The European Agency for the Evaluation of Medicinal Products
Human Medicines Evaluation Unit

London, 3 April, 1997
CPMP/578/95

COMMITTEE FOR PROPRIETARY MEDICINAL PRODUCTS
OPINION FOLLOWING AN ARTICLE 12 REFERRAL

NAFTIDROFURYL 200MG/10ML INFUSION

International Non-Proprietary Name (INN): **Naftidrofuryl**

BACKGROUND INFORMATION

On 22 February 1995, Luxembourg requested the CPMP, under Article 12 of Council Directive 75/319/EEC, to provide an Opinion "on the risks and benefit of parenteral Naftidrofuryl Infusion" due to concerns about safety, particularly cardiac and neurological toxicity, and efficacy.

According to the CPMP Opinion given on 8 June 1995, the balance of benefits and risks for parenteral naftidrofuryl was unfavourable, and the Committee recommended that all Marketing Authorisations for medicinal products containing naftidrofuryl for parenteral infusion should be withdrawn.

Some of the Marketing Authorisation Holders of Naftidrofuryl appealed against the Opinion and grounds for appeal were submitted on 11 August 1995.

On the 19 October 1995, the CPMP having considered the grounds for appeal adopted a final Opinion maintaining the conclusions of the Opinion dated 8 June 1995.

A copy of the final Opinion for Naftidrofuryl Infusion is provided on the Internet, together with its Annex. Translations of the Opinion and its Annex, are also provided on the Internet in French, German, and Spanish.

The final Opinion was converted into a Decision by the European Commission on 26 June 1996.

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