30 January 1989

T.W.A. Little
Ministry of Agriculture,
Fisheries and Food
The Central Veterinary Laboratory
New Haw, Weybridge, Surrey

Dear Dr. Little:

B.S.E. and Veterinary Medicines

Thank you very much indeed for your letter of the 26th of January outlining to me various steps that are proposing to take in order to reduce the risk from B.S.E. in veterinary medicines. It is, as you say, an extremely difficult problem. I know my colleagues will be most interested in your reply which I will put before them at our next meeting.

Yours sincerely,

Sir Richard Southwood, F.R.S.
TRES:jch

cc
CVO
Mr Cruickshank
Dr Watson
Mr Kidd
Mr A Taylor
Dr Thornton
Mr A Laurence
Mr Wilesmith
Dr Adams, DOH
PROPOSED JOINT CSM/VPC GUIDELINES FOR INDUSTRY

The following guidelines are addressed to product licence holders and applicants.

1. Scope
   It is intended that all products licensed under the Medicines Act 1968 for human or veterinary use, that are administered parenterally or to open wounds, should conform to these guidelines if they contain material from a bovine source, or if bovine material has been used during their manufacture.

   Although these guidelines relate to BSE and materials of bovine origin, they should also be considered as applicable to material from sheep, goats, deer, and some other animals susceptible to scrapie-like agents, which are not suitable alternative sources.

2. Cattle source
   Bovine material should come from cattle, taken from a closed herd in the female line since 1980, in which no animal has been clinically suspected of having BSE, and which has not been fed rations containing ruminant derived protein during that period.

3. Tissues excluded
   No nerve or neural tissue, spleen, thymus and other lymphoid tissue, placental tissue or cell cultures of bovine origin should be used in the manufacture of medicinal products.

4. Collection techniques
   All possible measures should be taken to avoid contamination of the bovine material with BSE agent, in particular:

   no tissue is to be used in medicinal products when collected postmortem from a bovine animal after brain penetrative stunning.

   all tissue collected from the bovine animal should be taken aseptically using sterile equipment. Needles, syringes, scalpel blades etc should be disposable items.

   it is recommended that whenever possible, source animals should be calves up to 6 months old.

   for serum: all cellular components must be removed.

   for foetal calf serum: great care should be taken to avoid contamination by placenta and foetal fluids. All cellular components must be removed.

5. Sterilisation
   When sterilization procedures are used, they should be demonstrated to be capable of inactivating scrapie-like agents - at present thought to be autoclaving using a porous load cycle at 134°C-138°C for 18 minutes at 30 psi.

6. Product
   Whenever possible, the product should be terminally sterilised by a validated method.