I STEPS TAKEN FOR THE ASSESSMENT

1. Submission of the dossier

The company Ciba Geigy submitted an application to the EMEA on 4 November 1996 for the granting of a Community marketing authorisation for Clomicalm in accordance with Council Regulation (EEC) No 2309/93. The application was validated on 12 November 1996. Novartis Tiergesundheit GmbH, Germany has since taken over all responsibilities of Ciba Geigy for the applications and will be the recognised marketing authorisation holder.

During its meeting of April 1996, the Committee for Veterinary Medicinal Products appointed Dr. S. Eglit as Rapporteur and Dr. L. Corbalan as Co-Rapporteur for the assessment of the application from Novartis Tiergesundheit GmbH, Germany.

2. Steps taken for the assessment of the product

1. The company Ciba Geigy submitted an application to the EMEA on 4 November 1996 for the granting of a Community marketing authorisation for Clomicalm in accordance with Council Regulation (EEC) No 2309/93. This application was validated on 12 November 1996. Novartis Tiergesundheit GmbH, Germany has since taken over all responsibilities of Ciba Geigy for the applications and is the recognised marketing authorisation holder.

2. The centralised procedure started on 13 November 1996.

3. The Rapporteur and Co-Rapporteur's assessment report was circulated to all CVMP Members on 31 January 1997.

4. The consolidated list of questions, as agreed by the CVMP during its meeting held on 11-13 March 1997, was sent to the applicant on 12 March 1997 at which time the clock was stopped.

5. The applicant circulated the responses to the CVMP list of questions on 15 August 1997, thus restarting the time clock. Supplementary documents were presented on 6 October 1997.

6. The joint Rapporteur and Co-rapporteur 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 15 September 1997.

7. The joint Rapporteur and Co-rapporteur assessment report, the summary of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 14 –16 October 1997. The Committee considered that the answers provided did not fully address the points raised in the list of questions. The applicant agreed to clarify points of issue and to modify the SPC and product literature. Therefore, the CVMP agreed that the time clock need not be stopped for further explanations at a hearing. At the November meeting of the Committee the Rapporteur and Co-Rapporteur recommended a positive opinion for the granting of a Community marketing authorisation for Clomicalm based on comments received from CVMP members.

8. The CVMP issued a positive opinion for the granting of a Community marketing authorisation for Clomicalm in the light of the current scientific standards on 12 November 1997 by majority consensus.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. MANUFACTURER RESPONSIBLE FOR IMPORT AND BATCH RELEASE IN THE EEA

Name and address of the manufacturer responsible for import and batch release in the European Economic Area

Novartis Santé Animale S.A.
Usine de Huningue
26, rue de la Chapelle
F-68332 Huningue Cedex
France

Manufacturing Authorisation issued on 4 July 1997 by Agence Nationale de Médicaments Vétérinaire, France.

2. CONDITIONS OR RESTRICTIONS OF SUPPLY AND USE

Veterinary medicinal product subjects to 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. PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable

D. STATEMENT OF THE MRLs

Not applicable