been referred to Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993 as amended.

This application is a mixed bibliographic application submitted under Article 10 1) ii) of Directive 2001/83/EC whereby results of pharmacological and toxicological tests and clinical trials have been replaced by detailed references to published literature demonstrating that some of the constituents (levodopa/carbidopa) have a well established medicinal use, with recognised efficacy and an acceptable level of safety.

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

Rapporteur: Dr Pekka Kurki Co-Rapporteur: Pr Christina Sampaio

Scientific Advice

The applicant received Scientific Advice from the CPMP on 18 November 1999. The Scientific Advice pertained to parts III and IV of the dossier.

Licensing status:

Stalevo has been given a Marketing Authorisation in the USA on 12 June 2003

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 23 September 2002.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 4 December 2002 (Annex 1). The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 2 December 2002
- During the meeting on 21-23 January 2003 the CPMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 23 January 2003.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 19 March 2003
- The response Assessment Report on the applicant’s responses to the List of Questions was circulated to all CPMP members on 28 April 2003
- During the CPMP meeting on 20-22 May 2003 the List of outstanding issues was adopted and sent to the applicant on 22 May 2003.
- The applicant submitted the responses to the CPMP consolidated List of Questions on 4 June 2003
- The response Assessment Report on the applicant’s responses to the List of Outstanding Issues was circulated to all CPMP members on 16 June 2003
- During the meeting on 24-26 June 2003 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 on 26 June 2003.

- The CPMP opinions were forwarded, in all official languages of the European Union, to the European Commission, which adopted the corresponding Decisions on 17 October 2003.