No.

PL/0086/0088

Coy.

Hoechst UK Ltd

Product

Serum Cholinesterase

Therapeutic Class

Enzyme

Active Constituent

Serum Cholinesterase

SUB-COMMITTEE ON BIOLOGICALS 12 JANUARY 1983

RECOMMENDATION

On the evidence before them the Sub-Committee on grounds of quality and safety were unable to recommend the grant of a Product Licence.

The Sub-Committee considered that:

1. There was inadequate information provided on the manufacturing and control processes presented in support of the Product Licence application.

2. The standardisation of material was unsatisfactory. This would require both enzymatic and biological assay, together with a clear specification.

3. Inadequate evidence was provided on safety in respect of transmission of infection, especially non-A non-B hepatitis.

4. In the event of the grant of a Product Licence the indications should be strictly confined to genetically determined scoline apnoea.

No.

PL 0086/0088

Coy.

Hoechst UK Ltd

Product

Serum Cholinesterase

Therapeutic Class

Enzyme

Active Constituent

Serum Cholinesterase

Sub-Committee on Safety, Efficacy and Adverse Reactions

7.1.83

Recommendation

The Sub-Committee were unable to make a recommendation on the grant of a Product Licence for this preparation because:-

(1) There was limited evidence of efficacy in the proposed indications.

(2) There was a need to consider whether there were alternative treatments for these conditions.

(3) There were serious potential adverse affects (particularly hepatitis).

The Sub-Committee recommended that two experts should be consulted on the above (particularly (1) and (2)) before advice was given to the Licensing Authority.

40