I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

Further to the submission of a letter of intent by Fort Dodge Animal Health Holland on 19 April 2005, the Committee for Veterinary Medicinal Products (CVMP) accepted on 18 May 2005 that Promeris Duo was eligible for the submission of a dossier for the granting of a Community marketing authorisation via the centralised system as provided for under Part B of the Annex to Council Regulation (EEC) No 726/2004.

The CVMP appointed Dr Johannes Hoogland from the Netherlands as Rapporteur and Dr Michael Holzhauser-Alberti from France as Co-Rapporteur for the assessment of the application for Promeris Duo during its meeting of 12-13 April 2005.

The company Fort Dodge Animal Health Holland submitted an application to the EMEA on 28 June 2005 for the granting of a Community marketing authorisation in accordance with Council Regulation (EEC) No 726/2004.

The application was validated on 12 July 2005

2. Steps taken for the assessment of the product

- The consolidated list of questions as agreed by the CVMP during its meeting held on 8-10 November 2005 was sent to the Applicant and the clock stopped.
- 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 11 October 2006 a positive Opinion for the granting of a Community marketing authorisation for Promeris Duo.

The European Commission granted a marketing authorisation valid throughout the European Union for Promeris Duo on 19.12.2006.

A. MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Wyeth Lederle Italia S.p.A.
Via Franco Gorgone
95030 Catania
Italy

The printed package insert of the medicinal product must state the name and address of the manufacturer responsible for the release of the concerned batch.

B. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION REGARDING SUPPLY OR USE

To be supplied only on veterinary prescription.

The holder of this marketing authorisation must inform the European Commission about the marketing plans for the medicinal product authorised by this decision.

C. CONDITIONS OR RESTRICTIONS OF THE MARKETING AUTHORISATION WITH REGARD TO SAFE AND EFFECTIVE USE

Not applicable.

D. STATEMENT OF THE MRLs

Not applicable.

