I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Pfizer Ltd. submitted an application to the EMEA on 3 November 1998 for the granting of a Community marketing authorisation for Stronghold in accordance with Council Regulation (EEC) No. 2309/93. The Committee for Veterinary Medicinal Products had appointed J. O'Brien from the United Kingdom as Rapporteur and C. Himonas from Greece as Co-Rapporteur for the assessment of the application during its meeting of June 1998. The application was validated on 17 November 1998.

2. Steps taken for the assessment of the product

- The CVMP at its meeting in June 1998 agreed that Stronghold was eligible for the submission of an application for granting of a Community marketing authorisation via the centralised system.
- The company Pfizer Ltd. submitted an application to the EMEA on 3 November 1998 for the granting of a Community marketing authorisation for Stronghold in accordance with Council Regulation (EEC) No. 2309/93.
- The application was validated on 17 November 1998.
- The Rapporteur and Co-Rapporteur's assessment reports were circulated to CVMP Members on 22 January 1999 and 9 February 1999.
- The consolidated list of questions, as agreed by the CVMP during its meeting held in March 1999, was sent to the Applicant on 17 March 1999 and the clock stopped on Day 120.
- The Applicant circulated the responses to the CVMP list of questions by 15 April 1999, at which point the clock was restarted.
- 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 CVMP Members on 17 May 1999.
- The joint Rapporteur and Co-Rapporteur assessment report, the overview of the scientific data and the overall conclusions were discussed during the meeting of the Committee held on 15 - 17 June 1999. The Committee considered that some of the answers provided did not address satisfactorily the points raised in the list of questions and therefore agreed that the Applicant should be invited to provide oral explanations. The clock was stopped on 16 June 1999 on Day 182 of the procedure.
- The Applicant provided oral explanations on 13 July 1999 during the July meeting of the Committee and the clock was restarted on 14 July 1999 (Day 183 of the procedure).

- 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 14 July 1999, a positive opinion for the granting of a Community marketing authorisation for Stronghold.

II GENERAL CONDITIONS FOR THE MARKETING AUTHORISATION

1. MANUFACTURING AUTHORISATIONS AND INSPECTION STATUS

Manufacturer of the active substance:

Pfizer Ltd.
Ramsgate Road
Sandwich
Kent, CT13 9NJ
United Kingdom

Pfizer Inc.
Eastern Point Road
Groton
CT 06340-1123
USA

Manufacturer of the finished product:

Pfizer Inc.
Animal Health (Plant)
1107 S. State Route 291
Lees Summit, MO
USA

Assembler of the finished product:

Packaging Co-ordinators Inc.
3001 Red Lion Road
Philadelphia
PA 19114-1123
USA

Anderson Packaging Inc.
4545 Assembly Drive
Rockford, Illinois
IL61109
USA

Manufacturer of the medicinal product responsible for batch release:

Quality Operations Department
Pfizer Ltd.
Ramsgate Road
Sandwich
Kent, CT13 9NJ

United Kingdom

Manufacturing Authorisation issued on 9 December 1996 by Department of Health, Medicines Control Agency, Chester, UK.

2. PROPOSED CONDITIONS OR RESTRICTIONS OF SUPPLY AND USE

Veterinary medicinal product subject to prescription.

3. PROHIBITION OF SALE, SUPPLY AND/OR USE

n/a